Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Finerenon (KERENDIA®)

Bayer Vital GmbH

Modul 4A, Anhang 4-H

Erwachsene mit chronischer Nierenerkrankung (Stadium 3 und 4 mit Albuminurie) und Diabetes mellitus Typ II

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 22.02.2023

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4.2 Disposition

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

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			13911
Screening failures			8177
Randomized	2649	2645	5294
GCP VIOLATIONS	27	25	52
Full analysis set	2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Study drug never administered	5 (0.2%)	10 (0.4%)	15 (0.3%)
Treated	2617 (99.8%)	2610 (99.6%)	5227 (99.7%)
Did not complete study	9 (0.3%)	8 (0.3%)	17 (0.3%)
WITHDRAWN CONSENT	4 (0.2%)	5 (0.2%)	9 (0.2%)
LOST TO FOLLOW-UP	5 (0.2%)	3 (0.1%)	8 (0.2%)
Completed study	2613 (99.7%)	2612 (99.7%)	5225 (99.7%)

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Lost to follow-up includes all study non-completers who have not withdrawn consent.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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Completed epoch	1847 (70.4%)	1871 (71.4%)	3718 (70.9%)
Not completed	775 (29.6%)	749 (28.6%)	1524 (29.1%)
Primary reason			
ADVERSE EVENT	293 (11.2%)	278 (10.6%)	571 (10.9%)
DEATH	118 (4.5%)	149 (5.7%)	267 (5.1%)
WITHDRAWAL BY SUBJECT	146 (5.6%)	156 (6.0%)	302 (5.8%)
LOST TO FOLLOW-UP	5 (0.2%)	3 (0.1%)	8 (0.2%)
PREGNANCY	0	1 (<0.1%)	1 (<0.1%)
PROGRESSIVE DISEASE	0	1 (<0.1%)	1 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	18 (0.7%)	6 (0.2%)	24 (0.5%)
PHYSICIAN DECISION	149 (5.7%)	105 (4.0%)	254 (4.8%)
TECHNICAL PROBLEMS	29 (1.1%)	29 (1.1%)	58 (1.1%)
DETERIORATION OF GENERAL CONDITIONS	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
PROTOCOL DEVIATION	6 (0.2%)	13 (0.5%)	19 (0.4%)
SITE TERMINATED BY SPONSOR	6 (0.2%)	2 (<0.1%)	8 (0.2%)
OTHER	4 (0.2%)	3 (0.1%)	7 (0.1%)

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4.3 Demographic characteristics

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

TEXT	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Race (N)			
WHITE	1637 (62.4%)	1663 (63.5%)	3300 (63.0%)
BLACK OR AFRICAN AMERICAN	130 (5.0%)	115 (4.4%)	245 (4.7%)
ASIAN	678 (25.9%)	679 (25.9%)	1357 (25.9%)
AMERICAN INDIAN OR ALASKA NATIVE	67 (2.6%)	64 (2.4%)	131 (2.5%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	9 (0.3%)	7 (0.3%)	16 (0.3%)
NOT REPORTED	9 (0.3%)	9 (0.3%)	18 (0.3%)
MULTIPLE	92 (3.5%)	83 (3.2%)	175 (3.3%)
Sex (N)			
Male	1800 (68.6%)	1876 (71.6%)	3676 (70.1%)
Female	822 (31.4%)	744 (28.4%)	1566 (29.9%)
Age (YEARS)			
n	2622	2620	5242
Mean	65.57	65.81	65.69
SD	9.01	9.09	9.05
Min	32.0	30.0	30.0
Q1	60.00	60.00	60.00
Median	66.00	66.00	66.00
Q3	72.00	72.00	72.00
Max	90.0	97.0	97.0
Run-in age group (years) category (N)			
18 - 44 years	44 (1.7%)	56 (2.1%)	100 (1.9%)
45 - 64 years	1062 (40.5%)	1022 (39.0%)	2084 (39.8%)
65 - 74 years	1096 (41.8%)	1107 (42.3%)	2203 (42.0%)
>= 75 years	420 (16.0%)	435 (16.6%)	855 (16.3%)
Age group (years) category 3 (N)			
< 65 years	1106 (42.2%)	1078 (41.1%)	2184 (41.7%)
>= 65 years	1516 (57.8%)	1542 (58.9%)	3058 (58.3%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	2197 (83.8%)	2213 (84.5%)	4410 (84.1%)
HISPANIC OR LATINO	417 (15.9%)	394 (15.0%)	811 (15.5%)
NOT REPORTED	8 (0.3%)	13 (0.5%)	21 (0.4%)

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

TEXT	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Region (N)			
Europe	1078 (41.1%)	1064 (40.6%)	2142 (40.9%)
North America	425 (16.2%)	437 (16.7%)	862 (16.4%)
Asia	751 (28.6%)	748 (28.5%)	1499 (28.6%)
Latin America	274 (10.5%)	274 (10.5%)	548 (10.5%)
Others	94 (3.6%)	97 (3.7%)	191 (3.6%)
Baseline Weight (kg)			
n	2615	2615	5230
Mean	86.69	87.45	87.07
SD	19.83	20.13	19.98
Min	40.0	34.0	34.0
Q1	72.40	73.00	72.80
Median	84.70	85.60	85.10
Q3	98.60	98.70	98.60
Max	182.8	188.9	188.9
Baseline weight (kg) category (N)			
missing	7 (0.3%)	5 (0.2%)	12 (0.2%)
< 60 kg	174 (6.6%)	146 (5.6%)	320 (6.1%)
60 - < 90 kg	1415 (54.0%)	1398 (53.4%)	2813 (53.7%)
>= 90 kg	1026 (39.1%)	1071 (40.9%)	2097 (40.0%)
Baseline Height (cm)			
n	2618	2620	5238
Mean	166.50	167.30	166.90
SD	9.54	9.68	9.61
Min	137.0	136.0	136.0
Q1	160.00	160.80	160.00
Median	167.00	167.75	167.05
Q3	173.00	174.00	173.20
Max	196.0	207.0	207.0

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

TEXT	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline Body Mass Index (kg/m2)			
n	2611	2615	5226
Mean	31.12	31.11	31.11
SD	6.05	6.03	6.04
Min	15.5	14.5	14.5
Q1	26.80	26.90	26.90
Median	30.40	30.30	30.40
Q3	34.40	34.50	34.50
Max	63.7	63.2	63.7
Baseline BMI (kg/m2) category 2 (N)			
missing	11 (0.4%)	5 (0.2%)	16 (0.3%)
< 30 kg/m2	1225 (46.7%)	1244 (47.5%)	2469 (47.1%)
>= 30 kg/m2	1386 (52.9%)	1371 (52.3%)	2757 (52.6%)
Baseline BMI (kg/m2) category 3 (N)			
missing	11 (0.4%)	5 (0.2%)	16 (0.3%)
< 20 kg/m2	22 (0.8%)	26 (1.0%)	48 (0.9%)
20 - < 25 kg/m2	327 (12.5%)	322 (12.3%)	649 (12.4%)
25 - < 30 kg/m2	876 (33.4%)	896 (34.2%)	1772 (33.8%)
30 - < 35 kg/m2	795 (30.3%)	770 (29.4%)	1565 (29.9%)
>= 35 kg/m2	591 (22.5%)	601 (22.9%)	1192 (22.7%)
Baseline Hip Circumference (cm)			
n	2611	2608	5219
Mean	107.19	107.23	107.21
SD	13.90	13.87	13.88
Min	42.0	48.3	42.0
Q1	98.00	98.00	98.00
Median	106.00	105.45	106.00
Q3	114.30	114.00	114.00
Max	203.2	170.0	203.2

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

TEXT	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline waist circumference (cm)			
n	2612	2612	5224
Mean	106.49	107.00	106.75
SD	15.03	15.47	15.26
Min	41.0	50.0	41.0
Q1	96.00	96.00	96.00
Median	106.00	106.00	106.00
Q3	116.00	117.00	116.00
Max	161.0	200.0	200.0
Baseline waist circumf. (cm) cat. (N)			
missing	10 (0.4%)	8 (0.3%)	18 (0.3%)
normal	316 (12.1%)	336 (12.8%)	652 (12.4%)
increased	498 (19.0%)	486 (18.5%)	984 (18.8%)
substantially increased	1798 (68.6%)	1790 (68.3%)	3588 (68.4%)
Baseline waist-hip ratio (N)			
n	2610	2607	5217
Mean	1.00	1.00	1.00
SD	0.11	0.12	0.11
Min	0.6	0.5	0.5
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.05	1.05
Max	2.5	2.4	2.5
Smoking History (N)			
NEVER	1275 (48.6%)	1266 (48.3%)	2541 (48.5%)
FORMER	970 (37.0%)	994 (37.9%)	1964 (37.5%)
CURRENT	377 (14.4%)	360 (13.7%)	737 (14.1%)

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

TEXT	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Alcohol Use (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
ABSTINENT	1607 (61.3%)	1602 (61.1%)	3209 (61.2%)
LIGHT	870 (33.2%)	862 (32.9%)	1732 (33.0%)
MODERATE	135 (5.1%)	141 (5.4%)	276 (5.3%)
HEAVY	10 (0.4%)	14 (0.5%)	24 (0.5%)

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

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline potassium (mmol/L)			
n	2621	2619	5240
Arithm. Mean	4.37	4.38	4.38
Arithm. SD	0.46	0.46	0.46
Min	2.6	2.6	2.6
Q1	4.10	4.10	4.10
Median	4.40	4.40	4.40
Q3	4.70	4.70	4.70
Max	6.2	6.9	6.9
Baseline ser. potassium (mmol/L) cat.(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<= 4.5 mmol/L	1737 (66.2%)	1703 (65.0%)	3440 (65.6%)
> 4.5 mmol/L	884 (33.7%)	916 (35.0%)	1800 (34.3%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<=4.8 mmol/L	2257 (86.1%)	2254 (86.0%)	4511 (86.1%)
>4.8 to <=5.0 mmol/L	178 (6.8%)	181 (6.9%)	359 (6.8%)
>5.0 mmol/L	186 (7.1%)	184 (7.0%)	370 (7.1%)
Basel. potass (mmol/L) median FAS (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1275 (48.6%)	1240 (47.3%)	2515 (48.0%)
> 4.30 mmol/L (median in FAS)	1346 (51.3%)	1379 (52.6%)	2725 (52.0%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	789 (30.1%)	770 (29.4%)	1559 (29.7%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	486 (18.5%)	470 (17.9%)	956 (18.2%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	673 (25.7%)	679 (25.9%)	1352 (25.8%)
>4.6 mmol/L (>Q3 in FAS)	673 (25.7%)	700 (26.7%)	1373 (26.2%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	2619	2618	5237
Arithm. Mean	138.11	137.89	138.00
Arithm. SD	14.37	14.50	14.43
Min	77.0	82.3	77.0
Q1	128.67	128.33	128.67
Median	138.33	138.33	138.33
Q3	147.67	148.33	148.00
Max	197.0	195.3	197.0
Baseline SBP (mmHg) category (N)			
missing	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
< 130 mmHg	724 (27.6%)	724 (27.6%)	1448 (27.6%)
130 - < 160 mmHg	1762 (67.2%)	1766 (67.4%)	3528 (67.3%)
>= 160 mmHg	133 (5.1%)	128 (4.9%)	261 (5.0%)
Baseline SBP (mmHg) median for FAS (N)			
missing	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
<= 137.00 mmHg (median in FAS)	1223 (46.6%)	1229 (46.9%)	2452 (46.8%)
> 137.00 mmHg (median in FAS)	1396 (53.2%)	1389 (53.0%)	2785 (53.1%)
Baseline Diastolic Blood Pressure (mmHg)			
n	2619	2618	5237
Arithm. Mean	75.68	75.67	75.67
Arithm. SD	9.67	9.66	9.66
Min	41.3	44.3	41.3
Q1	69.33	69.67	69.33
Median	76.00	76.33	76.00
Q3	82.00	82.33	82.33
Max	109.3	102.3	109.3
Baseline Heart Rate (BEATS/MIN)			
n	2617	2618	5235
Arithm. Mean	72.30	72.21	72.26
Arithm. SD	11.54	11.41	11.47
Min	37.0	37.7	37.0
Q1	64.67	64.00	64.00
Median	72.00	71.67	71.67
Q3	79.67	79.67	79.67
Max	155.7	117.0	155.7

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	2621	2619	5240
Arithm. Mean	42.69	42.60	42.64
Arithm. SD	11.18	11.19	11.19
Min	15.8	15.8	15.8
Q1	33.90	33.90	33.90
Median	41.70	41.70	41.70
Q3	50.30	50.10	50.20
Max	107.2	99.4	107.2
Baseline eGFR (mL/min/1.73m2) cat.(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
< 25 mL/min/1.73m2	66 (2.5%)	69 (2.6%)	135 (2.6%)
25 - < 45 mL/min/1.73m2	1472 (56.1%)	1500 (57.3%)	2972 (56.7%)
45 - < 60 mL/min/1.73m2	915 (34.9%)	871 (33.2%)	1786 (34.1%)
>= 60 mL/min/1.73m2	168 (6.4%)	179 (6.8%)	347 (6.6%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
< 30 mL/min/1.73m2	340 (13.0%)	353 (13.5%)	693 (13.2%)
30 - < 60 mL/min/1.73m2	2113 (80.6%)	2087 (79.7%)	4200 (80.1%)
60 - < 90 mL/min/1.73m2	164 (6.3%)	175 (6.7%)	339 (6.5%)
>= 90 mL/min/1.73m2	4 (0.2%)	4 (0.2%)	8 (0.2%)
Screening eGFR (mL/min/1.73m2)			
n	2620	2619	5239
Arithm. Mean	42.21	42.34	42.28
Arithm. SD	9.61	9.52	9.56
Min	25.0	21.6	21.6
Q1	34.25	34.40	34.30
Median	42.30	42.00	42.10
Q3	50.20	50.20	50.20
Max	59.9	69.1	69.1
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
< 25 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
25 - < 45 mL/min/1.73m2	1558 (59.4%)	1546 (59.0%)	3104 (59.2%)
45 - < 60 mL/min/1.73m2	1062 (40.5%)	1071 (40.9%)	2133 (40.7%)
>= 60 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
< 30 mL/min/1.73m2	339 (12.9%)	300 (11.5%)	639 (12.2%)
30 - < 60 mL/min/1.73m2	2281 (87.0%)	2318 (88.5%)	4599 (87.7%)
60 - < 90 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
Baseline UACR (mg/g)			
n	2620	2619	5239
Geom. Mean	797.68	814.72	806.15
Geom. SD	2.68	2.71	2.70
Min	5.6	7.4	5.6
Q1	438.58	448.47	443.39
Median	840.31	878.12	860.21
Q3	1643.20	1689.29	1668.11
Max	7692.3	8806.2	8806.2
Baseline albuminuria (mg/g) cat. (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	11 (0.4%)	12 (0.5%)	23 (0.4%)
High albuminuria (30 mg/g - < 300 mg/g)	331 (12.6%)	323 (12.3%)	654 (12.5%)
Very high albuminuria (>= 300 mg/g)	2278 (86.9%)	2284 (87.2%)	4562 (87.0%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
<= 514.7 mg/g (median in FAS)	800 (30.5%)	772 (29.5%)	1572 (30.0%)
> 514.7 mg/g (median in FAS)	1820 (69.4%)	1847 (70.5%)	3667 (70.0%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
NO	2087 (79.6%)	2089 (79.7%)	4176 (79.7%)
YES	534 (20.4%)	530 (20.2%)	1064 (20.3%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Baseline Creatinine (mg/dL)			
n	2621	2619	5240
Arithm. Mean	1.61	1.63	1.62
Arithm. SD	0.40	0.40	0.40
Min	0.6	0.7	0.6
Q1	1.32	1.33	1.33
Median	1.56	1.58	1.57
Q3	1.87	1.85	1.87
Max	3.2	4.6	4.6
Baseline Albumin (g/dL) in Serum			
n	2621	2619	5240
Arithm. Mean	4.09	4.09	4.09
Arithm. SD	0.34	0.34	0.34
Min	2.1	2.6	2.1
Q1	3.90	3.90	3.90
Median	4.10	4.10	4.10
Q3	4.30	4.30	4.30
Max	5.2	5.1	5.2
Baseline Hemoglobin (g/dL) in Blood			
n	2618	2618	5236
Arithm. Mean	12.91	12.95	12.93
Arithm. SD	1.70	1.73	1.71
Min	6.8	7.7	6.8
Q1	11.70	11.70	11.70
Median	12.90	12.90	12.90
Q3	14.10	14.10	14.10
Max	19.4	19.7	19.7
Baseline Hemoglobin A1C (%)			
n	2615	2616	5231
Arithm. Mean	7.66	7.68	7.67
Arithm. SD	1.32	1.37	1.34
Min	4.3	3.8	3.8
Q1	6.70	6.70	6.70
Median	7.50	7.40	7.50
Q3	8.40	8.50	8.50
Max	12.5	12.9	12.9

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	7 (0.3%)	4 (0.2%)	11 (0.2%)
<= 7.5%	1353 (51.6%)	1381 (52.7%)	2734 (52.2%)
> 7.5%	1262 (48.1%)	1235 (47.1%)	2497 (47.6%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	7 (0.3%)	4 (0.2%)	11 (0.2%)
<=6.7 % (<= Q1 in FAS)	697 (26.6%)	718 (27.4%)	1415 (27.0%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	656 (25.0%)	663 (25.3%)	1319 (25.2%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	656 (25.0%)	619 (23.6%)	1275 (24.3%)
>8.5 % (>Q3 in FAS)	606 (23.1%)	616 (23.5%)	1222 (23.3%)
Baseline C Reactive Protein (mg/L)			
n	2621	2617	5238
Arithm. Mean	4.57	4.57	4.57
Arithm. SD	8.92	8.72	8.82
Min	0.1	0.1	0.1
Q1	0.91	0.94	0.92
Median	2.24	2.29	2.27
Q3	5.17	5.27	5.20
Max	160.0	184.0	184.0
Basel. C Reactive Protein Quartiles (N)			
missing	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
<=0.95 % (<= Q1 in FAS)	682 (26.0%)	662 (25.3%)	1344 (25.6%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	621 (23.7%)	620 (23.7%)	1241 (23.7%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	656 (25.0%)	665 (25.4%)	1321 (25.2%)
>5.13 % (>Q3 in FAS)	662 (25.2%)	670 (25.6%)	1332 (25.4%)
Stratification factor 3 (N)			
CVD present	1215 (46.3%)	1213 (46.3%)	2428 (46.3%)
CVD absent	1407 (53.7%)	1407 (53.7%)	2814 (53.7%)
Hyperkalemia (based on MLG) in MH (N)			
NO	2550 (97.3%)	2537 (96.8%)	5087 (97.0%)
YES	72 (2.7%)	83 (3.2%)	155 (3.0%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Hepatic impairment in medical history(N)			
NO	2209 (84.2%)	2204 (84.1%)	4413 (84.2%)
YES	413 (15.8%)	416 (15.9%)	829 (15.8%)
Child Pugh (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
likely Child Pugh A	2459 (93.8%)	2460 (93.9%)	4919 (93.8%)
likely Child Pugh B	157 (6.0%)	155 (5.9%)	312 (6.0%)
certain Child Pugh B	4 (0.2%)	4 (0.2%)	8 (0.2%)
Duration of diabetes (in years) (N)			
n	2616	2616	5232
Arithm. Mean	16.68	16.63	16.66
Arithm. SD	8.83	8.80	8.81
Min	0.2	0.2	0.2
Q1	10.18	10.15	10.17
Median	16.14	16.16	16.15
Q3	21.33	21.56	21.46
Max	53.2	62.1	62.1
ACEI use (N)			
NO	1758 (67.0%)	1720 (65.6%)	3478 (66.3%)
YES	864 (33.0%)	900 (34.4%)	1764 (33.7%)
ARB use (N)			
NO	868 (33.1%)	903 (34.5%)	1771 (33.8%)
YES	1754 (66.9%)	1717 (65.5%)	3471 (66.2%)
Beta blocker use at baseline (N)			
NO	1257 (47.9%)	1221 (46.6%)	2478 (47.3%)
YES	1365 (52.1%)	1399 (53.4%)	2764 (52.7%)
Diuretic use at baseline (N)			
NO	1148 (43.8%)	1099 (41.9%)	2247 (42.9%)
YES	1474 (56.2%)	1521 (58.1%)	2995 (57.1%)
Statins use at baseline (N)			
NO	660 (25.2%)	664 (25.3%)	1324 (25.3%)
YES	1962 (74.8%)	1956 (74.7%)	3918 (74.7%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Anti-diabetic use at baseline (N)			
NO	84 (3.2%)	63 (2.4%)	147 (2.8%)
YES	2538 (96.8%)	2557 (97.6%)	5095 (97.2%)
Insul. and analo. use at baseline (N)			
NO	912 (34.8%)	956 (36.5%)	1868 (35.6%)
YES	1710 (65.2%)	1664 (63.5%)	3374 (64.4%)
Dip pep 4 inhibitors use at baseline (N)			
NO	1904 (72.6%)	1911 (72.9%)	3815 (72.8%)
YES	718 (27.4%)	709 (27.1%)	1427 (27.2%)
GLP1 agonists use at baseline (N)			
NO	2452 (93.5%)	2434 (92.9%)	4886 (93.2%)
YES	170 (6.5%)	186 (7.1%)	356 (6.8%)
SGLT-2 inhib. use at baseline (N)			
NO	2519 (96.1%)	2503 (95.5%)	5022 (95.8%)
YES	103 (3.9%)	117 (4.5%)	220 (4.2%)
Biguanides use at baseline (N)			
NO	1515 (57.8%)	1549 (59.1%)	3064 (58.5%)
YES	1107 (42.2%)	1071 (40.9%)	2178 (41.5%)
Sulfonamides use at baseline (N)			
NO	2023 (77.2%)	2001 (76.4%)	4024 (76.8%)
YES	599 (22.8%)	619 (23.6%)	1218 (23.2%)
Alpha gluc. inhib. use at baseline (N)			
NO	2472 (94.3%)	2468 (94.2%)	4940 (94.2%)
YES	150 (5.7%)	152 (5.8%)	302 (5.8%)
Meglitinides use at baseline (N)			
NO	2464 (94.0%)	2471 (94.3%)	4935 (94.1%)
YES	158 (6.0%)	149 (5.7%)	307 (5.9%)

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

	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Thiazolidinediones use at baseline (N)			
NO	2510 (95.7%)	2523 (96.3%)	5033 (96.0%)
YES	112 (4.3%)	97 (3.7%)	209 (4.0%)
Potassium supplement use at baseline (N)			
NO	2540 (96.9%)	2542 (97.0%)	5082 (96.9%)
YES	82 (3.1%)	78 (3.0%)	160 (3.1%)
Potassium lowering use at baseline (N)			
NO	2553 (97.4%)	2554 (97.5%)	5107 (97.4%)
YES	69 (2.6%)	66 (2.5%)	135 (2.6%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	23 (0.9%)	23 (0.9%)	46 (0.9%)
unclassified	34 (1.3%)	33 (1.3%)	67 (1.3%)
moderate	62 (2.4%)	53 (2.0%)	115 (2.2%)
weak	1657 (63.2%)	1617 (61.7%)	3274 (62.5%)
none	846 (32.3%)	894 (34.1%)	1740 (33.2%)
Potency CYP3A4 inducer at baseline (N)			
strong	5 (0.2%)	2 (<0.1%)	7 (0.1%)
unclassified	19 (0.7%)	19 (0.7%)	38 (0.7%)
moderate	11 (0.4%)	10 (0.4%)	21 (0.4%)
weak	101 (3.9%)	104 (4.0%)	205 (3.9%)
none	2486 (94.8%)	2485 (94.8%)	4971 (94.8%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:20
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4.5 Medical History

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Number (%) of subjects with at least one medical history finding	2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Blood and lymphatic system disorders	542 (20.7%)	508 (19.4%)	1050 (20.0%)
Anaemia	342 (13.0%)	316 (12.1%)	658 (12.6%)
Anaemia folate deficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaemia macrocytic	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Anaemia megaloblastic	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Anaemia of chronic disease	10 (0.4%)	7 (0.3%)	17 (0.3%)
Anaemia vitamin B12 deficiency	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Antiphospholipid syndrome	1 (<0.1%)	0	1 (<0.1%)
Aplastic anaemia	0	1 (<0.1%)	1 (<0.1%)
Blood loss anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone marrow oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coagulopathy	0	2 (<0.1%)	2 (<0.1%)
Cytopenia	0	1 (<0.1%)	1 (<0.1%)
Eosinophilia	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Febrile neutropenia	1 (<0.1%)	0	1 (<0.1%)
Haemolytic uraemic syndrome	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic disorder	1 (<0.1%)	0	1 (<0.1%)
Hyperchromic anaemia	2 (<0.1%)	0	2 (<0.1%)
Hypercoagulation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperfibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Hypergammaglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperviscosity syndrome	1 (<0.1%)	0	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Immune thrombocytopenia	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	64 (2.4%)	48 (1.8%)	112 (2.1%)
Leukocytosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Leukopenia	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lymphadenitis	2 (<0.1%)	0	2 (<0.1%)
Lymphadenopathy	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Lymphadenopathy mediastinal	2 (<0.1%)	0	2 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Lymphoid tissue hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Microcytic anaemia	3 (0.1%)	6 (0.2%)	9 (0.2%)
Microcytosis	0	2 (<0.1%)	2 (<0.1%)
Nephrogenic anaemia	58 (2.2%)	69 (2.6%)	127 (2.4%)
Normochromic anaemia	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Normochromic normocytic anaemia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Normocytic anaemia	7 (0.3%)	10 (0.4%)	17 (0.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Pancytopenia	0	3 (0.1%)	3 (<0.1%)
Pernicious anaemia	9 (0.3%)	3 (0.1%)	12 (0.2%)
Polycythaemia	3 (0.1%)	5 (0.2%)	8 (0.2%)
Spleen disorder	1 (<0.1%)	0	1 (<0.1%)
Splenic calcification	0	1 (<0.1%)	1 (<0.1%)
Splenic granuloma	1 (<0.1%)	0	1 (<0.1%)
Splenomegaly	9 (0.3%)	11 (0.4%)	20 (0.4%)
Thrombocytopenia	16 (0.6%)	24 (0.9%)	40 (0.8%)
Thrombocytosis	4 (0.2%)	4 (0.2%)	8 (0.2%)
Cardiac disorders	1270 (48.4%)	1278 (48.8%)	2548 (48.6%)
Acute coronary syndrome	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Acute left ventricular failure	3 (0.1%)	0	3 (<0.1%)
Acute myocardial infarction	4 (0.2%)	4 (0.2%)	8 (0.2%)
Angina pectoris	113 (4.3%)	111 (4.2%)	224 (4.3%)
Angina unstable	19 (0.7%)	20 (0.8%)	39 (0.7%)
Aortic valve calcification	2 (<0.1%)	0	2 (<0.1%)
Aortic valve disease	4 (0.2%)	3 (0.1%)	7 (0.1%)
Aortic valve incompetence	15 (0.6%)	20 (0.8%)	35 (0.7%)
Aortic valve sclerosis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Aortic valve stenosis	10 (0.4%)	11 (0.4%)	21 (0.4%)
Arrhythmia	25 (1.0%)	27 (1.0%)	52 (1.0%)
Arrhythmia supraventricular	2 (<0.1%)	0	2 (<0.1%)
Arteriosclerosis coronary artery	29 (1.1%)	32 (1.2%)	61 (1.2%)
Atrial enlargement	0	1 (<0.1%)	1 (<0.1%)
Atrial fibrillation	216 (8.2%)	193 (7.4%)	409 (7.8%)
Atrial flutter	12 (0.5%)	17 (0.6%)	29 (0.6%)
Atrial tachycardia	0	2 (<0.1%)	2 (<0.1%)
Atrioventricular block	6 (0.2%)	8 (0.3%)	14 (0.3%)
Atrioventricular block complete	3 (0.1%)	8 (0.3%)	11 (0.2%)
Atrioventricular block first degree	47 (1.8%)	47 (1.8%)	94 (1.8%)
Atrioventricular block second degree	10 (0.4%)	3 (0.1%)	13 (0.2%)
Bifascicular block	0	2 (<0.1%)	2 (<0.1%)
Bradyarrhythmia	1 (<0.1%)	0	1 (<0.1%)
Bradycardia	13 (0.5%)	11 (0.4%)	24 (0.5%)
Brugada syndrome	1 (<0.1%)	0	1 (<0.1%)
Bundle branch block	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bundle branch block left	48 (1.8%)	39 (1.5%)	87 (1.7%)
Bundle branch block right	38 (1.4%)	51 (1.9%)	89 (1.7%)
Cardiac aneurysm	0	3 (0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Cardiac arrest	2 (<0.1%)	0	2 (<0.1%)
Cardiac discomfort	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac dysfunction	0	3 (0.1%)	3 (<0.1%)
Cardiac failure	41 (1.6%)	74 (2.8%)	115 (2.2%)
Cardiac failure acute	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Cardiac failure chronic	74 (2.8%)	93 (3.5%)	167 (3.2%)
Cardiac failure congestive	48 (1.8%)	42 (1.6%)	90 (1.7%)
Cardiac flutter	2 (<0.1%)	0	2 (<0.1%)
Cardiac hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac septal hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac tamponade	0	2 (<0.1%)	2 (<0.1%)
Cardiac valve disease	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Cardiac valve sclerosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiogenic shock	0	1 (<0.1%)	1 (<0.1%)
Cardiomegaly	10 (0.4%)	8 (0.3%)	18 (0.3%)
Cardiomyopathy	11 (0.4%)	16 (0.6%)	27 (0.5%)
Cardiorenal syndrome	0	2 (<0.1%)	2 (<0.1%)
Cardiovascular disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiovascular insufficiency	2 (<0.1%)	0	2 (<0.1%)
Chronic left ventricular failure	11 (0.4%)	6 (0.2%)	17 (0.3%)
Chronic right ventricular failure	1 (<0.1%)	0	1 (<0.1%)
Chronotropic incompetence	0	1 (<0.1%)	1 (<0.1%)
Conduction disorder	1 (<0.1%)	0	1 (<0.1%)
Congestive cardiomyopathy	11 (0.4%)	4 (0.2%)	15 (0.3%)
Cor pulmonale	0	2 (<0.1%)	2 (<0.1%)
Coronary artery disease	783 (29.9%)	799 (30.5%)	1582 (30.2%)
Coronary artery occlusion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Coronary artery stenosis	5 (0.2%)	4 (0.2%)	9 (0.2%)
Defect conduction intraventricular	3 (0.1%)	3 (0.1%)	6 (0.1%)
Diabetic cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Diastolic dysfunction	15 (0.6%)	17 (0.6%)	32 (0.6%)
Dilatation atrial	1 (<0.1%)	0	1 (<0.1%)
Extrasystoles	3 (0.1%)	5 (0.2%)	8 (0.2%)
Heart valve incompetence	1 (<0.1%)	0	1 (<0.1%)
Hypertensive cardiomyopathy	7 (0.3%)	9 (0.3%)	16 (0.3%)
Hypertensive heart disease	44 (1.7%)	47 (1.8%)	91 (1.7%)
Intracardiac mass	0	1 (<0.1%)	1 (<0.1%)
Ischaemic cardiomyopathy	17 (0.6%)	5 (0.2%)	22 (0.4%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Left atrial dilatation	8 (0.3%)	6 (0.2%)	14 (0.3%)
Left atrial enlargement	5 (0.2%)	7 (0.3%)	12 (0.2%)
Left atrial hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dysfunction	5 (0.2%)	13 (0.5%)	18 (0.3%)
Left ventricular enlargement	0	3 (0.1%)	3 (<0.1%)
Left ventricular failure	10 (0.4%)	19 (0.7%)	29 (0.6%)
Left ventricular hypertrophy	90 (3.4%)	68 (2.6%)	158 (3.0%)
Metabolic cardiomyopathy	9 (0.3%)	3 (0.1%)	12 (0.2%)
Mitral valve calcification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mitral valve disease	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Mitral valve incompetence	46 (1.8%)	72 (2.7%)	118 (2.3%)
Mitral valve prolapse	6 (0.2%)	3 (0.1%)	9 (0.2%)
Mitral valve sclerosis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Mitral valve stenosis	6 (0.2%)	5 (0.2%)	11 (0.2%)
Myocardial fibrosis	8 (0.3%)	8 (0.3%)	16 (0.3%)
Myocardial infarction	352 (13.4%)	363 (13.9%)	715 (13.6%)
Myocardial ischaemia	117 (4.5%)	94 (3.6%)	211 (4.0%)
Myocardial necrosis	0	1 (<0.1%)	1 (<0.1%)
Myocarditis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodal arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Nodal rhythm	0	1 (<0.1%)	1 (<0.1%)
Palpitations	6 (0.2%)	8 (0.3%)	14 (0.3%)
Pericardial effusion	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Pericarditis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pericarditis adhesive	0	2 (<0.1%)	2 (<0.1%)
Pericarditis constrictive	0	1 (<0.1%)	1 (<0.1%)
Pleuropericarditis	1 (<0.1%)	0	1 (<0.1%)
Prinzmetal angina	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Pulmonary valve disease	1 (<0.1%)	0	1 (<0.1%)
Pulmonary valve incompetence	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Restrictive cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Rheumatic heart disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Right atrial dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Right ventricular hypertrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Silent myocardial infarction	2 (<0.1%)	0	2 (<0.1%)
Sinoatrial block	2 (<0.1%)	0	2 (<0.1%)
Sinus arrest	0	1 (<0.1%)	1 (<0.1%)
Sinus arrhythmia	6 (0.2%)	4 (0.2%)	10 (0.2%)
Sinus bradycardia	21 (0.8%)	20 (0.8%)	41 (0.8%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Sinus node dysfunction	11 (0.4%)	6 (0.2%)	17 (0.3%)
Sinus tachycardia	8 (0.3%)	3 (0.1%)	11 (0.2%)
Supraventricular extrasystoles	22 (0.8%)	14 (0.5%)	36 (0.7%)
Supraventricular tachycardia	13 (0.5%)	6 (0.2%)	19 (0.4%)
Systolic dysfunction	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tachyarrhythmia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tachycardia	4 (0.2%)	7 (0.3%)	11 (0.2%)
Tachycardia paroxysmal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tricuspid valve disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tricuspid valve incompetence	28 (1.1%)	25 (1.0%)	53 (1.0%)
Trifascicular block	1 (<0.1%)	0	1 (<0.1%)
Ventricular arrhythmia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Ventricular extrasystoles	27 (1.0%)	30 (1.1%)	57 (1.1%)
Ventricular fibrillation	2 (<0.1%)	0	2 (<0.1%)
Ventricular hypertrophy	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Ventricular hypokinesia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Ventricular tachycardia	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Wolff-Parkinson-White syndrome	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Congenital, familial and genetic disorders	144 (5.5%)	113 (4.3%)	257 (4.9%)
Accessory kidney	0	1 (<0.1%)	1 (<0.1%)
Accessory spleen	1 (<0.1%)	0	1 (<0.1%)
Adenomatous polyposis coli	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Anomalous arrangement of pancreaticobiliary duct	0	1 (<0.1%)	1 (<0.1%)
Antithrombin III deficiency	0	1 (<0.1%)	1 (<0.1%)
Arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biliary hamartoma	0	1 (<0.1%)	1 (<0.1%)
Cardiac septal defect	1 (<0.1%)	0	1 (<0.1%)
Coarctation of the aorta	1 (<0.1%)	0	1 (<0.1%)
Colour blindness	0	1 (<0.1%)	1 (<0.1%)
Congenital arterial malformation	1 (<0.1%)	0	1 (<0.1%)
Congenital cystic kidney disease	5 (0.2%)	5 (0.2%)	10 (0.2%)
Congenital flat feet	1 (<0.1%)	0	1 (<0.1%)
Congenital neurological disorder	0	1 (<0.1%)	1 (<0.1%)
Congenital neuropathy	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	5 (0.2%)	6 (0.2%)	11 (0.2%)
Corneal dystrophy	0	2 (<0.1%)	2 (<0.1%)
Cryptorchism	0	2 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Dolichocolon	2 (<0.1%)	0	2 (<0.1%)
Ectopic kidney	0	1 (<0.1%)	1 (<0.1%)
Ectopic thyroid	1 (<0.1%)	0	1 (<0.1%)
Factor V Leiden mutation	0	2 (<0.1%)	2 (<0.1%)
Familial periodic paralysis	0	1 (<0.1%)	1 (<0.1%)
Familial tremor	1 (<0.1%)	0	1 (<0.1%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Fragile X syndrome	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Glycogen storage disease type I	1 (<0.1%)	0	1 (<0.1%)
Haemochromatosis trait	0	1 (<0.1%)	1 (<0.1%)
Haemophilia	0	1 (<0.1%)	1 (<0.1%)
Hamartoma	1 (<0.1%)	0	1 (<0.1%)
Hereditary haemochromatosis	1 (<0.1%)	0	1 (<0.1%)
Hereditary palmoplantar keratoderma	0	1 (<0.1%)	1 (<0.1%)
Hereditary spastic paraplegia	1 (<0.1%)	0	1 (<0.1%)
Hydrocele	9 (0.3%)	3 (0.1%)	12 (0.2%)
Hypertrophic cardiomyopathy	5 (0.2%)	5 (0.2%)	10 (0.2%)
Hypospadias	3 (0.1%)	0	3 (<0.1%)
Ichthyosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Kidney duplex	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	1 (<0.1%)	1 (<0.1%)
Klippel-Trenaunay syndrome	0	1 (<0.1%)	1 (<0.1%)
Limb malformation	1 (<0.1%)	0	1 (<0.1%)
Muscular dystrophy	3 (0.1%)	0	3 (<0.1%)
Myocardial bridging	1 (<0.1%)	0	1 (<0.1%)
Osteopetrosis	0	1 (<0.1%)	1 (<0.1%)
Peutz-Jeghers syndrome	1 (<0.1%)	0	1 (<0.1%)
Phimosis	9 (0.3%)	3 (0.1%)	12 (0.2%)
Polycystic liver disease	0	2 (<0.1%)	2 (<0.1%)
Porokeratosis	0	1 (<0.1%)	1 (<0.1%)
Porphyria	1 (<0.1%)	0	1 (<0.1%)
Preauricular cyst	0	1 (<0.1%)	1 (<0.1%)
Primary hypercholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	6 (0.2%)	5 (0.2%)	11 (0.2%)
Renal fusion anomaly	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal hypoplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retinitis pigmentosa	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Sacralisation	0	1 (<0.1%)	1 (<0.1%)
Sickle cell anaemia	0	1 (<0.1%)	1 (<0.1%)
Spina bifida	2 (<0.1%)	0	2 (<0.1%)
Supernumerary rib	0	1 (<0.1%)	1 (<0.1%)
Thalassaemia	4 (0.2%)	3 (0.1%)	7 (0.1%)
Thalassaemia alpha	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thalassaemia beta	2 (<0.1%)	0	2 (<0.1%)
Thalassaemia minor	4 (0.2%)	3 (0.1%)	7 (0.1%)
Tilted disc syndrome	0	1 (<0.1%)	1 (<0.1%)
Type IIa hyperlipidaemia	8 (0.3%)	6 (0.2%)	14 (0.3%)
Type IIb hyperlipidaemia	4 (0.2%)	5 (0.2%)	9 (0.2%)
Type V hyperlipidaemia	43 (1.6%)	31 (1.2%)	74 (1.4%)
Usher's syndrome	0	1 (<0.1%)	1 (<0.1%)
Vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery hypoplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Von Willebrand's disease	1 (<0.1%)	0	1 (<0.1%)
Xeroderma pigmentosum	0	1 (<0.1%)	1 (<0.1%)
Ear and labyrinth disorders	135 (5.1%)	138 (5.3%)	273 (5.2%)
Auditory disorder	7 (0.3%)	2 (<0.1%)	9 (0.2%)
Aural polyp	0	1 (<0.1%)	1 (<0.1%)
Cerumen impaction	1 (<0.1%)	0	1 (<0.1%)
Conductive deafness	0	1 (<0.1%)	1 (<0.1%)
Deafness	29 (1.1%)	23 (0.9%)	52 (1.0%)
Deafness bilateral	6 (0.2%)	6 (0.2%)	12 (0.2%)
Deafness neurosensory	12 (0.5%)	25 (1.0%)	37 (0.7%)
Deafness unilateral	7 (0.3%)	5 (0.2%)	12 (0.2%)
Ear canal stenosis	0	1 (<0.1%)	1 (<0.1%)
Ear pain	0	2 (<0.1%)	2 (<0.1%)
Ear pruritus	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	1 (<0.1%)	0	1 (<0.1%)
Excessive cerumen production	2 (<0.1%)	0	2 (<0.1%)
External ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Hypoacusis	24 (0.9%)	17 (0.6%)	41 (0.8%)
Inner ear disorder	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Middle ear adhesions	0	1 (<0.1%)	1 (<0.1%)
Mixed deafness	0	2 (<0.1%)	2 (<0.1%)
Motion sickness	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	1 (<0.1%)	0	1 (<0.1%)
Presbyacusis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Sudden hearing loss	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Tinnitus	16 (0.6%)	14 (0.5%)	30 (0.6%)
Tympanic membrane perforation	3 (0.1%)	0	3 (<0.1%)
Vertigo	31 (1.2%)	30 (1.1%)	61 (1.2%)
Vertigo positional	6 (0.2%)	12 (0.5%)	18 (0.3%)
Vestibular ataxia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vestibular disorder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Endocrine disorders	457 (17.4%)	443 (16.9%)	900 (17.2%)
Acromegaly	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Adrenal disorder	0	1 (<0.1%)	1 (<0.1%)
Adrenal insufficiency	0	1 (<0.1%)	1 (<0.1%)
Adrenal mass	0	3 (0.1%)	3 (<0.1%)
Androgen deficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	0	1 (<0.1%)
Autoimmune thyroiditis	16 (0.6%)	20 (0.8%)	36 (0.7%)
Basedow's disease	4 (0.2%)	5 (0.2%)	9 (0.2%)
Cushing's syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Empty sella syndrome	0	1 (<0.1%)	1 (<0.1%)
Euthyroid sick syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Goitre	96 (3.7%)	59 (2.3%)	155 (3.0%)
Hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hyperparathyroidism	26 (1.0%)	30 (1.1%)	56 (1.1%)
Hyperparathyroidism primary	4 (0.2%)	0	4 (<0.1%)
Hyperparathyroidism secondary	45 (1.7%)	46 (1.8%)	91 (1.7%)
Hyperpituitarism	0	1 (<0.1%)	1 (<0.1%)
Hyperplasia adrenal	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hyperprolactinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperthyroidism	16 (0.6%)	16 (0.6%)	32 (0.6%)
Hypogonadism	7 (0.3%)	13 (0.5%)	20 (0.4%)
Hypogonadism male	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Hypoparathyroidism	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Hypothyroidic goitre	0	2 (<0.1%)	2 (<0.1%)
Hypothyroidism	238 (9.1%)	229 (8.7%)	467 (8.9%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	1 (<0.1%)	4 (0.2%)	5 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Primary hyperaldosteronism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Primary hypogonadism	0	2 (<0.1%)	2 (<0.1%)
Primary hypothyroidism	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Secondary hyperthyroidism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Secondary hypogonadism	2 (<0.1%)	0	2 (<0.1%)
Testicular failure	1 (<0.1%)	0	1 (<0.1%)
Thyroid atrophy	1 (<0.1%)	0	1 (<0.1%)
Thyroid cyst	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Thyroid disorder	5 (0.2%)	3 (0.1%)	8 (0.2%)
Thyroid mass	29 (1.1%)	33 (1.3%)	62 (1.2%)
Thyroiditis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Thyroiditis chronic	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	0	1 (<0.1%)
Toxic nodular goitre	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye disorders	1559 (59.5%)	1565 (59.7%)	3124 (59.6%)
Age-related macular degeneration	8 (0.3%)	4 (0.2%)	12 (0.2%)
Amaurosis	3 (0.1%)	10 (0.4%)	13 (0.2%)
Amaurosis fugax	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Amblyopia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Amblyopia strabismic	0	1 (<0.1%)	1 (<0.1%)
Angle closure glaucoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Aniseikonia	0	1 (<0.1%)	1 (<0.1%)
Anisometropia	0	1 (<0.1%)	1 (<0.1%)
Aphakia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arcus lipoides	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerotic retinopathy	9 (0.3%)	6 (0.2%)	15 (0.3%)
Asthenopia	5 (0.2%)	6 (0.2%)	11 (0.2%)
Astigmatism	18 (0.7%)	7 (0.3%)	25 (0.5%)
Blepharitis	8 (0.3%)	5 (0.2%)	13 (0.2%)
Blepharochalasis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blindness	6 (0.2%)	9 (0.3%)	15 (0.3%)
Blindness unilateral	12 (0.5%)	11 (0.4%)	23 (0.4%)
Borderline glaucoma	5 (0.2%)	6 (0.2%)	11 (0.2%)
Cataract	426 (16.2%)	469 (17.9%)	895 (17.1%)
Cataract cortical	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Cataract diabetic	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Cataract nuclear	8 (0.3%)	4 (0.2%)	12 (0.2%)
Cataract subcapsular	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Central vision loss	0	1 (<0.1%)	1 (<0.1%)
Chalazion	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Chorioretinal atrophy	1 (<0.1%)	0	1 (<0.1%)
Chorioretinopathy	1 (<0.1%)	0	1 (<0.1%)
Choroidal neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Conjunctival haemorrhage	0	4 (0.2%)	4 (<0.1%)
Conjunctival pallor	1 (<0.1%)	0	1 (<0.1%)
Conjunctivitis allergic	19 (0.7%)	13 (0.5%)	32 (0.6%)
Conjunctivochalasis	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	0	1 (<0.1%)	1 (<0.1%)
Corneal erosion	0	2 (<0.1%)	2 (<0.1%)
Corneal infiltrates	0	1 (<0.1%)	1 (<0.1%)
Corneal oedema	0	1 (<0.1%)	1 (<0.1%)
Corneal opacity	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	1 (<0.1%)	0	1 (<0.1%)
Cystoid macular oedema	0	7 (0.3%)	7 (0.1%)
Dacryostenosis acquired	0	3 (0.1%)	3 (<0.1%)
Dermatochalasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic blindness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic eye disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic ophthalmoplegia	1 (<0.1%)	0	1 (<0.1%)
Diabetic retinal oedema	15 (0.6%)	12 (0.5%)	27 (0.5%)
Diabetic retinopathy	1233 (47.0%)	1255 (47.9%)	2488 (47.5%)
Diplopia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dry age-related macular degeneration	4 (0.2%)	3 (0.1%)	7 (0.1%)
Dry eye	46 (1.8%)	48 (1.8%)	94 (1.8%)
Dysmetropsia	1 (<0.1%)	0	1 (<0.1%)
Entropion	1 (<0.1%)	0	1 (<0.1%)
Exfoliation syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exudative retinopathy	1 (<0.1%)	0	1 (<0.1%)
Eye allergy	0	1 (<0.1%)	1 (<0.1%)
Eye disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye pruritus	1 (<0.1%)	0	1 (<0.1%)
Eye ulcer	0	1 (<0.1%)	1 (<0.1%)
Eyelid cyst	1 (<0.1%)	0	1 (<0.1%)
Eyelid oedema	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Floppy eyelid syndrome	0	1 (<0.1%)	1 (<0.1%)
Glaucoma	150 (5.7%)	157 (6.0%)	307 (5.9%)
Hyalosis asteroid	1 (<0.1%)	0	1 (<0.1%)
Hypermetropia	14 (0.5%)	13 (0.5%)	27 (0.5%)
Iridocyclitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Iris neovascularisation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Keratitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Keratoconus	0	1 (<0.1%)	1 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Lacrimation increased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lagophthalmos	1 (<0.1%)	0	1 (<0.1%)
Lenticular opacities	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	19 (0.7%)	18 (0.7%)	37 (0.7%)
Macular fibrosis	7 (0.3%)	6 (0.2%)	13 (0.2%)
Macular oedema	19 (0.7%)	26 (1.0%)	45 (0.9%)
Macular rupture	0	1 (<0.1%)	1 (<0.1%)
Macular scar	1 (<0.1%)	0	1 (<0.1%)
Macular thickening	0	1 (<0.1%)	1 (<0.1%)
Maculopathy	15 (0.6%)	10 (0.4%)	25 (0.5%)
Meibomian gland dysfunction	1 (<0.1%)	0	1 (<0.1%)
Mydriasis	1 (<0.1%)	0	1 (<0.1%)
Myopia	20 (0.8%)	22 (0.8%)	42 (0.8%)
Myopic chorioretinal degeneration	1 (<0.1%)	0	1 (<0.1%)
Neovascular age-related macular degeneration	1 (<0.1%)	0	1 (<0.1%)
Normal tension glaucoma	2 (<0.1%)	0	2 (<0.1%)
Ocular discomfort	0	1 (<0.1%)	1 (<0.1%)
Ocular hypertension	6 (0.2%)	9 (0.3%)	15 (0.3%)
Ocular ischaemic syndrome	2 (<0.1%)	0	2 (<0.1%)
Ocular myasthenia	0	2 (<0.1%)	2 (<0.1%)
Open angle glaucoma	12 (0.5%)	7 (0.3%)	19 (0.4%)
Ophthalmoplegia	1 (<0.1%)	0	1 (<0.1%)
Optic atrophy	5 (0.2%)	0	5 (<0.1%)
Optic disc traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Optic ischaemic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Optic nerve cupping	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Papilloedema	0	1 (<0.1%)	1 (<0.1%)
Pathologic myopia	2 (<0.1%)	0	2 (<0.1%)
Periorbital oedema	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Photophobia	0	2 (<0.1%)	2 (<0.1%)
Pinguecula	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Posterior capsule opacification	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Presbyopia	15 (0.6%)	24 (0.9%)	39 (0.7%)
Pseudo-blepharoptosis	0	1 (<0.1%)	1 (<0.1%)
Pseudopapilloedema	1 (<0.1%)	0	1 (<0.1%)
Pterygium	5 (0.2%)	5 (0.2%)	10 (0.2%)
Punctate keratitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pupils unequal	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	4 (0.2%)	4 (0.2%)	8 (0.2%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal degeneration	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Retinal depigmentation	1 (<0.1%)	0	1 (<0.1%)
Retinal detachment	14 (0.5%)	12 (0.5%)	26 (0.5%)
Retinal disorder	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Retinal drusen	1 (<0.1%)	0	1 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	4 (0.2%)	10 (0.4%)	14 (0.3%)
Retinal neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Retinal oedema	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Retinal pigment epitheliopathy	0	1 (<0.1%)	1 (<0.1%)
Retinal tear	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Retinal vascular disorder	6 (0.2%)	5 (0.2%)	11 (0.2%)
Retinal vascular occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal vascular thrombosis	0	3 (0.1%)	3 (<0.1%)
Retinal vein occlusion	5 (0.2%)	9 (0.3%)	14 (0.3%)
Retinal vein thrombosis	3 (0.1%)	0	3 (<0.1%)
Retinopathy	4 (0.2%)	7 (0.3%)	11 (0.2%)
Retinopathy hypertensive	46 (1.8%)	31 (1.2%)	77 (1.5%)
Retinopathy proliferative	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Retinoschisis	1 (<0.1%)	0	1 (<0.1%)
Rhegmatogenous retinal detachment	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scleral haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Scleritis	1 (<0.1%)	0	1 (<0.1%)
Strabismus	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Swelling of eyelid	1 (<0.1%)	0	1 (<0.1%)
Tractional retinal detachment	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Trichiasis	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Vision blurred	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Visual acuity reduced	5 (0.2%)	4 (0.2%)	9 (0.2%)
Visual impairment	9 (0.3%)	9 (0.3%)	18 (0.3%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vitreous detachment	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Vitreous floaters	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Vitreous haemorrhage	28 (1.1%)	17 (0.6%)	45 (0.9%)
Vitreous opacities	6 (0.2%)	4 (0.2%)	10 (0.2%)
Vitreous prolapse	1 (<0.1%)	0	1 (<0.1%)
Xerophthalmia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorders	923 (35.2%)	980 (37.4%)	1903 (36.3%)
Abdominal adhesions	0	2 (<0.1%)	2 (<0.1%)
Abdominal discomfort	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Abdominal distension	6 (0.2%)	5 (0.2%)	11 (0.2%)
Abdominal hernia	17 (0.6%)	24 (0.9%)	41 (0.8%)
Abdominal incarcerated hernia	0	2 (<0.1%)	2 (<0.1%)
Abdominal mass	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	12 (0.5%)	10 (0.4%)	22 (0.4%)
Abdominal pain lower	2 (<0.1%)	0	2 (<0.1%)
Abdominal pain upper	6 (0.2%)	10 (0.4%)	16 (0.3%)
Abdominal symptom	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal wall oedema	0	1 (<0.1%)	1 (<0.1%)
Abnormal faeces	1 (<0.1%)	0	1 (<0.1%)
Acid peptic disease	6 (0.2%)	6 (0.2%)	12 (0.2%)
Alcoholic pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal fistula	4 (0.2%)	3 (0.1%)	7 (0.1%)
Anal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Anal incontinence	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Anal pruritus	1 (<0.1%)	0	1 (<0.1%)
Anal sphincter atony	1 (<0.1%)	0	1 (<0.1%)
Ascites	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Autoimmune pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Barrett's oesophagus	9 (0.3%)	11 (0.4%)	20 (0.4%)
Bowel movement irregularity	1 (<0.1%)	0	1 (<0.1%)
Breath odour	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Change of bowel habit	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic gastritis	78 (3.0%)	97 (3.7%)	175 (3.3%)
Coeliac disease	3 (0.1%)	0	3 (<0.1%)
Colitis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Colitis ischaemic	1 (<0.1%)	0	1 (<0.1%)
Colitis microscopic	1 (<0.1%)	0	1 (<0.1%)
Colitis ulcerative	6 (0.2%)	5 (0.2%)	11 (0.2%)
Constipation	148 (5.6%)	161 (6.1%)	309 (5.9%)
Crohn's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dental caries	7 (0.3%)	7 (0.3%)	14 (0.3%)
Dental cyst	1 (<0.1%)	0	1 (<0.1%)
Diabetic enteropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic gastroparesis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Diaphragmatic hernia	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Diarrhoea	43 (1.6%)	31 (1.2%)	74 (1.4%)
Dieulafoy's vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Diverticular perforation	0	1 (<0.1%)	1 (<0.1%)
Diverticulum	24 (0.9%)	23 (0.9%)	47 (0.9%)
Diverticulum intestinal	33 (1.3%)	26 (1.0%)	59 (1.1%)
Diverticulum intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Diverticulum oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dry mouth	0	2 (<0.1%)	2 (<0.1%)
Dumping syndrome	0	1 (<0.1%)	1 (<0.1%)
Duodenal perforation	0	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duodenal ulcer	24 (0.9%)	34 (1.3%)	58 (1.1%)
Duodenal ulcer haemorrhage	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duodenitis	8 (0.3%)	14 (0.5%)	22 (0.4%)
Duodenogastric reflux	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Dysbiosis	0	2 (<0.1%)	2 (<0.1%)
Dyskinesia oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dyspepsia	48 (1.8%)	51 (1.9%)	99 (1.9%)
Dysphagia	5 (0.2%)	4 (0.2%)	9 (0.2%)
Enlarged uvula	1 (<0.1%)	0	1 (<0.1%)
Enteritis	1 (<0.1%)	0	1 (<0.1%)
Enterocele	0	1 (<0.1%)	1 (<0.1%)
Enterocolitis	0	1 (<0.1%)	1 (<0.1%)
Epigastric discomfort	2 (<0.1%)	0	2 (<0.1%)
Epulis	0	1 (<0.1%)	1 (<0.1%)
Erosive duodenitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Erosive oesophagitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Eructation	1 (<0.1%)	0	1 (<0.1%)
Flatulence	6 (0.2%)	6 (0.2%)	12 (0.2%)
Functional gastrointestinal disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastric disorder	4 (0.2%)	4 (0.2%)	8 (0.2%)
Gastric haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	0	2 (<0.1%)	2 (<0.1%)
Gastric polyps	8 (0.3%)	15 (0.6%)	23 (0.4%)
Gastric ulcer	30 (1.1%)	30 (1.1%)	60 (1.1%)
Gastric ulcer haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastric xanthoma	1 (<0.1%)	0	1 (<0.1%)
Gastritis	103 (3.9%)	87 (3.3%)	190 (3.6%)
Gastritis erosive	12 (0.5%)	9 (0.3%)	21 (0.4%)
Gastritis haemorrhagic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastroduodenal ulcer	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Gastrointestinal angiectasia	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal angiodysplasia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastrointestinal disorder	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Gastrointestinal haemorrhage	4 (0.2%)	8 (0.3%)	12 (0.2%)
Gastrointestinal motility disorder	5 (0.2%)	0	5 (<0.1%)
Gastrointestinal polyp	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal tract mucosal pigmentation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal ulcer	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal ulcer haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	248 (9.5%)	275 (10.5%)	523 (10.0%)
Gastrooesophageal sphincter insufficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haematemesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematochezia	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Haemorrhoidal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Haemorrhoids	46 (1.8%)	45 (1.7%)	91 (1.7%)
Hiatus hernia	39 (1.5%)	45 (1.7%)	84 (1.6%)
Ileus	4 (0.2%)	0	4 (<0.1%)
Ileus paralytic	0	1 (<0.1%)	1 (<0.1%)
Impaired gastric emptying	6 (0.2%)	8 (0.3%)	14 (0.3%)
Inguinal hernia	27 (1.0%)	31 (1.2%)	58 (1.1%)
Intestinal cyst	0	1 (<0.1%)	1 (<0.1%)
Intestinal metaplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Intestinal mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Intestinal obstruction	3 (0.1%)	10 (0.4%)	13 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Intestinal polyp	5 (0.2%)	3 (0.1%)	8 (0.2%)
Intra-abdominal fluid collection	1 (<0.1%)	0	1 (<0.1%)
Irritable bowel syndrome	21 (0.8%)	28 (1.1%)	49 (0.9%)
Jejunal ulcer	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	0	1 (<0.1%)	1 (<0.1%)
Large intestinal stenosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine perforation	1 (<0.1%)	0	1 (<0.1%)
Large intestine polyp	54 (2.1%)	80 (3.1%)	134 (2.6%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lower gastrointestinal haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Lumbar hernia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Malabsorption	1 (<0.1%)	0	1 (<0.1%)
Mallory-Weiss syndrome	1 (<0.1%)	0	1 (<0.1%)
Mesenteric arteriosclerosis	1 (<0.1%)	0	1 (<0.1%)
Mouth haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nausea	11 (0.4%)	17 (0.6%)	28 (0.5%)
Obstruction gastric	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obstructive defaecation	1 (<0.1%)	0	1 (<0.1%)
Obstructive pancreatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal achalasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal disorder	0	1 (<0.1%)	1 (<0.1%)
Oesophageal spasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophagitis	17 (0.6%)	13 (0.5%)	30 (0.6%)
Oesophagitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Oral discomfort	1 (<0.1%)	0	1 (<0.1%)
Oral disorder	0	2 (<0.1%)	2 (<0.1%)
Pancreatic cyst	7 (0.3%)	6 (0.2%)	13 (0.2%)
Pancreatic disorder	0	1 (<0.1%)	1 (<0.1%)
Pancreatic duct dilatation	0	1 (<0.1%)	1 (<0.1%)
Pancreatic failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	4 (0.2%)	3 (0.1%)	7 (0.1%)
Pancreatitis	9 (0.3%)	14 (0.5%)	23 (0.4%)
Pancreatitis acute	10 (0.4%)	10 (0.4%)	20 (0.4%)
Pancreatitis chronic	29 (1.1%)	21 (0.8%)	50 (1.0%)
Pancreatitis relapsing	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Parotid gland enlargement	0	3 (0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Pathological tooth fracture	0	1 (<0.1%)	1 (<0.1%)
Peptic ulcer	25 (1.0%)	15 (0.6%)	40 (0.8%)
Periodontal disease	101 (3.9%)	118 (4.5%)	219 (4.2%)
Portal hypertensive gastropathy	1 (<0.1%)	0	1 (<0.1%)
Proctitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Pyloric sphincter insufficiency	0	1 (<0.1%)	1 (<0.1%)
Rectal haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal polyp	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Rectal prolapse	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Rectal ulcer	1 (<0.1%)	0	1 (<0.1%)
Reflux gastritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Retroperitoneal fibrosis	0	1 (<0.1%)	1 (<0.1%)
Retroperitoneal haematoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland calculus	0	1 (<0.1%)	1 (<0.1%)
Salivary gland disorder	0	1 (<0.1%)	1 (<0.1%)
Salivary gland mass	1 (<0.1%)	0	1 (<0.1%)
Small intestinal obstruction	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Steatorrhoea	1 (<0.1%)	0	1 (<0.1%)
Stomach mass	1 (<0.1%)	0	1 (<0.1%)
Stomatitis	0	3 (0.1%)	3 (<0.1%)
Swollen tongue	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth deposit	0	1 (<0.1%)	1 (<0.1%)
Tooth impacted	1 (<0.1%)	0	1 (<0.1%)
Tooth loss	3 (0.1%)	0	3 (<0.1%)
Toothache	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Trichoglossia	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	36 (1.4%)	28 (1.1%)	64 (1.2%)
Upper gastrointestinal haemorrhage	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Varices oesophageal	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Vomiting	4 (0.2%)	9 (0.3%)	13 (0.2%)
General disorders and administration site conditions	345 (13.2%)	376 (14.4%)	721 (13.8%)
Adhesion	0	1 (<0.1%)	1 (<0.1%)
Adverse drug reaction	0	1 (<0.1%)	1 (<0.1%)
Asthenia	7 (0.3%)	14 (0.5%)	21 (0.4%)
Chest discomfort	6 (0.2%)	3 (0.1%)	9 (0.2%)
Chest pain	20 (0.8%)	17 (0.6%)	37 (0.7%)
Chronic fatigue syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Complication associated with device	0	1 (<0.1%)	1 (<0.1%)
Cyst	9 (0.3%)	7 (0.3%)	16 (0.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Disease susceptibility	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	13 (0.5%)	16 (0.6%)	29 (0.6%)
Fat tissue increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fatigue	30 (1.1%)	30 (1.1%)	60 (1.1%)
Gait disturbance	6 (0.2%)	7 (0.3%)	13 (0.2%)
Generalised oedema	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Granuloma	0	1 (<0.1%)	1 (<0.1%)
Gravitational oedema	0	3 (0.1%)	3 (<0.1%)
Hernia	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Impaired healing	1 (<0.1%)	0	1 (<0.1%)
Inflammation	5 (0.2%)	3 (0.1%)	8 (0.2%)
Influenza like illness	1 (<0.1%)	0	1 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Lithiasis	0	1 (<0.1%)	1 (<0.1%)
Localised oedema	0	2 (<0.1%)	2 (<0.1%)
Malaise	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Mass	0	2 (<0.1%)	2 (<0.1%)
Metaplasia	1 (<0.1%)	0	1 (<0.1%)
Multiple organ dysfunction syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodule	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-cardiac chest pain	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Oedema	50 (1.9%)	62 (2.4%)	112 (2.1%)
Oedema due to cardiac disease	0	1 (<0.1%)	1 (<0.1%)
Oedema due to renal disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Oedema peripheral	196 (7.5%)	197 (7.5%)	393 (7.5%)
Pain	14 (0.5%)	14 (0.5%)	28 (0.5%)
Peripheral swelling	12 (0.5%)	15 (0.6%)	27 (0.5%)
Polyp	0	4 (0.2%)	4 (<0.1%)
Pyrexia	3 (0.1%)	5 (0.2%)	8 (0.2%)
Sensation of foreign body	0	1 (<0.1%)	1 (<0.1%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Systemic inflammatory response syndrome	2 (<0.1%)	0	2 (<0.1%)
Temperature intolerance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thirst	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular stent thrombosis	1 (<0.1%)	0	1 (<0.1%)
Xerosis	1 (<0.1%)	0	1 (<0.1%)
Hepatobiliary disorders	475 (18.1%)	496 (18.9%)	971 (18.5%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Alcoholic liver disease	5 (0.2%)	3 (0.1%)	8 (0.2%)
Bile duct stone	6 (0.2%)	5 (0.2%)	11 (0.2%)
Biliary colic	0	1 (<0.1%)	1 (<0.1%)
Biliary cyst	1 (<0.1%)	0	1 (<0.1%)
Biliary dilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Biliary dyskinesia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cholangitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholecystitis	13 (0.5%)	17 (0.6%)	30 (0.6%)
Cholecystitis acute	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Cholecystitis chronic	22 (0.8%)	20 (0.8%)	42 (0.8%)
Cholelithiasis	133 (5.1%)	128 (4.9%)	261 (5.0%)
Cholestasis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Chronic hepatitis	5 (0.2%)	7 (0.3%)	12 (0.2%)
Cirrhosis alcoholic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cryptogenic cirrhosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic hepatopathy	4 (0.2%)	6 (0.2%)	10 (0.2%)
Drug-induced liver injury	1 (<0.1%)	0	1 (<0.1%)
Gallbladder cholesterolosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gallbladder disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gallbladder enlargement	0	1 (<0.1%)	1 (<0.1%)
Gallbladder polyp	21 (0.8%)	28 (1.1%)	49 (0.9%)
Hepatic cirrhosis	5 (0.2%)	13 (0.5%)	18 (0.3%)
Hepatic cyst	11 (0.4%)	23 (0.9%)	34 (0.6%)
Hepatic failure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic fibrosis	0	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	14 (0.5%)	14 (0.5%)	28 (0.5%)
Hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Hepatic lesion	0	1 (<0.1%)	1 (<0.1%)
Hepatic mass	0	3 (0.1%)	3 (<0.1%)
Hepatic steatosis	292 (11.1%)	282 (10.8%)	574 (11.0%)
Hepatitis	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	0	3 (0.1%)	3 (<0.1%)
Hepatocellular injury	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hepatomegaly	6 (0.2%)	11 (0.4%)	17 (0.3%)
Hepatosplenomegaly	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Hyperplastic cholecystopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Jaundice	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Liver disorder	8 (0.3%)	17 (0.6%)	25 (0.5%)
Liver injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Non-alcoholic steatohepatitis	4 (0.2%)	5 (0.2%)	9 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Nonalcoholic fatty liver disease	15 (0.6%)	12 (0.5%)	27 (0.5%)
Portal hypertension	0	1 (<0.1%)	1 (<0.1%)
Post cholecystectomy syndrome	3 (0.1%)	0	3 (<0.1%)
Primary biliary cholangitis	0	1 (<0.1%)	1 (<0.1%)
Sphincter of Oddi dysfunction	0	1 (<0.1%)	1 (<0.1%)
Steatohepatitis	9 (0.3%)	6 (0.2%)	15 (0.3%)
Immune system disorders	171 (6.5%)	137 (5.2%)	308 (5.9%)
Allergic oedema	1 (<0.1%)	0	1 (<0.1%)
Allergy to animal	2 (<0.1%)	0	2 (<0.1%)
Allergy to arthropod sting	3 (0.1%)	3 (0.1%)	6 (0.1%)
Allergy to chemicals	1 (<0.1%)	0	1 (<0.1%)
Allergy to metals	2 (<0.1%)	0	2 (<0.1%)
Allergy to plants	1 (<0.1%)	0	1 (<0.1%)
Amyloidosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Anaphylactic shock	1 (<0.1%)	0	1 (<0.1%)
Contrast media allergy	1 (<0.1%)	0	1 (<0.1%)
Drug hypersensitivity	68 (2.6%)	62 (2.4%)	130 (2.5%)
Dust allergy	3 (0.1%)	0	3 (<0.1%)
Flour sensitivity	1 (<0.1%)	0	1 (<0.1%)
Food allergy	8 (0.3%)	3 (0.1%)	11 (0.2%)
Hypersensitivity	15 (0.6%)	10 (0.4%)	25 (0.5%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immunodeficiency common variable	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	5 (0.2%)	6 (0.2%)	11 (0.2%)
Milk allergy	0	1 (<0.1%)	1 (<0.1%)
Mite allergy	0	1 (<0.1%)	1 (<0.1%)
Multiple allergies	3 (0.1%)	5 (0.2%)	8 (0.2%)
Mycotic allergy	2 (<0.1%)	0	2 (<0.1%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to colouring	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	1 (<0.1%)	1 (<0.1%)
Rubber sensitivity	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Sarcoidosis	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Seasonal allergy	83 (3.2%)	60 (2.3%)	143 (2.7%)
Infections and infestations	622 (23.7%)	639 (24.4%)	1261 (24.1%)
Abdominal abscess	0	1 (<0.1%)	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abscess	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Abscess limb	4 (0.2%)	5 (0.2%)	9 (0.2%)
Abscess neck	2 (<0.1%)	0	2 (<0.1%)
Abscess soft tissue	0	1 (<0.1%)	1 (<0.1%)
Acarodermatitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Acute hepatitis B	0	1 (<0.1%)	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Alveolar osteitis	0	1 (<0.1%)	1 (<0.1%)
American trypanosomiasis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal abscess	3 (0.1%)	6 (0.2%)	9 (0.2%)
Appendicitis	19 (0.7%)	22 (0.8%)	41 (0.8%)
Appendicitis perforated	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Arthritis infective	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic HIV infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)
Bacteraemia	2 (<0.1%)	0	2 (<0.1%)
Bacterial disease carrier	1 (<0.1%)	0	1 (<0.1%)
Bacteriuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bartholin's abscess	0	1 (<0.1%)	1 (<0.1%)
Blister infected	0	1 (<0.1%)	1 (<0.1%)
Body tinea	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Bone abscess	0	1 (<0.1%)	1 (<0.1%)
Bone tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Borrelia infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Boutonneuse fever	0	1 (<0.1%)	1 (<0.1%)
Brain abscess	0	1 (<0.1%)	1 (<0.1%)
Bronchiolitis	0	2 (<0.1%)	2 (<0.1%)
Bronchitis	30 (1.1%)	25 (1.0%)	55 (1.0%)
Bursitis infective	1 (<0.1%)	0	1 (<0.1%)
Candida infection	1 (<0.1%)	0	1 (<0.1%)
Carbuncle	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cellulitis	29 (1.1%)	28 (1.1%)	57 (1.1%)
Cervicitis	1 (<0.1%)	0	1 (<0.1%)
Chest wall abscess	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	0	3 (0.1%)	3 (<0.1%)
Cholecystitis infective	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic hepatitis B	5 (0.2%)	3 (0.1%)	8 (0.2%)
Chronic hepatitis C	6 (0.2%)	6 (0.2%)	12 (0.2%)
Chronic sinusitis	10 (0.4%)	10 (0.4%)	20 (0.4%)
Chronic tonsillitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Clostridium difficile colitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coccidioidomycosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Conjunctivitis	29 (1.1%)	21 (0.8%)	50 (1.0%)
Cutaneous leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Cystitis	9 (0.3%)	12 (0.5%)	21 (0.4%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	0	2 (<0.1%)	2 (<0.1%)
Dermatophytosis of nail	11 (0.4%)	9 (0.3%)	20 (0.4%)
Device related infection	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Diabetic foot infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic gangrene	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Diverticulitis	9 (0.3%)	13 (0.5%)	22 (0.4%)
Diverticulitis intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Ear infection	4 (0.2%)	3 (0.1%)	7 (0.1%)
Ear infection fungal	0	1 (<0.1%)	1 (<0.1%)
Echinococciasis	2 (<0.1%)	0	2 (<0.1%)
Empyema	1 (<0.1%)	0	1 (<0.1%)
Encephalitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	1 (<0.1%)	0	1 (<0.1%)
Endophthalmitis	0	1 (<0.1%)	1 (<0.1%)
Enteritis infectious	1 (<0.1%)	0	1 (<0.1%)
Enterocolitis infectious	1 (<0.1%)	0	1 (<0.1%)
Epididymitis	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Erysipelas	6 (0.2%)	10 (0.4%)	16 (0.3%)
Escherichia sepsis	0	1 (<0.1%)	1 (<0.1%)
Eye infection	0	1 (<0.1%)	1 (<0.1%)
Eye infection fungal	0	1 (<0.1%)	1 (<0.1%)
Focal peritonitis	2 (<0.1%)	0	2 (<0.1%)
Folliculitis	8 (0.3%)	4 (0.2%)	12 (0.2%)
Fournier's gangrene	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fungal infection	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Fungal skin infection	6 (0.2%)	5 (0.2%)	11 (0.2%)
Furuncle	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Gangrene	2 (<0.1%)	9 (0.3%)	11 (0.2%)
Gastritis bacterial	0	1 (<0.1%)	1 (<0.1%)
Gastroenteritis	9 (0.3%)	3 (0.1%)	12 (0.2%)
Gastroenteritis salmonella	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis viral	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Genital herpes	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Genitourinary tract infection	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Gingivitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Groin abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
HIV carrier	0	1 (<0.1%)	1 (<0.1%)
HIV infection	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic fever with renal syndrome	1 (<0.1%)	0	1 (<0.1%)
Helicobacter gastritis	4 (0.2%)	3 (0.1%)	7 (0.1%)
Helicobacter infection	5 (0.2%)	3 (0.1%)	8 (0.2%)
Hepatic echinococciasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis A	4 (0.2%)	4 (0.2%)	8 (0.2%)
Hepatitis B	18 (0.7%)	13 (0.5%)	31 (0.6%)
Hepatitis C	11 (0.4%)	16 (0.6%)	27 (0.5%)
Herpes ophthalmic	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Herpes simplex	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Herpes zoster	16 (0.6%)	16 (0.6%)	32 (0.6%)
Histoplasmosis	0	1 (<0.1%)	1 (<0.1%)
Hordeolum	1 (<0.1%)	0	1 (<0.1%)
Infected dermal cyst	0	1 (<0.1%)	1 (<0.1%)
Infected skin ulcer	1 (<0.1%)	0	1 (<0.1%)
Infection	0	4 (0.2%)	4 (<0.1%)
Infectious pleural effusion	0	1 (<0.1%)	1 (<0.1%)
Infective myositis	0	1 (<0.1%)	1 (<0.1%)
Influenza	6 (0.2%)	9 (0.3%)	15 (0.3%)
Intervertebral discitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint abscess	1 (<0.1%)	0	1 (<0.1%)
Joint tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Kidney infection	1 (<0.1%)	0	1 (<0.1%)
Klebsiella infection	0	1 (<0.1%)	1 (<0.1%)
Labyrinthitis	7 (0.3%)	3 (0.1%)	10 (0.2%)
Laryngitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Latent syphilis	0	1 (<0.1%)	1 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Liver abscess	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Localised infection	8 (0.3%)	5 (0.2%)	13 (0.2%)
Lower respiratory tract infection	1 (<0.1%)	0	1 (<0.1%)
Lung abscess	1 (<0.1%)	0	1 (<0.1%)
Lyme disease	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lymph node tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Malaria	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mastoiditis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Meningitis	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Meningitis bacterial	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Meningitis viral	0	1 (<0.1%)	1 (<0.1%)
Molluscum contagiosum	1 (<0.1%)	0	1 (<0.1%)
Mumps	0	2 (<0.1%)	2 (<0.1%)
Myringitis	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	20 (0.8%)	24 (0.9%)	44 (0.8%)
Necrotising fasciitis	0	2 (<0.1%)	2 (<0.1%)
Neuroborreliosis	1 (<0.1%)	0	1 (<0.1%)
Neurocysticercosis	1 (<0.1%)	0	1 (<0.1%)
Neurosyphilis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Onychomycosis	39 (1.5%)	39 (1.5%)	78 (1.5%)
Ophthalmic herpes simplex	2 (<0.1%)	0	2 (<0.1%)
Ophthalmic herpes zoster	0	2 (<0.1%)	2 (<0.1%)
Oral candidiasis	0	1 (<0.1%)	1 (<0.1%)
Oral fungal infection	1 (<0.1%)	0	1 (<0.1%)
Oral herpes	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Orchitis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Osteomyelitis	19 (0.7%)	19 (0.7%)	38 (0.7%)
Osteomyelitis acute	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis chronic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Otitis externa	4 (0.2%)	5 (0.2%)	9 (0.2%)
Otitis media	4 (0.2%)	3 (0.1%)	7 (0.1%)
Otitis media acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Otitis media chronic	4 (0.2%)	7 (0.3%)	11 (0.2%)
Otitis media fungal	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	1 (<0.1%)	0	1 (<0.1%)
Paronychia	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Parotid abscess	0	1 (<0.1%)	1 (<0.1%)
Pelvic inflammatory disease	1 (<0.1%)	0	1 (<0.1%)
Perichondritis	0	1 (<0.1%)	1 (<0.1%)
Pericoronitis	0	1 (<0.1%)	1 (<0.1%)
Periodontitis	0	1 (<0.1%)	1 (<0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Peritonsillar abscess	1 (<0.1%)	0	1 (<0.1%)
Periumbilical abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	6 (0.2%)	11 (0.4%)	17 (0.3%)
Pilonidal cyst	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Plasmodium falciparum infection	0	1 (<0.1%)	1 (<0.1%)
Pneumonia	34 (1.3%)	45 (1.7%)	79 (1.5%)
Pneumonia bacterial	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Pneumonia influenzal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia legionella	0	1 (<0.1%)	1 (<0.1%)
Poliomyelitis	3 (0.1%)	0	3 (<0.1%)
Post procedural infection	0	2 (<0.1%)	2 (<0.1%)
Postoperative wound infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prostatic abscess	1 (<0.1%)	0	1 (<0.1%)
Psoas abscess	0	1 (<0.1%)	1 (<0.1%)
Pulmonary echinococciasis	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	16 (0.6%)	18 (0.7%)	34 (0.6%)
Pulpitis dental	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Pustule	1 (<0.1%)	0	1 (<0.1%)
Pyelonephritis	5 (0.2%)	8 (0.3%)	13 (0.2%)
Pyelonephritis acute	0	3 (0.1%)	3 (<0.1%)
Pyelonephritis chronic	40 (1.5%)	36 (1.4%)	76 (1.4%)
Pyoderma	0	1 (<0.1%)	1 (<0.1%)
Pyonephrosis	0	1 (<0.1%)	1 (<0.1%)
Pyuria	0	1 (<0.1%)	1 (<0.1%)
Rectal abscess	0	1 (<0.1%)	1 (<0.1%)
Renal abscess	0	2 (<0.1%)	2 (<0.1%)
Renal cyst infection	0	1 (<0.1%)	1 (<0.1%)
Renal tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	3 (0.1%)	8 (0.3%)	11 (0.2%)
Respiratory tract infection viral	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Rhinitis	18 (0.7%)	9 (0.3%)	27 (0.5%)
Schistosomiasis liver	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	3 (0.1%)	6 (0.2%)	9 (0.2%)
Septic shock	1 (<0.1%)	0	1 (<0.1%)
Sinusitis	16 (0.6%)	13 (0.5%)	29 (0.6%)
Skin candida	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin infection	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Soft tissue infection	3 (0.1%)	0	3 (<0.1%)
Staphylococcal bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal infection	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Staphylococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Stoma site abscess	1 (<0.1%)	0	1 (<0.1%)
Streptococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Strongyloidiasis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	4 (0.2%)	4 (0.2%)	8 (0.2%)
Subdiaphragmatic abscess	0	1 (<0.1%)	1 (<0.1%)
Tetanus	0	1 (<0.1%)	1 (<0.1%)
Tick-borne viral encephalitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Tinea cruris	4 (0.2%)	0	4 (<0.1%)
Tinea infection	4 (0.2%)	7 (0.3%)	11 (0.2%)
Tinea pedis	26 (1.0%)	28 (1.1%)	54 (1.0%)
Tinea versicolour	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tonsillitis	5 (0.2%)	4 (0.2%)	9 (0.2%)
Tooth abscess	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Tooth infection	1 (<0.1%)	0	1 (<0.1%)
Tracheitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tracheobronchitis	0	1 (<0.1%)	1 (<0.1%)
Trematode infection	0	2 (<0.1%)	2 (<0.1%)
Trichophytosis	1 (<0.1%)	0	1 (<0.1%)
Tuberculosis	13 (0.5%)	8 (0.3%)	21 (0.4%)
Tuberculous laryngitis	1 (<0.1%)	0	1 (<0.1%)
Tuberculous pleurisy	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	36 (1.4%)	35 (1.3%)	71 (1.4%)
Urethritis	1 (<0.1%)	0	1 (<0.1%)
Urinary tract infection	53 (2.0%)	59 (2.3%)	112 (2.1%)
Urinary tract infection bacterial	1 (<0.1%)	0	1 (<0.1%)
Urosepsis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Vaginal infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Varicella	0	2 (<0.1%)	2 (<0.1%)
Varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Vestibular neuronitis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Viral hepatitis carrier	8 (0.3%)	7 (0.3%)	15 (0.3%)
Viral infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Viral myocarditis	1 (<0.1%)	0	1 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	0	2 (<0.1%)
Vulval abscess	0	1 (<0.1%)	1 (<0.1%)
Vulvitis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal mycotic infection	0	1 (<0.1%)	1 (<0.1%)
Wound infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injury, poisoning and procedural complications	225 (8.6%)	214 (8.2%)	439 (8.4%)
Abdominal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Accident	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Animal scratch	0	1 (<0.1%)	1 (<0.1%)
Ankle fracture	6 (0.2%)	11 (0.4%)	17 (0.3%)
Arterial injury	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	2 (<0.1%)	3 (0.1%)	5 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Asbestosis	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Back injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blindness traumatic	1 (<0.1%)	0	1 (<0.1%)
Bone contusion	1 (<0.1%)	0	1 (<0.1%)
Bone fissure	0	1 (<0.1%)	1 (<0.1%)
Brain contusion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Burns third degree	0	1 (<0.1%)	1 (<0.1%)
Carotid artery restenosis	1 (<0.1%)	0	1 (<0.1%)
Cartilage injury	0	1 (<0.1%)	1 (<0.1%)
Cataract operation complication	1 (<0.1%)	0	1 (<0.1%)
Cervical vertebral fracture	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Chest injury	0	4 (0.2%)	4 (<0.1%)
Clavicle fracture	5 (0.2%)	5 (0.2%)	10 (0.2%)
Concussion	4 (0.2%)	4 (0.2%)	8 (0.2%)
Contraindicated product administered	1 (<0.1%)	0	1 (<0.1%)
Contusion	5 (0.2%)	4 (0.2%)	9 (0.2%)
Corneal abrasion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary vascular graft occlusion	0	1 (<0.1%)	1 (<0.1%)
Craniocerebral injury	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Deafness traumatic	0	1 (<0.1%)	1 (<0.1%)
Dislocation of sternum	0	1 (<0.1%)	1 (<0.1%)
Electric shock	0	1 (<0.1%)	1 (<0.1%)
Epicondylitis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Exposure to communicable disease	0	2 (<0.1%)	2 (<0.1%)
Exposure to radiation	0	1 (<0.1%)	1 (<0.1%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye injury	3 (0.1%)	0	3 (<0.1%)
Face injury	1 (<0.1%)	0	1 (<0.1%)
Facial bones fracture	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Fall	6 (0.2%)	7 (0.3%)	13 (0.2%)
Femoral neck fracture	2 (<0.1%)	0	2 (<0.1%)
Femur fracture	10 (0.4%)	3 (0.1%)	13 (0.2%)
Fibula fracture	7 (0.3%)	4 (0.2%)	11 (0.2%)
Foot fracture	10 (0.4%)	6 (0.2%)	16 (0.3%)
Forearm fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Foreign body	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fracture	0	1 (<0.1%)	1 (<0.1%)
Fractured sacrum	0	1 (<0.1%)	1 (<0.1%)
Gingival injury	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hand fracture	4 (0.2%)	3 (0.1%)	7 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Head injury	4 (0.2%)	3 (0.1%)	7 (0.1%)
Heart injury	0	1 (<0.1%)	1 (<0.1%)
Heat exhaustion	1 (<0.1%)	0	1 (<0.1%)
Hip fracture	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Humerus fracture	6 (0.2%)	6 (0.2%)	12 (0.2%)
Incision site haematoma	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia	12 (0.5%)	2 (<0.1%)	14 (0.3%)
Injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint dislocation	6 (0.2%)	5 (0.2%)	11 (0.2%)
Joint injury	3 (0.1%)	4 (0.2%)	7 (0.1%)
Kidney contusion	0	1 (<0.1%)	1 (<0.1%)
Kidney rupture	0	1 (<0.1%)	1 (<0.1%)
Laryngeal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament injury	1 (<0.1%)	0	1 (<0.1%)
Ligament rupture	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Ligament sprain	5 (0.2%)	9 (0.3%)	14 (0.3%)
Limb injury	14 (0.5%)	9 (0.3%)	23 (0.4%)
Limb traumatic amputation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Lower limb fracture	7 (0.3%)	8 (0.3%)	15 (0.3%)
Lumbar vertebral fracture	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Meniscus injury	8 (0.3%)	10 (0.4%)	18 (0.3%)
Multiple injuries	0	1 (<0.1%)	1 (<0.1%)
Muscle injury	0	1 (<0.1%)	1 (<0.1%)
Muscle rupture	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Muscle strain	3 (0.1%)	4 (0.2%)	7 (0.1%)
Occupational exposure to toxic agent	1 (<0.1%)	0	1 (<0.1%)
Osteochondral fracture	0	1 (<0.1%)	1 (<0.1%)
Palate injury	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	3 (0.1%)	0	3 (<0.1%)
Pelvic fracture	2 (<0.1%)	0	2 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve injury	1 (<0.1%)	0	1 (<0.1%)
Pneumocephalus	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post laminectomy syndrome	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Post procedural haematoma	0	1 (<0.1%)	1 (<0.1%)
Post procedural hypoparathyroidism	0	1 (<0.1%)	1 (<0.1%)
Post procedural hypothyroidism	3 (0.1%)	5 (0.2%)	8 (0.2%)
Post-traumatic neck syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Post-traumatic pain	3 (0.1%)	3 (0.1%)	6 (0.1%)
Procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Radial nerve injury	1 (<0.1%)	0	1 (<0.1%)
Radiation injury	0	1 (<0.1%)	1 (<0.1%)
Radius fracture	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Reactive gastropathy	0	1 (<0.1%)	1 (<0.1%)
Rib fracture	5 (0.2%)	6 (0.2%)	11 (0.2%)
Road traffic accident	7 (0.3%)	4 (0.2%)	11 (0.2%)
Scapula fracture	1 (<0.1%)	0	1 (<0.1%)
Scar	2 (<0.1%)	0	2 (<0.1%)
Skin abrasion	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Skin graft failure	1 (<0.1%)	0	1 (<0.1%)
Skin injury	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin laceration	4 (0.2%)	3 (0.1%)	7 (0.1%)
Skin wound	4 (0.2%)	0	4 (<0.1%)
Skull fracture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Soft tissue injury	1 (<0.1%)	0	1 (<0.1%)
Spinal compression fracture	0	4 (0.2%)	4 (<0.1%)
Spinal fracture	5 (0.2%)	5 (0.2%)	10 (0.2%)
Stab wound	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sternal fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Stoma complication	1 (<0.1%)	0	1 (<0.1%)
Stomal hernia	1 (<0.1%)	0	1 (<0.1%)
Stress fracture	1 (<0.1%)	0	1 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	0	1 (<0.1%)
Subdural haematoma	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tendon injury	1 (<0.1%)	0	1 (<0.1%)
Tendon rupture	7 (0.3%)	3 (0.1%)	10 (0.2%)
Thermal burn	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Thoracic vertebral fracture	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Tibia fracture	6 (0.2%)	6 (0.2%)	12 (0.2%)
Tooth fracture	1 (<0.1%)	0	1 (<0.1%)
Toxicity to various agents	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Traumatic arthritis	0	1 (<0.1%)	1 (<0.1%)
Traumatic fracture	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Traumatic haemothorax	0	1 (<0.1%)	1 (<0.1%)
Traumatic liver injury	0	1 (<0.1%)	1 (<0.1%)
Ulna fracture	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	4 (0.2%)	11 (0.4%)	15 (0.3%)
Vascular pseudoaneurysm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Wound necrosis	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Wrist fracture	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Investigations	308 (11.7%)	309 (11.8%)	617 (11.8%)
Activated partial thromboplastin time prolonged	1 (<0.1%)	0	1 (<0.1%)
Alanine aminotransferase increased	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Albumin urine present	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Amylase increased	0	3 (0.1%)	3 (<0.1%)
Angiocardiogram	23 (0.9%)	9 (0.3%)	32 (0.6%)
Angiogram	9 (0.3%)	5 (0.2%)	14 (0.3%)
Angiogram cerebral	1 (<0.1%)	0	1 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Ankle brachial index	1 (<0.1%)	0	1 (<0.1%)
Aortic bruit	0	1 (<0.1%)	1 (<0.1%)
Aortogram	1 (<0.1%)	0	1 (<0.1%)
Arteriogram	2 (<0.1%)	0	2 (<0.1%)
Arteriogram coronary normal	1 (<0.1%)	0	1 (<0.1%)
Arteriogram renal	1 (<0.1%)	0	1 (<0.1%)
Arthroscopy	6 (0.2%)	3 (0.1%)	9 (0.2%)
Aspartate aminotransferase increased	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Aspiration pleural cavity	0	2 (<0.1%)	2 (<0.1%)
Biopsy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Biopsy breast	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Biopsy kidney	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Biopsy liver normal	0	1 (<0.1%)	1 (<0.1%)
Biopsy lymph gland	0	1 (<0.1%)	1 (<0.1%)
Biopsy prostate	2 (<0.1%)	0	2 (<0.1%)
Biopsy skin	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	4 (0.2%)	5 (0.2%)	9 (0.2%)
Blood bicarbonate decreased	2 (<0.1%)	0	2 (<0.1%)
Blood cholesterol increased	32 (1.2%)	31 (1.2%)	63 (1.2%)
Blood creatine increased	0	1 (<0.1%)	1 (<0.1%)
Blood creatine phosphokinase increased	36 (1.4%)	48 (1.8%)	84 (1.6%)
Blood creatinine increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood glucose abnormal	0	1 (<0.1%)	1 (<0.1%)
Blood homocysteine increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood iron decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood lactate dehydrogenase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood magnesium decreased	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Blood magnesium increased	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Blood parathyroid hormone increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Blood potassium decreased	0	3 (0.1%)	3 (<0.1%)
Blood potassium increased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Blood pressure increased	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Blood sodium decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood testosterone decreased	6 (0.2%)	4 (0.2%)	10 (0.2%)
Blood testosterone increased	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Blood urea increased	0	2 (<0.1%)	2 (<0.1%)
Blood uric acid increased	9 (0.3%)	14 (0.5%)	23 (0.4%)
Blood urine present	1 (<0.1%)	0	1 (<0.1%)
Blood zinc decreased	1 (<0.1%)	0	1 (<0.1%)
Body mass index increased	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Bone densitometry	1 (<0.1%)	0	1 (<0.1%)
Bone density decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bronchoscopy normal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	12 (0.5%)	17 (0.6%)	29 (0.6%)
Carbon dioxide decreased	0	2 (<0.1%)	2 (<0.1%)
Cardiac murmur	19 (0.7%)	20 (0.8%)	39 (0.7%)
Cardiac stress test	0	1 (<0.1%)	1 (<0.1%)
Cardiac stress test abnormal	1 (<0.1%)	0	1 (<0.1%)
Cardiac ventriculogram	1 (<0.1%)	0	1 (<0.1%)
Carotid bruit	3 (0.1%)	6 (0.2%)	9 (0.2%)
Carotid intima-media thickness increased	1 (<0.1%)	0	1 (<0.1%)
Catheterisation cardiac	15 (0.6%)	20 (0.8%)	35 (0.7%)
Catheterisation cardiac normal	0	1 (<0.1%)	1 (<0.1%)
Chest X-ray abnormal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Computerised tomogram head abnormal	0	1 (<0.1%)	1 (<0.1%)
Crystal urine present	0	1 (<0.1%)	1 (<0.1%)
Cystoscopy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
ECG signs of myocardial infarction	0	1 (<0.1%)	1 (<0.1%)
ECG signs of ventricular hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Echocardiogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ejection fraction decreased	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Ejection fraction normal	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QT interval abnormal	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Electrocardiogram QT prolonged	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Electrocardiogram ST segment abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram ST-T change	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Electrocardiogram ST-T segment abnormal	3 (0.1%)	0	3 (<0.1%)
Electrocardiogram T wave abnormal	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Electrocardiogram T wave alternans	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave amplitude decreased	4 (0.2%)	3 (0.1%)	7 (0.1%)
Electrocardiogram T wave inversion	4 (0.2%)	3 (0.1%)	7 (0.1%)
Electrocardiogram U-wave prominent	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram abnormal	5 (0.2%)	4 (0.2%)	9 (0.2%)
Electrocardiogram high voltage	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram repolarisation abnormality	7 (0.3%)	4 (0.2%)	11 (0.2%)
Endoscopic retrograde cholangiopancreatography	0	1 (<0.1%)	1 (<0.1%)
Endoscopy upper gastrointestinal tract	0	1 (<0.1%)	1 (<0.1%)
Eosinophil count increased	0	1 (<0.1%)	1 (<0.1%)
False positive investigation result	0	2 (<0.1%)	2 (<0.1%)
Forced vital capacity decreased	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase increased	16 (0.6%)	14 (0.5%)	30 (0.6%)
Gastric pH decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glomerular filtration rate decreased	0	1 (<0.1%)	1 (<0.1%)
Glucose tolerance increased	0	1 (<0.1%)	1 (<0.1%)
Glycosylated haemoglobin increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haemoglobin decreased	0	1 (<0.1%)	1 (<0.1%)
Heart rate increased	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Heart rate normal	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Helicobacter test positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatic enzyme abnormal	0	1 (<0.1%)	1 (<0.1%)
Hepatic enzyme increased	3 (0.1%)	3 (0.1%)	6 (0.1%)
Hepatitis B surface antigen positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis C antibody positive	3 (0.1%)	0	3 (<0.1%)
Hepatitis C virus test positive	0	1 (<0.1%)	1 (<0.1%)
High density lipoprotein increased	1 (<0.1%)	0	1 (<0.1%)
Inflammatory marker increased	1 (<0.1%)	0	1 (<0.1%)
Influenza A virus test positive	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intraocular pressure test abnormal	0	1 (<0.1%)	1 (<0.1%)
Investigation	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Keratometry	1 (<0.1%)	0	1 (<0.1%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)
Light chain analysis increased	0	1 (<0.1%)	1 (<0.1%)
Lipase increased	0	2 (<0.1%)	2 (<0.1%)
Lipids abnormal	1 (<0.1%)	0	1 (<0.1%)
Lipids increased	1 (<0.1%)	0	1 (<0.1%)
Lipoprotein (a) increased	0	2 (<0.1%)	2 (<0.1%)
Liver function test abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Liver function test increased	0	3 (0.1%)	3 (<0.1%)
Mean cell volume increased	1 (<0.1%)	0	1 (<0.1%)
Monocyte count increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial necrosis marker increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial strain	0	2 (<0.1%)	2 (<0.1%)
N-terminal prohormone brain natriuretic peptide increased	0	1 (<0.1%)	1 (<0.1%)
Neutrophil count increased	1 (<0.1%)	0	1 (<0.1%)
Ophthalmological examination normal	0	1 (<0.1%)	1 (<0.1%)
Oxygen consumption increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Parasite stool test positive	1 (<0.1%)	0	1 (<0.1%)
Pedal pulse decreased	0	2 (<0.1%)	2 (<0.1%)
Peripheral arteriogram	0	1 (<0.1%)	1 (<0.1%)
Peripheral pulse decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Platelet count decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Polymerase chain reaction positive	0	1 (<0.1%)	1 (<0.1%)
Popliteal pulse	0	1 (<0.1%)	1 (<0.1%)
Proctosigmoidoscopy	0	1 (<0.1%)	1 (<0.1%)
Prostatic specific antigen increased	5 (0.2%)	8 (0.3%)	13 (0.2%)
Pulmonary imaging procedure abnormal	1 (<0.1%)	0	1 (<0.1%)
Pulse absent	0	1 (<0.1%)	1 (<0.1%)
QRS axis abnormal	3 (0.1%)	11 (0.4%)	14 (0.3%)
Red blood cell sedimentation rate increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Red cell distribution width increased	0	1 (<0.1%)	1 (<0.1%)
Renal function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Scan myocardial perfusion abnormal	0	1 (<0.1%)	1 (<0.1%)
Smear cervix abnormal	0	1 (<0.1%)	1 (<0.1%)
Stress echocardiogram	0	1 (<0.1%)	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test normal	2 (<0.1%)	0	2 (<0.1%)
Thyroxine abnormal	0	1 (<0.1%)	1 (<0.1%)
Transaminases increased	0	4 (0.2%)	4 (<0.1%)
Transferrin saturation decreased	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	4 (0.2%)	2 (<0.1%)	6 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Troponin increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tuberculin test positive	0	1 (<0.1%)	1 (<0.1%)
Ultrasound Doppler	1 (<0.1%)	0	1 (<0.1%)
Ultrasound kidney abnormal	1 (<0.1%)	0	1 (<0.1%)
Ultrasound scan	1 (<0.1%)	0	1 (<0.1%)
Ureteroscopy	0	1 (<0.1%)	1 (<0.1%)
Urinary casts present	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	3 (0.1%)	0	3 (<0.1%)
Vitamin D decreased	7 (0.3%)	11 (0.4%)	18 (0.3%)
Vitamin K decreased	1 (<0.1%)	0	1 (<0.1%)
Weight decreased	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Weight increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
White blood cell count increased	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Metabolism and nutrition disorders	2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Abnormal loss of weight	0	1 (<0.1%)	1 (<0.1%)
Abnormal weight gain	0	1 (<0.1%)	1 (<0.1%)
Acidosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Calcium deficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Central obesity	14 (0.5%)	15 (0.6%)	29 (0.6%)
Decreased appetite	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Dehydration	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Diabetes mellitus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetes mellitus inadequate control	3 (0.1%)	5 (0.2%)	8 (0.2%)
Diabetic complication	1 (<0.1%)	0	1 (<0.1%)
Diabetic dyslipidaemia	2 (<0.1%)	0	2 (<0.1%)
Diabetic ketoacidosis	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Diabetic ketosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic metabolic decompensation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Dyslipidaemia	889 (33.9%)	882 (33.7%)	1771 (33.8%)
Electrolyte imbalance	1 (<0.1%)	0	1 (<0.1%)
Fluid overload	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Fluid retention	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Folate deficiency	7 (0.3%)	7 (0.3%)	14 (0.3%)
Food intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	1 (<0.1%)	0	1 (<0.1%)
Gout	273 (10.4%)	268 (10.2%)	541 (10.3%)
Haemochromatosis	0	1 (<0.1%)	1 (<0.1%)
Haemosiderosis	0	1 (<0.1%)	1 (<0.1%)
Hypercalcaemia	6 (0.2%)	12 (0.5%)	18 (0.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Hyperchloraemia	1 (<0.1%)	0	1 (<0.1%)
Hypercholesterolaemia	320 (12.2%)	296 (11.3%)	616 (11.8%)
Hypercreatininaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperglycaemia	4 (0.2%)	5 (0.2%)	9 (0.2%)
Hyperglycaemic hyperosmolar nonketotic syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperhomocysteinaemia	9 (0.3%)	4 (0.2%)	13 (0.2%)
Hyperkalaemia	69 (2.6%)	81 (3.1%)	150 (2.9%)
Hyperlipidaemia	743 (28.3%)	784 (29.9%)	1527 (29.1%)
Hypernatraemia	1 (<0.1%)	0	1 (<0.1%)
Hyperphagia	1 (<0.1%)	0	1 (<0.1%)
Hyperphosphataemia	6 (0.2%)	7 (0.3%)	13 (0.2%)
Hyperproteinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypertriglyceridaemia	69 (2.6%)	61 (2.3%)	130 (2.5%)
Hyperuricaemia	523 (19.9%)	542 (20.7%)	1065 (20.3%)
Hypo HDL cholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Hypoalbuminaemia	6 (0.2%)	8 (0.3%)	14 (0.3%)
Hypocalcaemia	6 (0.2%)	11 (0.4%)	17 (0.3%)
Hypoglycaemia	19 (0.7%)	14 (0.5%)	33 (0.6%)
Hypokalaemia	25 (1.0%)	31 (1.2%)	56 (1.1%)
Hypolipidaemia	1 (<0.1%)	0	1 (<0.1%)
Hypomagnesaemia	8 (0.3%)	7 (0.3%)	15 (0.3%)
Hypometabolism	0	1 (<0.1%)	1 (<0.1%)
Hyponatraemia	7 (0.3%)	9 (0.3%)	16 (0.3%)
Hypophosphataemia	0	2 (<0.1%)	2 (<0.1%)
Hypoproteinaemia	7 (0.3%)	7 (0.3%)	14 (0.3%)
Hypouricaemia	1 (<0.1%)	0	1 (<0.1%)
Hypovitaminosis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency	22 (0.8%)	25 (1.0%)	47 (0.9%)
Ketoacidosis	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	1 (<0.1%)	0	1 (<0.1%)
Lactose intolerance	3 (0.1%)	3 (0.1%)	6 (0.1%)
Latent autoimmune diabetes in adults	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipid metabolism disorder	7 (0.3%)	15 (0.6%)	22 (0.4%)
Lipoedema	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Metabolic acidosis	9 (0.3%)	13 (0.5%)	22 (0.4%)
Metabolic alkalosis	0	3 (0.1%)	3 (<0.1%)
Metabolic disorder	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Metabolic syndrome	24 (0.9%)	23 (0.9%)	47 (0.9%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Obesity	1048 (40.0%)	988 (37.7%)	2036 (38.8%)
Overweight	31 (1.2%)	31 (1.2%)	62 (1.2%)
Pancreatogenous diabetes	0	1 (<0.1%)	1 (<0.1%)
Polydipsia	1 (<0.1%)	0	1 (<0.1%)
Purine metabolism disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tetany	1 (<0.1%)	0	1 (<0.1%)
Type 2 diabetes mellitus	2621 (>99.9%)	2619 (>99.9%)	5240 (>99.9%)
Vitamin B complex deficiency	7 (0.3%)	1 (<0.1%)	8 (0.2%)
Vitamin B1 deficiency	1 (<0.1%)	0	1 (<0.1%)
Vitamin B12 deficiency	49 (1.9%)	44 (1.7%)	93 (1.8%)
Vitamin C deficiency	1 (<0.1%)	0	1 (<0.1%)
Vitamin D deficiency	262 (10.0%)	239 (9.1%)	501 (9.6%)
Zinc deficiency	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal and connective tissue disorders	982 (37.5%)	1002 (38.2%)	1984 (37.8%)
Acquired claw toe	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle deformity	1 (<0.1%)	0	1 (<0.1%)
Ankle impingement	0	1 (<0.1%)	1 (<0.1%)
Ankylosing spondylitis	4 (0.2%)	5 (0.2%)	9 (0.2%)
Arthralgia	118 (4.5%)	133 (5.1%)	251 (4.8%)
Arthritis	54 (2.1%)	55 (2.1%)	109 (2.1%)
Arthritis reactive	1 (<0.1%)	0	1 (<0.1%)
Arthropathy	7 (0.3%)	11 (0.4%)	18 (0.3%)
Articular calcification	1 (<0.1%)	0	1 (<0.1%)
Axial spondyloarthritis	1 (<0.1%)	0	1 (<0.1%)
Back disorder	1 (<0.1%)	7 (0.3%)	8 (0.2%)
Back pain	171 (6.5%)	202 (7.7%)	373 (7.1%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	0	3 (0.1%)	3 (<0.1%)
Bone formation increased	0	1 (<0.1%)	1 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Bone pain	2 (<0.1%)	0	2 (<0.1%)
Bursitis	7 (0.3%)	9 (0.3%)	16 (0.3%)
Cervical spinal stenosis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Chondrocalcinosis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Chondrocalcinosis pyrophosphate	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic kidney disease-mineral and bone disorder	7 (0.3%)	14 (0.5%)	21 (0.4%)
Costochondritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Crystal arthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deformity thorax	1 (<0.1%)	0	1 (<0.1%)
Destructive spondyloarthropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic amyotrophy	1 (<0.1%)	0	1 (<0.1%)
Diastasis recti abdominis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diffuse idiopathic skeletal hyperostosis	0	2 (<0.1%)	2 (<0.1%)
Dupuytren's contracture	9 (0.3%)	7 (0.3%)	16 (0.3%)
Enthesopathy	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Exostosis	11 (0.4%)	9 (0.3%)	20 (0.4%)
Extremity contracture	1 (<0.1%)	0	1 (<0.1%)
Facet joint syndrome	0	4 (0.2%)	4 (<0.1%)
Fasciitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Fibromyalgia	8 (0.3%)	12 (0.5%)	20 (0.4%)
Flank pain	3 (0.1%)	3 (0.1%)	6 (0.1%)
Foot deformity	19 (0.7%)	18 (0.7%)	37 (0.7%)
Gouty arthritis	45 (1.7%)	39 (1.5%)	84 (1.6%)
Gouty tophus	1 (<0.1%)	0	1 (<0.1%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)
Hand deformity	0	1 (<0.1%)	1 (<0.1%)
Hypercreatinaemia	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc compression	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc degeneration	25 (1.0%)	17 (0.6%)	42 (0.8%)
Intervertebral disc disorder	27 (1.0%)	22 (0.8%)	49 (0.9%)
Intervertebral disc displacement	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Intervertebral disc protrusion	69 (2.6%)	63 (2.4%)	132 (2.5%)
Intervertebral disc space narrowing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Jaw cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint contracture	0	1 (<0.1%)	1 (<0.1%)
Joint deposit	2 (<0.1%)	0	2 (<0.1%)
Joint effusion	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Joint instability	0	1 (<0.1%)	1 (<0.1%)
Joint noise	0	1 (<0.1%)	1 (<0.1%)
Joint range of motion decreased	4 (0.2%)	0	4 (<0.1%)
Joint swelling	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Knee deformity	1 (<0.1%)	0	1 (<0.1%)
Kyphosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament disorder	0	1 (<0.1%)	1 (<0.1%)
Limb asymmetry	1 (<0.1%)	0	1 (<0.1%)
Limb discomfort	0	1 (<0.1%)	1 (<0.1%)
Limb mass	0	2 (<0.1%)	2 (<0.1%)
Lumbar spinal stenosis	20 (0.8%)	18 (0.7%)	38 (0.7%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Meniscal degeneration	2 (<0.1%)	0	2 (<0.1%)
Metatarsalgia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Mobility decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle atrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle contracture	1 (<0.1%)	0	1 (<0.1%)
Muscle disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle spasms	77 (2.9%)	79 (3.0%)	156 (3.0%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	5 (0.2%)	11 (0.4%)	16 (0.3%)
Musculoskeletal chest pain	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Musculoskeletal discomfort	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Musculoskeletal disorder	2 (<0.1%)	0	2 (<0.1%)
Musculoskeletal pain	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Musculoskeletal stiffness	3 (0.1%)	5 (0.2%)	8 (0.2%)
Myalgia	28 (1.1%)	26 (1.0%)	54 (1.0%)
Myofascial pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myopathy	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Myositis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Neck mass	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Neck pain	14 (0.5%)	21 (0.8%)	35 (0.7%)
Neuropathic arthropathy	14 (0.5%)	22 (0.8%)	36 (0.7%)
Nodal osteoarthritis	0	1 (<0.1%)	1 (<0.1%)
Osteitis	3 (0.1%)	3 (0.1%)	6 (0.1%)
Osteitis deformans	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteoarthritis	297 (11.3%)	317 (12.1%)	614 (11.7%)
Osteoarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteochondrosis	31 (1.2%)	32 (1.2%)	63 (1.2%)
Osteolysis	0	2 (<0.1%)	2 (<0.1%)
Osteonecrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Osteopenia	17 (0.6%)	26 (1.0%)	43 (0.8%)
Osteoporosis	66 (2.5%)	67 (2.6%)	133 (2.5%)
Osteosclerosis	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	44 (1.7%)	38 (1.5%)	82 (1.6%)
Pain in jaw	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Patellofemoral pain syndrome	0	1 (<0.1%)	1 (<0.1%)
Periarthritis	19 (0.7%)	23 (0.9%)	42 (0.8%)
Plantar fascial fibromatosis	1 (<0.1%)	0	1 (<0.1%)
Plantar fasciitis	4 (0.2%)	5 (0.2%)	9 (0.2%)
Polyarthritis	2 (<0.1%)	7 (0.3%)	9 (0.2%)
Polymyalgia rheumatica	3 (0.1%)	6 (0.2%)	9 (0.2%)
Polymyositis	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Prognathism	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Rhabdomyolysis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Rheumatic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rheumatic fever	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rheumatoid arthritis	20 (0.8%)	21 (0.8%)	41 (0.8%)
Rotator cuff syndrome	36 (1.4%)	19 (0.7%)	55 (1.0%)
Sacroiliitis	1 (<0.1%)	0	1 (<0.1%)
Sarcopenia	0	1 (<0.1%)	1 (<0.1%)
Scoliosis	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Senile osteoporosis	0	1 (<0.1%)	1 (<0.1%)
Seronegative arthritis	1 (<0.1%)	0	1 (<0.1%)
Sjogren's syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Soft tissue disorder	1 (<0.1%)	0	1 (<0.1%)
Soft tissue mass	0	1 (<0.1%)	1 (<0.1%)
Soft tissue swelling	1 (<0.1%)	0	1 (<0.1%)
Spinal deformity	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal ligament ossification	1 (<0.1%)	0	1 (<0.1%)
Spinal osteoarthritis	102 (3.9%)	112 (4.3%)	214 (4.1%)
Spinal pain	10 (0.4%)	7 (0.3%)	17 (0.3%)
Spinal retrolisthesis	0	2 (<0.1%)	2 (<0.1%)
Spinal stenosis	23 (0.9%)	24 (0.9%)	47 (0.9%)
Spondylitis	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Spondyloarthropathy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Spondylolisthesis	8 (0.3%)	6 (0.2%)	14 (0.3%)
Spondylolysis	2 (<0.1%)	0	2 (<0.1%)
Still's disease	1 (<0.1%)	0	1 (<0.1%)
Symphysiolysis	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	3 (0.1%)	5 (0.2%)	8 (0.2%)
Synovitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Systemic lupus erythematosus	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Temporomandibular joint syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tendon disorder	3 (0.1%)	3 (0.1%)	6 (0.1%)
Tendonitis	7 (0.3%)	11 (0.4%)	18 (0.3%)
Tenosynovitis	5 (0.2%)	3 (0.1%)	8 (0.2%)
Tenosynovitis stenosans	4 (0.2%)	3 (0.1%)	7 (0.1%)
Torticollis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Trigger finger	25 (1.0%)	12 (0.5%)	37 (0.7%)
Vertebral foraminal stenosis	2 (<0.1%)	0	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Vertebral osteophyte	0	2 (<0.1%)	2 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	367 (14.0%)	388 (14.8%)	755 (14.4%)
Acoustic neuroma	0	1 (<0.1%)	1 (<0.1%)
Acrochordon	3 (0.1%)	4 (0.2%)	7 (0.1%)
Acute myeloid leukaemia	0	2 (<0.1%)	2 (<0.1%)
Adenocarcinoma of colon	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Adenoma benign	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Adrenal adenoma	12 (0.5%)	10 (0.4%)	22 (0.4%)
Adrenal gland cancer	0	2 (<0.1%)	2 (<0.1%)
Adrenal neoplasm	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyofibroblastoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyolipoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Appendix adenoma	0	1 (<0.1%)	1 (<0.1%)
B-cell lymphoma	0	1 (<0.1%)	1 (<0.1%)
Basal cell carcinoma	28 (1.1%)	23 (0.9%)	51 (1.0%)
Benign breast neoplasm	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Benign ear neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign endocrine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign female reproductive tract neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign hepatic neoplasm	2 (<0.1%)	0	2 (<0.1%)
Benign laryngeal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign lung neoplasm	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Benign neoplasm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Benign neoplasm of adrenal gland	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of choroid	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of prostate	0	2 (<0.1%)	2 (<0.1%)
Benign neoplasm of skin	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Benign neoplasm of thyroid gland	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Benign neoplasm of urethra	0	1 (<0.1%)	1 (<0.1%)
Benign oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign ovarian tumour	0	2 (<0.1%)	2 (<0.1%)
Benign renal neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign salivary gland neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder cancer	4 (0.2%)	10 (0.4%)	14 (0.3%)
Bladder cancer recurrent	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Bladder neoplasm	4 (0.2%)	5 (0.2%)	9 (0.2%)
Bladder transitional cell carcinoma	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Blepharal papilloma	1 (<0.1%)	0	1 (<0.1%)
Bone cancer	0	1 (<0.1%)	1 (<0.1%)
Bone neoplasm	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bowen's disease	0	1 (<0.1%)	1 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Brain neoplasm benign	0	2 (<0.1%)	2 (<0.1%)
Breast adenoma	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	23 (0.9%)	14 (0.5%)	37 (0.7%)
Breast neoplasm	3 (0.1%)	3 (0.1%)	6 (0.1%)
Carcinoid tumour of the gastrointestinal tract	1 (<0.1%)	0	1 (<0.1%)
Cervix carcinoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholesteatoma	0	2 (<0.1%)	2 (<0.1%)
Chondroma	0	1 (<0.1%)	1 (<0.1%)
Chronic lymphocytic leukaemia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Chronic lymphocytic leukaemia stage 0	0	1 (<0.1%)	1 (<0.1%)
Chronic myelomonocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)
Clear cell renal cell carcinoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colon adenoma	11 (0.4%)	8 (0.3%)	19 (0.4%)
Colon cancer	13 (0.5%)	14 (0.5%)	27 (0.5%)
Colon cancer stage 0	1 (<0.1%)	0	1 (<0.1%)
Colon neoplasm	3 (0.1%)	0	3 (<0.1%)
Colorectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	0	4 (0.2%)	4 (<0.1%)
Dermatofibrosarcoma protuberans	1 (<0.1%)	0	1 (<0.1%)
Dysplastic naevus	1 (<0.1%)	0	1 (<0.1%)
Ear neoplasm	1 (<0.1%)	0	1 (<0.1%)
Endobronchial lipoma	1 (<0.1%)	0	1 (<0.1%)
Endometrial cancer	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Essential thrombocythaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye naevus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Female reproductive neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibroadenoma of breast	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fibroma	0	2 (<0.1%)	2 (<0.1%)
Focal nodular hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Gallbladder neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastric adenoma	2 (<0.1%)	0	2 (<0.1%)
Gastric cancer	4 (0.2%)	4 (0.2%)	8 (0.2%)
Gastric sarcoma	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Gastrointestinal submucosal tumour	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastrointestinal tract adenoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gingival cancer	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	2 (<0.1%)	0	2 (<0.1%)
Haemangioma of bone	1 (<0.1%)	0	1 (<0.1%)
Haemangioma of liver	8 (0.3%)	9 (0.3%)	17 (0.3%)
Haemangioma of skin	0	1 (<0.1%)	1 (<0.1%)
Haemangioma of spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic cancer	0	2 (<0.1%)	2 (<0.1%)
Hepatic cancer metastatic	1 (<0.1%)	0	1 (<0.1%)
Hepatic neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hepatocellular carcinoma	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	1 (<0.1%)	0	1 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	3 (0.1%)	3 (0.1%)	6 (0.1%)
Intra-abdominal haemangioma	1 (<0.1%)	0	1 (<0.1%)
Intraductal papillary mucinous neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Intraductal proliferative breast lesion	1 (<0.1%)	0	1 (<0.1%)
Intraocular melanoma	1 (<0.1%)	0	1 (<0.1%)
Invasive ductal breast carcinoma	1 (<0.1%)	0	1 (<0.1%)
Iris melanoma	0	1 (<0.1%)	1 (<0.1%)
Juvenile angiofibroma	0	1 (<0.1%)	1 (<0.1%)
Kaposi's sarcoma	0	1 (<0.1%)	1 (<0.1%)
Large granular lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine benign neoplasm	3 (0.1%)	10 (0.4%)	13 (0.2%)
Laryngeal cancer	0	1 (<0.1%)	1 (<0.1%)
Laryngeal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Leiomyoma	1 (<0.1%)	0	1 (<0.1%)
Lentigo maligna	1 (<0.1%)	0	1 (<0.1%)
Leukaemia	0	2 (<0.1%)	2 (<0.1%)
Light chain disease	0	1 (<0.1%)	1 (<0.1%)
Lip neoplasm malignant stage unspecified	1 (<0.1%)	0	1 (<0.1%)
Lip squamous cell carcinoma	4 (0.2%)	0	4 (<0.1%)
Lipoma	13 (0.5%)	15 (0.6%)	28 (0.5%)
Liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Lung carcinoma cell type unspecified stage 0	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm malignant	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Lymphoma	1 (<0.1%)	0	1 (<0.1%)
Malignant lymphoid neoplasm	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	6 (0.2%)	9 (0.3%)	15 (0.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Malignant melanoma in situ	0	2 (<0.1%)	2 (<0.1%)
Malignant melanoma stage IV	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eyelid	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Meningioma	3 (0.1%)	4 (0.2%)	7 (0.1%)
Metastases to liver	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metastases to lung	0	2 (<0.1%)	2 (<0.1%)
Monoclonal gammopathy	4 (0.2%)	3 (0.1%)	7 (0.1%)
Myelodysplastic syndrome	3 (0.1%)	0	3 (<0.1%)
Nasal sinus cancer	0	1 (<0.1%)	1 (<0.1%)
Neoplasm	1 (<0.1%)	0	1 (<0.1%)
Neoplasm malignant	0	1 (<0.1%)	1 (<0.1%)
Neoplasm prostate	5 (0.2%)	5 (0.2%)	10 (0.2%)
Neoplasm skin	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Neuroendocrine tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurofibroma	0	2 (<0.1%)	2 (<0.1%)
Nodular melanoma	0	1 (<0.1%)	1 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Non-secretory adenoma of pituitary	0	1 (<0.1%)	1 (<0.1%)
Non-small cell lung cancer	1 (<0.1%)	0	1 (<0.1%)
Oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal papilloma	0	2 (<0.1%)	2 (<0.1%)
Oral neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oral papilloma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ovarian germ cell teratoma benign	1 (<0.1%)	0	1 (<0.1%)
Ovarian neoplasm	2 (<0.1%)	0	2 (<0.1%)
Papillary cystadenoma lymphomatosum	3 (0.1%)	0	3 (<0.1%)
Papillary thyroid cancer	1 (<0.1%)	0	1 (<0.1%)
Paraproteinaemia	1 (<0.1%)	0	1 (<0.1%)
Parathyroid tumour benign	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Penile squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	5 (0.2%)	4 (0.2%)	9 (0.2%)
Plasma cell myeloma	3 (0.1%)	3 (0.1%)	6 (0.1%)
Pleomorphic adenoma	1 (<0.1%)	0	1 (<0.1%)
Pleomorphic liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Polycythaemia vera	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prolactin-producing pituitary tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prostate cancer	26 (1.0%)	39 (1.5%)	65 (1.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Prostate cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Prostate cancer stage I	1 (<0.1%)	0	1 (<0.1%)
Prostatic adenoma	12 (0.5%)	11 (0.4%)	23 (0.4%)
Rectal adenocarcinoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rectal cancer	8 (0.3%)	4 (0.2%)	12 (0.2%)
Rectal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	11 (0.4%)	4 (0.2%)	15 (0.3%)
Renal cell carcinoma	10 (0.4%)	7 (0.3%)	17 (0.3%)
Renal haemangioma	1 (<0.1%)	0	1 (<0.1%)
Renal hamartoma	5 (0.2%)	3 (0.1%)	8 (0.2%)
Renal neoplasm	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Renal oncocytoma	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cancer	0	1 (<0.1%)	1 (<0.1%)
Salivary gland neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Seborrhoeic keratosis	11 (0.4%)	9 (0.3%)	20 (0.4%)
Seminoma	0	1 (<0.1%)	1 (<0.1%)
Skin cancer	5 (0.2%)	5 (0.2%)	10 (0.2%)
Skin papilloma	4 (0.2%)	5 (0.2%)	9 (0.2%)
Spindle cell sarcoma	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Squamous cell carcinoma of lung	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Squamous cell carcinoma of skin	5 (0.2%)	5 (0.2%)	10 (0.2%)
Squamous cell carcinoma of the tongue	1 (<0.1%)	0	1 (<0.1%)
Sweat gland tumour	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testicular neoplasm	1 (<0.1%)	0	1 (<0.1%)
Testis cancer	0	1 (<0.1%)	1 (<0.1%)
Throat cancer	0	1 (<0.1%)	1 (<0.1%)
Thyroid B-cell lymphoma	0	1 (<0.1%)	1 (<0.1%)
Thyroid adenoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyroid cancer	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Thyroid neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tongue neoplasm	1 (<0.1%)	0	1 (<0.1%)
Tongue neoplasm benign	0	1 (<0.1%)	1 (<0.1%)
Tongue neoplasm malignant stage unspecified	0	2 (<0.1%)	2 (<0.1%)
Tonsil cancer	0	1 (<0.1%)	1 (<0.1%)
Tonsillar neoplasm	0	1 (<0.1%)	1 (<0.1%)
Transitional cell carcinoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Ureteric cancer	1 (<0.1%)	0	1 (<0.1%)
Urinary tract neoplasm	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	5 (0.2%)	1 (<0.1%)	6 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Uterine leiomyoma	28 (1.1%)	27 (1.0%)	55 (1.0%)
Vaginal cancer	0	1 (<0.1%)	1 (<0.1%)
Waldenstrom's macroglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Nervous system disorders	1355 (51.7%)	1363 (52.0%)	2718 (51.9%)
Amnesia	8 (0.3%)	7 (0.3%)	15 (0.3%)
Amnestic disorder	1 (<0.1%)	0	1 (<0.1%)
Anosmia	0	1 (<0.1%)	1 (<0.1%)
Aphasia	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Arachnoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Areflexia	1 (<0.1%)	0	1 (<0.1%)
Ataxia	4 (0.2%)	0	4 (<0.1%)
Athetosis	0	1 (<0.1%)	1 (<0.1%)
Autonomic nervous system imbalance	0	1 (<0.1%)	1 (<0.1%)
Autonomic neuropathy	4 (0.2%)	4 (0.2%)	8 (0.2%)
Axonal neuropathy	2 (<0.1%)	0	2 (<0.1%)
Balance disorder	3 (0.1%)	0	3 (<0.1%)
Basal ganglia haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal ganglia infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basilar artery stenosis	0	1 (<0.1%)	1 (<0.1%)
Bradykinesia	0	1 (<0.1%)	1 (<0.1%)
Brain injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brain oedema	0	1 (<0.1%)	1 (<0.1%)
Brain stem haematoma	0	1 (<0.1%)	1 (<0.1%)
Brain stem haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Brain stem infarction	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Brain stem stroke	1 (<0.1%)	0	1 (<0.1%)
Burning feet syndrome	1 (<0.1%)	0	1 (<0.1%)
Burning sensation	1 (<0.1%)	0	1 (<0.1%)
Cardiac autonomic neuropathy	3 (0.1%)	0	3 (<0.1%)
Carotid arteriosclerosis	62 (2.4%)	66 (2.5%)	128 (2.4%)
Carotid artery disease	5 (0.2%)	11 (0.4%)	16 (0.3%)
Carotid artery insufficiency	1 (<0.1%)	0	1 (<0.1%)
Carotid artery occlusion	7 (0.3%)	3 (0.1%)	10 (0.2%)
Carotid artery stenosis	51 (1.9%)	55 (2.1%)	106 (2.0%)
Carotid artery thrombosis	1 (<0.1%)	0	1 (<0.1%)
Carpal tunnel syndrome	35 (1.3%)	47 (1.8%)	82 (1.6%)
Central nervous system lesion	1 (<0.1%)	0	1 (<0.1%)
Central nervous system necrosis	0	1 (<0.1%)	1 (<0.1%)
Cerebellar haemorrhage	0	2 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Cerebellar ischaemia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar stroke	0	1 (<0.1%)	1 (<0.1%)
Cerebellar syndrome	1 (<0.1%)	0	1 (<0.1%)
Cerebral arteriosclerosis	19 (0.7%)	23 (0.9%)	42 (0.8%)
Cerebral artery embolism	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cerebral artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Cerebral artery stenosis	5 (0.2%)	3 (0.1%)	8 (0.2%)
Cerebral atrophy	9 (0.3%)	6 (0.2%)	15 (0.3%)
Cerebral circulatory failure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Cerebral disorder	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	4 (0.2%)	5 (0.2%)	9 (0.2%)
Cerebral hypoperfusion	3 (0.1%)	0	3 (<0.1%)
Cerebral infarction	18 (0.7%)	14 (0.5%)	32 (0.6%)
Cerebral ischaemia	20 (0.8%)	14 (0.5%)	34 (0.6%)
Cerebral microangiopathy	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Cerebral small vessel ischaemic disease	0	1 (<0.1%)	1 (<0.1%)
Cerebral thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrosclerosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrospinal fluid leakage	0	1 (<0.1%)	1 (<0.1%)
Cerebrovascular accident	12 (0.5%)	17 (0.6%)	29 (0.6%)
Cerebrovascular disorder	33 (1.3%)	42 (1.6%)	75 (1.4%)
Cerebrovascular insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cervical cord compression	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	2 (<0.1%)	8 (0.3%)	10 (0.2%)
Cervicobrachial syndrome	4 (0.2%)	8 (0.3%)	12 (0.2%)
Clonus	0	1 (<0.1%)	1 (<0.1%)
Cluster headache	2 (<0.1%)	0	2 (<0.1%)
Cognitive disorder	5 (0.2%)	3 (0.1%)	8 (0.2%)
Complex regional pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coordination abnormal	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dementia	4 (0.2%)	4 (0.2%)	8 (0.2%)
Dementia Alzheimer's type	6 (0.2%)	3 (0.1%)	9 (0.2%)
Demyelinating polyneuropathy	1 (<0.1%)	0	1 (<0.1%)
Demyelination	2 (<0.1%)	0	2 (<0.1%)
Diabetic autonomic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic coma	0	1 (<0.1%)	1 (<0.1%)
Diabetic encephalopathy	6 (0.2%)	3 (0.1%)	9 (0.2%)
Diabetic mononeuropathy	0	2 (<0.1%)	2 (<0.1%)
Diabetic neuropathy	678 (25.9%)	649 (24.8%)	1327 (25.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Disturbance in attention	1 (<0.1%)	0	1 (<0.1%)
Dizziness	42 (1.6%)	40 (1.5%)	82 (1.6%)
Dizziness postural	2 (<0.1%)	0	2 (<0.1%)
Drop attacks	0	1 (<0.1%)	1 (<0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysarthria	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Dysgeusia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Encephalomalacia	0	2 (<0.1%)	2 (<0.1%)
Encephalopathy	16 (0.6%)	14 (0.5%)	30 (0.6%)
Epilepsy	11 (0.4%)	3 (0.1%)	14 (0.3%)
Essential tremor	6 (0.2%)	7 (0.3%)	13 (0.2%)
Extrapyramidal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial paralysis	15 (0.6%)	28 (1.1%)	43 (0.8%)
Facial paresis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Frontal lobe epilepsy	0	1 (<0.1%)	1 (<0.1%)
Frontotemporal dementia	0	1 (<0.1%)	1 (<0.1%)
Gait spastic	1 (<0.1%)	0	1 (<0.1%)
Generalised tonic-clonic seizure	0	2 (<0.1%)	2 (<0.1%)
Guillain-Barre syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Haemorrhage intracranial	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic stroke	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Head discomfort	0	1 (<0.1%)	1 (<0.1%)
Head titubation	1 (<0.1%)	0	1 (<0.1%)
Headache	43 (1.6%)	45 (1.7%)	88 (1.7%)
Hemianaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hemiparesis	12 (0.5%)	14 (0.5%)	26 (0.5%)
Hemiplegia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hydrocephalus	1 (<0.1%)	0	1 (<0.1%)
Hyperaesthesia	0	1 (<0.1%)	1 (<0.1%)
Hyperreflexia	0	1 (<0.1%)	1 (<0.1%)
Hypersomnia	0	2 (<0.1%)	2 (<0.1%)
Hypertensive encephalopathy	4 (0.2%)	4 (0.2%)	8 (0.2%)
Hypertonia	13 (0.5%)	14 (0.5%)	27 (0.5%)
Hypoaesthesia	20 (0.8%)	22 (0.8%)	42 (0.8%)
Hypoxic-ischaemic encephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
IIIrd nerve paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intellectual disability	1 (<0.1%)	0	1 (<0.1%)
Intention tremor	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Intracranial aneurysm	7 (0.3%)	7 (0.3%)	14 (0.3%)
Intracranial pressure increased	0	1 (<0.1%)	1 (<0.1%)
Ischaemic cerebral infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic stroke	310 (11.8%)	337 (12.9%)	647 (12.3%)
Lacunar infarction	21 (0.8%)	13 (0.5%)	34 (0.6%)
Lacunar stroke	1 (<0.1%)	0	1 (<0.1%)
Lateral medullary syndrome	0	1 (<0.1%)	1 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)
Loss of consciousness	0	1 (<0.1%)	1 (<0.1%)
Lumbar radiculopathy	4 (0.2%)	9 (0.3%)	13 (0.2%)
Lumbosacral radiculopathy	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Memory impairment	3 (0.1%)	5 (0.2%)	8 (0.2%)
Meralgia paraesthetica	1 (<0.1%)	0	1 (<0.1%)
Metabolic encephalopathy	3 (0.1%)	6 (0.2%)	9 (0.2%)
Migraine	18 (0.7%)	8 (0.3%)	26 (0.5%)
Migraine with aura	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Migraine without aura	0	1 (<0.1%)	1 (<0.1%)
Mononeuritis	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy	2 (<0.1%)	0	2 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Monoplegia	1 (<0.1%)	0	1 (<0.1%)
Morton's neuralgia	0	1 (<0.1%)	1 (<0.1%)
Movement disorder	0	2 (<0.1%)	2 (<0.1%)
Multiple sclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myasthenia gravis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myelopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Narcolepsy	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neuralgia	26 (1.0%)	16 (0.6%)	42 (0.8%)
Neuralgic amyotrophy	1 (<0.1%)	0	1 (<0.1%)
Neuritis	1 (<0.1%)	0	1 (<0.1%)
Neuritis cranial	0	1 (<0.1%)	1 (<0.1%)
Neuropathy peripheral	125 (4.8%)	149 (5.7%)	274 (5.2%)
Normal pressure hydrocephalus	2 (<0.1%)	0	2 (<0.1%)
Occipital neuralgia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Optic neuritis	1 (<0.1%)	0	1 (<0.1%)
Orthostatic intolerance	1 (<0.1%)	0	1 (<0.1%)
Paraesthesia	17 (0.6%)	10 (0.4%)	27 (0.5%)
Paralysis recurrent laryngeal nerve	2 (<0.1%)	0	2 (<0.1%)
Paraparesis	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	12 (0.5%)	11 (0.4%)	23 (0.4%)
Parkinsonism	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Parosmia	1 (<0.1%)	0	1 (<0.1%)
Partial seizures	1 (<0.1%)	0	1 (<0.1%)
Periodic limb movement disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve paresis	0	1 (<0.1%)	1 (<0.1%)
Peripheral sensorimotor neuropathy	2 (<0.1%)	9 (0.3%)	11 (0.2%)
Peripheral sensory neuropathy	5 (0.2%)	3 (0.1%)	8 (0.2%)
Peroneal nerve palsy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Phantom limb syndrome	0	1 (<0.1%)	1 (<0.1%)
Piriformis syndrome	2 (<0.1%)	0	2 (<0.1%)
Polyneuropathy	37 (1.4%)	40 (1.5%)	77 (1.5%)
Poor quality sleep	2 (<0.1%)	0	2 (<0.1%)
Post herpetic neuralgia	3 (0.1%)	3 (0.1%)	6 (0.1%)
Post-traumatic epilepsy	1 (<0.1%)	0	1 (<0.1%)
Posterior reversible encephalopathy syndrome	0	1 (<0.1%)	1 (<0.1%)
Postictal paralysis	1 (<0.1%)	0	1 (<0.1%)
Postural tremor	2 (<0.1%)	0	2 (<0.1%)
Presyncope	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Quadriplegia	0	1 (<0.1%)	1 (<0.1%)
Radicular pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radiculopathy	7 (0.3%)	6 (0.2%)	13 (0.2%)
Resting tremor	1 (<0.1%)	0	1 (<0.1%)
Restless legs syndrome	15 (0.6%)	13 (0.5%)	28 (0.5%)
Reversible ischaemic neurological deficit	1 (<0.1%)	0	1 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	33 (1.3%)	33 (1.3%)	66 (1.3%)
Seizure	5 (0.2%)	4 (0.2%)	9 (0.2%)
Seizure like phenomena	1 (<0.1%)	0	1 (<0.1%)
Senile dementia	2 (<0.1%)	0	2 (<0.1%)
Sleep deficit	0	1 (<0.1%)	1 (<0.1%)
Somnolence	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Spinal claudication	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Spinal cord haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Spinal cord ischaemia	0	1 (<0.1%)	1 (<0.1%)
Spondylitic myelopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subarachnoid haemorrhage	4 (0.2%)	3 (0.1%)	7 (0.1%)
Subdural effusion	1 (<0.1%)	0	1 (<0.1%)
Syncope	17 (0.6%)	8 (0.3%)	25 (0.5%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Tardive dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Tension headache	7 (0.3%)	4 (0.2%)	11 (0.2%)
Thrombotic cerebral infarction	1 (<0.1%)	0	1 (<0.1%)
Transient global amnesia	0	1 (<0.1%)	1 (<0.1%)
Transient ischaemic attack	49 (1.9%)	33 (1.3%)	82 (1.6%)
Tremor	11 (0.4%)	8 (0.3%)	19 (0.4%)
Trigeminal nerve disorder	0	1 (<0.1%)	1 (<0.1%)
Trigeminal neuralgia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ulnar nerve palsy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ulnar tunnel syndrome	0	1 (<0.1%)	1 (<0.1%)
VIth nerve disorder	0	1 (<0.1%)	1 (<0.1%)
VIth nerve paralysis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
VIth nerve paresis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular dementia	0	2 (<0.1%)	2 (<0.1%)
Vascular encephalopathy	16 (0.6%)	22 (0.8%)	38 (0.7%)
Vertebral artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery stenosis	5 (0.2%)	5 (0.2%)	10 (0.2%)
Vertebrobasilar insufficiency	4 (0.2%)	5 (0.2%)	9 (0.2%)
Vertigo CNS origin	0	1 (<0.1%)	1 (<0.1%)
Visual field defect	3 (0.1%)	4 (0.2%)	7 (0.1%)
Vocal cord paralysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vocal cord paresis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
White matter lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	6 (0.2%)	7 (0.3%)	13 (0.2%)
Abortion incomplete	0	1 (<0.1%)	1 (<0.1%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Gestational diabetes	2 (<0.1%)	0	2 (<0.1%)
Postpartum haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Pre-eclampsia	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Product issues	0	1 (<0.1%)	1 (<0.1%)
Device breakage	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	415 (15.8%)	457 (17.4%)	872 (16.6%)
Abnormal dreams	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Acute stress disorder	1 (<0.1%)	0	1 (<0.1%)
Adjustment disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Adjustment disorder with anxiety	0	1 (<0.1%)	1 (<0.1%)
Adjustment disorder with depressed mood	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Affect lability	0	2 (<0.1%)	2 (<0.1%)
Affective disorder	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Agitation	0	1 (<0.1%)	1 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Alcoholism	5 (0.2%)	3 (0.1%)	8 (0.2%)
Anxiety	97 (3.7%)	119 (4.5%)	216 (4.1%)
Anxiety disorder	11 (0.4%)	19 (0.7%)	30 (0.6%)
Attention deficit hyperactivity disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Bipolar I disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bipolar disorder	4 (0.2%)	10 (0.4%)	14 (0.3%)
Bulimia nervosa	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Delirium	0	2 (<0.1%)	2 (<0.1%)
Depressed mood	3 (0.1%)	3 (0.1%)	6 (0.1%)
Depression	172 (6.6%)	198 (7.6%)	370 (7.1%)
Depressive symptom	3 (0.1%)	0	3 (<0.1%)
Dermatillomania	0	1 (<0.1%)	1 (<0.1%)
Dissociative amnesia	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Drug dependence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Generalised anxiety disorder	5 (0.2%)	5 (0.2%)	10 (0.2%)
Hallucination	0	1 (<0.1%)	1 (<0.1%)
Hallucination, visual	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Initial insomnia	0	1 (<0.1%)	1 (<0.1%)
Insomnia	133 (5.1%)	142 (5.4%)	275 (5.2%)
Libido decreased	2 (<0.1%)	0	2 (<0.1%)
Major depression	11 (0.4%)	15 (0.6%)	26 (0.5%)
Mental disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mental disorder due to a general medical condition	0	2 (<0.1%)	2 (<0.1%)
Middle insomnia	0	1 (<0.1%)	1 (<0.1%)
Mixed anxiety and depressive disorder	3 (0.1%)	8 (0.3%)	11 (0.2%)
Mood altered	1 (<0.1%)	0	1 (<0.1%)
Mood swings	1 (<0.1%)	0	1 (<0.1%)
Nervousness	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neurologic somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Neurosis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Nicotine dependence	5 (0.2%)	7 (0.3%)	12 (0.2%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Organic brain syndrome	0	1 (<0.1%)	1 (<0.1%)
Panic attack	0	1 (<0.1%)	1 (<0.1%)
Panic disorder	4 (0.2%)	3 (0.1%)	7 (0.1%)
Panic reaction	1 (<0.1%)	0	1 (<0.1%)
Persistent depressive disorder	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Personality disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phobia of driving	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic stress disorder	8 (0.3%)	8 (0.3%)	16 (0.3%)
Psychosexual disorder	0	1 (<0.1%)	1 (<0.1%)
Psychotic disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Schizoid personality disorder	1 (<0.1%)	0	1 (<0.1%)
Schizophrenia	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Sleep disorder	22 (0.8%)	17 (0.6%)	39 (0.7%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	0	2 (<0.1%)	2 (<0.1%)
Stress	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Suicide attempt	2 (<0.1%)	0	2 (<0.1%)
Tearfulness	0	1 (<0.1%)	1 (<0.1%)
Tic	0	1 (<0.1%)	1 (<0.1%)
Tobacco abuse	6 (0.2%)	6 (0.2%)	12 (0.2%)
Renal and urinary disorders	2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Acquired cystic kidney disease	12 (0.5%)	9 (0.3%)	21 (0.4%)
Acute kidney injury	27 (1.0%)	32 (1.2%)	59 (1.1%)
Albuminuria	119 (4.5%)	96 (3.7%)	215 (4.1%)
Azotaemia	3 (0.1%)	4 (0.2%)	7 (0.1%)
Bladder disorder	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bladder diverticulum	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder dysfunction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder leukoplakia	1 (<0.1%)	0	1 (<0.1%)
Bladder mass	1 (<0.1%)	0	1 (<0.1%)
Bladder neck obstruction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder neck sclerosis	1 (<0.1%)	0	1 (<0.1%)
Bladder outlet obstruction	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder prolapse	0	4 (0.2%)	4 (<0.1%)
Bladder tamponade	1 (<0.1%)	0	1 (<0.1%)
Bladder trabeculation	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Calculus bladder	4 (0.2%)	3 (0.1%)	7 (0.1%)
Calculus urethral	1 (<0.1%)	0	1 (<0.1%)
Calculus urinary	32 (1.2%)	27 (1.0%)	59 (1.1%)
Chronic kidney disease	2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Chyluria	1 (<0.1%)	0	1 (<0.1%)
Costovertebral angle tenderness	1 (<0.1%)	0	1 (<0.1%)
Cystitis interstitial	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	255 (9.7%)	260 (9.9%)	515 (9.8%)
Dysuria	7 (0.3%)	8 (0.3%)	15 (0.3%)
End stage renal disease	1 (<0.1%)	0	1 (<0.1%)
Focal segmental glomerulosclerosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Genitourinary symptom	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	12 (0.5%)	13 (0.5%)	25 (0.5%)
Glomerulonephritis membranous	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glomerulonephropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glycosuria	0	1 (<0.1%)	1 (<0.1%)
Haematuria	28 (1.1%)	34 (1.3%)	62 (1.2%)
Hydronephrosis	13 (0.5%)	17 (0.6%)	30 (0.6%)
Hypertensive nephropathy	9 (0.3%)	5 (0.2%)	14 (0.3%)
Hypertonic bladder	10 (0.4%)	10 (0.4%)	20 (0.4%)
Hyperuricosuria	0	2 (<0.1%)	2 (<0.1%)
Hypotonic urinary bladder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
IgA nephropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Incontinence	4 (0.2%)	3 (0.1%)	7 (0.1%)
Intercapillary glomerulosclerosis	1 (<0.1%)	5 (0.2%)	6 (0.1%)
Ischaemic nephropathy	1 (<0.1%)	0	1 (<0.1%)
Kidney enlargement	2 (<0.1%)	0	2 (<0.1%)
Kidney fibrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lower urinary tract symptoms	8 (0.3%)	4 (0.2%)	12 (0.2%)
Lupus nephritis	1 (<0.1%)	0	1 (<0.1%)
Microalbuminuria	59 (2.3%)	46 (1.8%)	105 (2.0%)
Micturition disorder	0	2 (<0.1%)	2 (<0.1%)
Micturition urgency	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nephritic syndrome	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Nephritis	0	5 (0.2%)	5 (<0.1%)
Nephroangiosclerosis	4 (0.2%)	9 (0.3%)	13 (0.2%)
Nephrocalcinosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Nephrogenic diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Nephrolithiasis	141 (5.4%)	149 (5.7%)	290 (5.5%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Nephropathy	20 (0.8%)	13 (0.5%)	33 (0.6%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)
Nephroptosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephrosclerosis	6 (0.2%)	3 (0.1%)	9 (0.2%)
Nephrotic syndrome	5 (0.2%)	14 (0.5%)	19 (0.4%)
Neurogenic bladder	11 (0.4%)	9 (0.3%)	20 (0.4%)
Nocturia	15 (0.6%)	35 (1.3%)	50 (1.0%)
Obstructive nephropathy	0	1 (<0.1%)	1 (<0.1%)
Oedematous kidney	2 (<0.1%)	0	2 (<0.1%)
Pelvi-ureteric obstruction	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	6 (0.2%)	10 (0.4%)	16 (0.3%)
Polyuria	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Post infection glomerulonephritis	1 (<0.1%)	0	1 (<0.1%)
Proteinuria	163 (6.2%)	164 (6.3%)	327 (6.2%)
Pyelocaliectasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Reflux nephropathy	0	1 (<0.1%)	1 (<0.1%)
Renal arteriosclerosis	0	2 (<0.1%)	2 (<0.1%)
Renal artery arteriosclerosis	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	6 (0.2%)	7 (0.3%)	13 (0.2%)
Renal atrophy	4 (0.2%)	3 (0.1%)	7 (0.1%)
Renal colic	17 (0.6%)	10 (0.4%)	27 (0.5%)
Renal cyst	124 (4.7%)	140 (5.3%)	264 (5.0%)
Renal disorder	2 (<0.1%)	0	2 (<0.1%)
Renal failure	16 (0.6%)	15 (0.6%)	31 (0.6%)
Renal hypertension	1 (<0.1%)	0	1 (<0.1%)
Renal hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal impairment	6 (0.2%)	3 (0.1%)	9 (0.2%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	1 (<0.1%)	0	1 (<0.1%)
Renal pain	0	1 (<0.1%)	1 (<0.1%)
Renal tubular acidosis	0	1 (<0.1%)	1 (<0.1%)
Renal tubular necrosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal vessel disorder	1 (<0.1%)	0	1 (<0.1%)
Single functional kidney	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Stag horn calculus	0	1 (<0.1%)	1 (<0.1%)
Stress urinary incontinence	5 (0.2%)	3 (0.1%)	8 (0.2%)
Subcapsular renal haematoma	2 (<0.1%)	0	2 (<0.1%)
Terminal dribbling	1 (<0.1%)	0	1 (<0.1%)
Trigonitis	1 (<0.1%)	0	1 (<0.1%)
Tubulointerstitial nephritis	0	4 (0.2%)	4 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Urate nephropathy	3 (0.1%)	0	3 (<0.1%)
Ureteral cyst	0	1 (<0.1%)	1 (<0.1%)
Ureteric stenosis	0	2 (<0.1%)	2 (<0.1%)
Ureterocele	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	13 (0.5%)	17 (0.6%)	30 (0.6%)
Urethral meatus stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral obstruction	0	1 (<0.1%)	1 (<0.1%)
Urethral stenosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Urge incontinence	4 (0.2%)	3 (0.1%)	7 (0.1%)
Urinary bladder polyp	3 (0.1%)	0	3 (<0.1%)
Urinary hesitation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Urinary incontinence	30 (1.1%)	32 (1.2%)	62 (1.2%)
Urinary retention	7 (0.3%)	7 (0.3%)	14 (0.3%)
Urinary tract disorder	1 (<0.1%)	0	1 (<0.1%)
Urinary tract obstruction	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Urine abnormality	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Urine flow decreased	0	1 (<0.1%)	1 (<0.1%)
Urine odour abnormal	0	1 (<0.1%)	1 (<0.1%)
Reproductive system and breast disorders	545 (20.8%)	571 (21.8%)	1116 (21.3%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Atrophic vulvovaginitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Balanoposthitis	2 (<0.1%)	0	2 (<0.1%)
Benign prostatic hyperplasia	359 (13.7%)	375 (14.3%)	734 (14.0%)
Breast calcifications	0	1 (<0.1%)	1 (<0.1%)
Breast cyst	2 (<0.1%)	0	2 (<0.1%)
Breast disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast fibrosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Breast hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Breast mass	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Calculus prostatic	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Cervical cyst	0	1 (<0.1%)	1 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	0	1 (<0.1%)	1 (<0.1%)
Cystocele	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Dysmenorrhoea	2 (<0.1%)	0	2 (<0.1%)
Endometrial hyperplasia	0	2 (<0.1%)	2 (<0.1%)
Endometrial thickening	0	1 (<0.1%)	1 (<0.1%)
Endometriosis	3 (0.1%)	1 (<0.1%)	4 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Epididymal cyst	0	1 (<0.1%)	1 (<0.1%)
Erectile dysfunction	122 (4.7%)	129 (4.9%)	251 (4.8%)
Fibrocystic breast disease	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Genital prolapse	0	2 (<0.1%)	2 (<0.1%)
Gynaecomastia	5 (0.2%)	8 (0.3%)	13 (0.2%)
Haematospermia	1 (<0.1%)	0	1 (<0.1%)
Hydrometra	1 (<0.1%)	0	1 (<0.1%)
Infertility	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mammary duct ectasia	0	1 (<0.1%)	1 (<0.1%)
Menometrorrhagia	1 (<0.1%)	0	1 (<0.1%)
Menopausal disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Menorrhagia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metrorrhagia	2 (<0.1%)	0	2 (<0.1%)
Monorchidism	1 (<0.1%)	0	1 (<0.1%)
Organic erectile dysfunction	3 (0.1%)	5 (0.2%)	8 (0.2%)
Ovarian cyst	8 (0.3%)	12 (0.5%)	20 (0.4%)
Pelvic adhesions	0	1 (<0.1%)	1 (<0.1%)
Pelvic fluid collection	1 (<0.1%)	0	1 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Perineal pain	1 (<0.1%)	0	1 (<0.1%)
Peyronie's disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Polycystic ovaries	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Prostatic calcification	7 (0.3%)	7 (0.3%)	14 (0.3%)
Prostatic cyst	0	1 (<0.1%)	1 (<0.1%)
Prostatic disorder	5 (0.2%)	6 (0.2%)	11 (0.2%)
Prostatic mass	0	1 (<0.1%)	1 (<0.1%)
Prostatism	5 (0.2%)	8 (0.3%)	13 (0.2%)
Prostatitis	8 (0.3%)	17 (0.6%)	25 (0.5%)
Prostatomegaly	24 (0.9%)	17 (0.6%)	41 (0.8%)
Pruritus genital	0	1 (<0.1%)	1 (<0.1%)
Rectocele	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal mass	0	1 (<0.1%)	1 (<0.1%)
Seminal vesicular disorder	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	1 (<0.1%)	0	1 (<0.1%)
Testicular torsion	1 (<0.1%)	0	1 (<0.1%)
Uterine cervix stenosis	1 (<0.1%)	0	1 (<0.1%)
Uterine enlargement	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Uterine haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine prolapse	0	1 (<0.1%)	1 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal polyp	0	1 (<0.1%)	1 (<0.1%)
Vaginal prolapse	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Varicocele	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Vulvovaginal dryness	2 (<0.1%)	0	2 (<0.1%)
Vulvovaginal pruritus	0	2 (<0.1%)	2 (<0.1%)
Vulvovaginal rash	0	1 (<0.1%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	640 (24.4%)	679 (25.9%)	1319 (25.2%)
Acute pulmonary oedema	0	4 (0.2%)	4 (<0.1%)
Acute respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Adenoidal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic pharyngitis	1 (<0.1%)	0	1 (<0.1%)
Allergic respiratory disease	1 (<0.1%)	0	1 (<0.1%)
Allergic sinusitis	1 (<0.1%)	0	1 (<0.1%)
Apnoea	1 (<0.1%)	0	1 (<0.1%)
Asthma	105 (4.0%)	115 (4.4%)	220 (4.2%)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	1 (<0.1%)	1 (<0.1%)
Atelectasis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bronchial disorder	0	2 (<0.1%)	2 (<0.1%)
Bronchial hyperreactivity	4 (0.2%)	3 (0.1%)	7 (0.1%)
Bronchial obstruction	1 (<0.1%)	0	1 (<0.1%)
Bronchiectasis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Bronchitis chronic	25 (1.0%)	41 (1.6%)	66 (1.3%)
Bronchospasm	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Catarrh	0	2 (<0.1%)	2 (<0.1%)
Cheyne-Stokes respiration	0	1 (<0.1%)	1 (<0.1%)
Childhood asthma	0	1 (<0.1%)	1 (<0.1%)
Chronic obstructive pulmonary disease	152 (5.8%)	156 (6.0%)	308 (5.9%)
Chronic respiratory disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic respiratory failure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cough	28 (1.1%)	37 (1.4%)	65 (1.2%)
Cough variant asthma	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Cystic lung disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Diaphragmatic disorder	0	1 (<0.1%)	1 (<0.1%)
Diaphragmatic paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysphonia	4 (0.2%)	1 (<0.1%)	5 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Dyspnoea	26 (1.0%)	30 (1.1%)	56 (1.1%)
Dyspnoea exertional	16 (0.6%)	9 (0.3%)	25 (0.5%)
Emphysema	13 (0.5%)	13 (0.5%)	26 (0.5%)
Epistaxis	7 (0.3%)	12 (0.5%)	19 (0.4%)
Haemoptysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hydrothorax	0	1 (<0.1%)	1 (<0.1%)
Hypercapnia	0	1 (<0.1%)	1 (<0.1%)
Hypersensitivity pneumonitis	1 (<0.1%)	0	1 (<0.1%)
Hypopnoea	0	1 (<0.1%)	1 (<0.1%)
Hypoventilation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoxia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Interstitial lung disease	8 (0.3%)	9 (0.3%)	17 (0.3%)
Laryngeal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	1 (<0.1%)
Laryngeal stenosis	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	0	1 (<0.1%)	1 (<0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Lung induration	1 (<0.1%)	0	1 (<0.1%)
Lung infiltration	1 (<0.1%)	0	1 (<0.1%)
Lung opacity	2 (<0.1%)	0	2 (<0.1%)
Nasal congestion	3 (0.1%)	4 (0.2%)	7 (0.1%)
Nasal discomfort	0	1 (<0.1%)	1 (<0.1%)
Nasal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Nasal polyps	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Nasal septum deviation	4 (0.2%)	5 (0.2%)	9 (0.2%)
Nasal septum perforation	1 (<0.1%)	0	1 (<0.1%)
Nasal turbinate hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obliterative bronchiolitis	0	1 (<0.1%)	1 (<0.1%)
Obstructive airways disorder	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Oropharyngeal pain	4 (0.2%)	0	4 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	0	1 (<0.1%)
Paranasal sinus inflammation	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal mass	0	1 (<0.1%)	1 (<0.1%)
Pickwickian syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pleural effusion	6 (0.2%)	10 (0.4%)	16 (0.3%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	1 (<0.1%)	0	1 (<0.1%)
Pleurisy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pneumonitis	4 (0.2%)	0	4 (<0.1%)
Pneumothorax	2 (<0.1%)	3 (0.1%)	5 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Productive cough	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Pulmonary alveolar haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Pulmonary arterial hypertension	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pulmonary calcification	1 (<0.1%)	0	1 (<0.1%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	16 (0.6%)	17 (0.6%)	33 (0.6%)
Pulmonary fibrosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pulmonary granuloma	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Pulmonary hypertension	21 (0.8%)	21 (0.8%)	42 (0.8%)
Pulmonary infarction	0	1 (<0.1%)	1 (<0.1%)
Pulmonary mass	23 (0.9%)	21 (0.8%)	44 (0.8%)
Pulmonary oedema	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Pulmonary sarcoidosis	3 (0.1%)	0	3 (<0.1%)
Respiratory acidosis	0	1 (<0.1%)	1 (<0.1%)
Respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Respiratory disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Respiratory failure	3 (0.1%)	6 (0.2%)	9 (0.2%)
Restrictive pulmonary disease	3 (0.1%)	6 (0.2%)	9 (0.2%)
Rhinitis allergic	66 (2.5%)	59 (2.3%)	125 (2.4%)
Rhinitis hypertrophic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rhinorrhoea	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Sinus disorder	2 (<0.1%)	0	2 (<0.1%)
Sinus perforation	0	1 (<0.1%)	1 (<0.1%)
Sinus polyp	0	1 (<0.1%)	1 (<0.1%)
Sleep apnoea syndrome	239 (9.1%)	238 (9.1%)	477 (9.1%)
Snoring	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Stridor	0	1 (<0.1%)	1 (<0.1%)
Throat irritation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tracheal stenosis	0	1 (<0.1%)	1 (<0.1%)
Upper respiratory tract inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper-airway cough syndrome	0	1 (<0.1%)	1 (<0.1%)
Vasomotor rhinitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vocal cord polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord thickening	1 (<0.1%)	0	1 (<0.1%)
Wheezing	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Skin and subcutaneous tissue disorders	395 (15.1%)	424 (16.2%)	819 (15.6%)
Acanthosis nigricans	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Acne	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Actinic keratosis	26 (1.0%)	24 (0.9%)	50 (1.0%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Alopecia	3 (0.1%)	4 (0.2%)	7 (0.1%)
Alopecia areata	1 (<0.1%)	0	1 (<0.1%)
Androgenetic alopecia	1 (<0.1%)	0	1 (<0.1%)
Angioedema	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Asteatosis	5 (0.2%)	3 (0.1%)	8 (0.2%)
Blister	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Chronic pigmented purpura	1 (<0.1%)	0	1 (<0.1%)
Chronic spontaneous urticaria	1 (<0.1%)	0	1 (<0.1%)
Dandruff	0	2 (<0.1%)	2 (<0.1%)
Decubitus ulcer	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dermal cyst	1 (<0.1%)	10 (0.4%)	11 (0.2%)
Dermatitis	30 (1.1%)	22 (0.8%)	52 (1.0%)
Dermatitis allergic	6 (0.2%)	7 (0.3%)	13 (0.2%)
Dermatitis atopic	6 (0.2%)	11 (0.4%)	17 (0.3%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	10 (0.4%)	7 (0.3%)	17 (0.3%)
Dermatitis herpetiformis	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Diabetic bullosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic dermopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Diabetic foot	47 (1.8%)	61 (2.3%)	108 (2.1%)
Diabetic neuropathic ulcer	1 (<0.1%)	0	1 (<0.1%)
Diabetic ulcer	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Drug eruption	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Dry skin	24 (0.9%)	27 (1.0%)	51 (1.0%)
Dyshidrotic eczema	1 (<0.1%)	0	1 (<0.1%)
Eczema	22 (0.8%)	31 (1.2%)	53 (1.0%)
Eczema asteatotic	6 (0.2%)	6 (0.2%)	12 (0.2%)
Eczema nummular	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Erythema	6 (0.2%)	5 (0.2%)	11 (0.2%)
Erythema nodosum	3 (0.1%)	0	3 (<0.1%)
Granuloma annulare	2 (<0.1%)	0	2 (<0.1%)
Granuloma skin	0	1 (<0.1%)	1 (<0.1%)
Hand dermatitis	2 (<0.1%)	0	2 (<0.1%)
Hidradenitis	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Hyperhidrosis	0	2 (<0.1%)	2 (<0.1%)
Hyperkeratosis	15 (0.6%)	13 (0.5%)	28 (0.5%)
Hypersensitivity vasculitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Idiopathic urticaria	0	1 (<0.1%)	1 (<0.1%)
Ingrowing nail	5 (0.2%)	6 (0.2%)	11 (0.2%)
Intertrigo	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Ischaemic skin ulcer	1 (<0.1%)	0	1 (<0.1%)
Keloid scar	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Lichen planus	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lichen sclerosus	1 (<0.1%)	0	1 (<0.1%)
Lichenification	2 (<0.1%)	0	2 (<0.1%)
Lipodystrophy acquired	4 (0.2%)	3 (0.1%)	7 (0.1%)
Lipohypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mechanical urticaria	0	1 (<0.1%)	1 (<0.1%)
Melanosis	1 (<0.1%)	0	1 (<0.1%)
Myxoid cyst	1 (<0.1%)	0	1 (<0.1%)
Nail disorder	0	1 (<0.1%)	1 (<0.1%)
Nail dystrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nail hypertrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neurodermatitis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Neuropathic ulcer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neutrophilic dermatosis	0	1 (<0.1%)	1 (<0.1%)
Onychalgia	0	1 (<0.1%)	1 (<0.1%)
Onycholysis	1 (<0.1%)	0	1 (<0.1%)
Palmoplantar keratoderma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Panniculitis	1 (<0.1%)	0	1 (<0.1%)
Peau d'orange	1 (<0.1%)	0	1 (<0.1%)
Pemphigoid	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pemphigus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Petechiae	0	1 (<0.1%)	1 (<0.1%)
Pigmentation disorder	2 (<0.1%)	0	2 (<0.1%)
Prurigo	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Pruritus	32 (1.2%)	39 (1.5%)	71 (1.4%)
Pruritus allergic	1 (<0.1%)	0	1 (<0.1%)
Pseudofolliculitis	0	1 (<0.1%)	1 (<0.1%)
Psoriasis	40 (1.5%)	49 (1.9%)	89 (1.7%)
Purpura	2 (<0.1%)	0	2 (<0.1%)
Pustular psoriasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rash	12 (0.5%)	20 (0.8%)	32 (0.6%)
Rash erythematous	1 (<0.1%)	0	1 (<0.1%)
Rash pruritic	0	1 (<0.1%)	1 (<0.1%)
Rosacea	6 (0.2%)	5 (0.2%)	11 (0.2%)
Scleroedema	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	13 (0.5%)	10 (0.4%)	23 (0.4%)
Sensitive skin	2 (<0.1%)	0	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Skin atrophy	0	1 (<0.1%)	1 (<0.1%)
Skin discolouration	0	1 (<0.1%)	1 (<0.1%)
Skin disorder	0	2 (<0.1%)	2 (<0.1%)
Skin dystrophy	0	2 (<0.1%)	2 (<0.1%)
Skin exfoliation	0	1 (<0.1%)	1 (<0.1%)
Skin fissures	1 (<0.1%)	0	1 (<0.1%)
Skin hyperpigmentation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	4 (0.2%)	7 (0.3%)	11 (0.2%)
Skin mass	0	1 (<0.1%)	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	27 (1.0%)	42 (1.6%)	69 (1.3%)
Skin wrinkling	0	1 (<0.1%)	1 (<0.1%)
Solar dermatitis	1 (<0.1%)	0	1 (<0.1%)
Solar lentigo	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	15 (0.6%)	11 (0.4%)	26 (0.5%)
Stevens-Johnson syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Telangiectasia	2 (<0.1%)	0	2 (<0.1%)
Urticaria	13 (0.5%)	9 (0.3%)	22 (0.4%)
Urticaria chronic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vasculitic rash	0	1 (<0.1%)	1 (<0.1%)
Vasculitic ulcer	0	1 (<0.1%)	1 (<0.1%)
Vitiligo	7 (0.3%)	8 (0.3%)	15 (0.3%)
Xeroderma	4 (0.2%)	3 (0.1%)	7 (0.1%)
Social circumstances	152 (5.8%)	138 (5.3%)	290 (5.5%)
Alcohol use	1 (<0.1%)	0	1 (<0.1%)
Corrective lens user	0	1 (<0.1%)	1 (<0.1%)
Denture wearer	3 (0.1%)	0	3 (<0.1%)
Diet noncompliance	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	0	1 (<0.1%)	1 (<0.1%)
Edentulous	4 (0.2%)	3 (0.1%)	7 (0.1%)
Ex-tobacco user	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Menopause	102 (3.9%)	79 (3.0%)	181 (3.5%)
Orthosis user	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	32 (1.2%)	40 (1.5%)	72 (1.4%)
Social problem	0	1 (<0.1%)	1 (<0.1%)
Stress at work	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Tobacco user	7 (0.3%)	9 (0.3%)	16 (0.3%)
Wheelchair user	1 (<0.1%)	0	1 (<0.1%)
Surgical and medical procedures	1036 (39.5%)	1035 (39.5%)	2071 (39.5%)
Abdominal hernia repair	3 (0.1%)	7 (0.3%)	10 (0.2%)
Abdominoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Abortion induced	0	1 (<0.1%)	1 (<0.1%)
Abscess drainage	4 (0.2%)	10 (0.4%)	14 (0.3%)
Acoustic neuroma removal	0	2 (<0.1%)	2 (<0.1%)
Adenoidectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenotonsillectomy	2 (<0.1%)	0	2 (<0.1%)
Adrenalectomy	2 (<0.1%)	0	2 (<0.1%)
Amblyopia therapy	0	1 (<0.1%)	1 (<0.1%)
Amputation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal fissure excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Anal fistula repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aneurysm repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angioplasty	8 (0.3%)	8 (0.3%)	16 (0.3%)
Ankle operation	2 (<0.1%)	0	2 (<0.1%)
Anticoagulant therapy	0	2 (<0.1%)	2 (<0.1%)
Aortic anastomosis	1 (<0.1%)	0	1 (<0.1%)
Aortic aneurysm repair	2 (<0.1%)	6 (0.2%)	8 (0.2%)
Aortic bypass	7 (0.3%)	3 (0.1%)	10 (0.2%)
Aortic stent insertion	0	4 (0.2%)	4 (<0.1%)
Aortic surgery	0	1 (<0.1%)	1 (<0.1%)
Aortic valve repair	0	4 (0.2%)	4 (<0.1%)
Aortic valve replacement	12 (0.5%)	13 (0.5%)	25 (0.5%)
Apicectomy	1 (<0.1%)	0	1 (<0.1%)
Appendicectomy	76 (2.9%)	107 (4.1%)	183 (3.5%)
Arterial stent insertion	4 (0.2%)	4 (0.2%)	8 (0.2%)
Arthrodesis	0	1 (<0.1%)	1 (<0.1%)
Atrial septal defect repair	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Autonomic ganglionectomy	0	1 (<0.1%)	1 (<0.1%)
Axillary lymphadenectomy	0	1 (<0.1%)	1 (<0.1%)
Baker's cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bariatric gastric balloon insertion	1 (<0.1%)	0	1 (<0.1%)
Benign breast lump removal	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Benign tumour excision	1 (<0.1%)	0	1 (<0.1%)
Bile duct stent insertion	1 (<0.1%)	0	1 (<0.1%)
Biliary tract operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Bladder calculus removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder catheter permanent	1 (<0.1%)	0	1 (<0.1%)
Bladder catheterisation	0	2 (<0.1%)	2 (<0.1%)
Bladder neoplasm surgery	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Bladder operation	2 (<0.1%)	0	2 (<0.1%)
Bladder polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blepharoplasty	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bone cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bone debridement	1 (<0.1%)	0	1 (<0.1%)
Bone graft	2 (<0.1%)	0	2 (<0.1%)
Bone lesion excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bone operation	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Bone prosthesis insertion	1 (<0.1%)	0	1 (<0.1%)
Bone trimming	0	1 (<0.1%)	1 (<0.1%)
Brachytherapy	1 (<0.1%)	0	1 (<0.1%)
Brachytherapy to prostate	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast conserving surgery	2 (<0.1%)	4 (0.2%)	6 (0.1%)
Breast cyst excision	0	2 (<0.1%)	2 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	0	3 (0.1%)	3 (<0.1%)
Burn operation	0	1 (<0.1%)	1 (<0.1%)
Bursa removal	1 (<0.1%)	0	1 (<0.1%)
CSF shunt operation	0	2 (<0.1%)	2 (<0.1%)
Caesarean section	18 (0.7%)	20 (0.8%)	38 (0.7%)
Cancer surgery	2 (<0.1%)	0	2 (<0.1%)
Cardiac ablation	3 (0.1%)	3 (0.1%)	6 (0.1%)
Cardiac operation	0	1 (<0.1%)	1 (<0.1%)
Cardiac pacemaker insertion	38 (1.4%)	41 (1.6%)	79 (1.5%)
Cardiac pacemaker replacement	1 (<0.1%)	0	1 (<0.1%)
Cardiac resynchronisation therapy	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Cardiovascular event prophylaxis	0	2 (<0.1%)	2 (<0.1%)
Cardioversion	4 (0.2%)	3 (0.1%)	7 (0.1%)
Carotid artery stent insertion	0	2 (<0.1%)	2 (<0.1%)
Carotid endarterectomy	32 (1.2%)	36 (1.4%)	68 (1.3%)
Carpal tunnel decompression	16 (0.6%)	14 (0.5%)	30 (0.6%)
Cataract operation	163 (6.2%)	143 (5.5%)	306 (5.8%)
Catheter placement	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Central venous catheterisation	1 (<0.1%)	0	1 (<0.1%)
Cerebral cyst excision	0	1 (<0.1%)	1 (<0.1%)
Cerebral endovascular aneurysm repair	0	2 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Cervical conisation	1 (<0.1%)	0	1 (<0.1%)
Chemotherapy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cholecystectomy	144 (5.5%)	147 (5.6%)	291 (5.6%)
Cholecystostomy	0	1 (<0.1%)	1 (<0.1%)
Cholelithotomy	1 (<0.1%)	0	1 (<0.1%)
Cholelithotripsy	1 (<0.1%)	0	1 (<0.1%)
Circumcision	3 (0.1%)	6 (0.2%)	9 (0.2%)
Colectomy	12 (0.5%)	9 (0.3%)	21 (0.4%)
Colon operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colostomy	0	5 (0.2%)	5 (<0.1%)
Continuous positive airway pressure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Corneal transplant	0	2 (<0.1%)	2 (<0.1%)
Coronary angioplasty	38 (1.4%)	34 (1.3%)	72 (1.4%)
Coronary arterial stent insertion	92 (3.5%)	79 (3.0%)	171 (3.3%)
Coronary artery bypass	107 (4.1%)	103 (3.9%)	210 (4.0%)
Coronary endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Coronary revascularisation	6 (0.2%)	3 (0.1%)	9 (0.2%)
Cox-Maze procedure	0	1 (<0.1%)	1 (<0.1%)
Craniotomy	0	1 (<0.1%)	1 (<0.1%)
Cyst removal	1 (<0.1%)	0	1 (<0.1%)
Cystostomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dacryocystorhinostomy	0	1 (<0.1%)	1 (<0.1%)
Debridement	3 (0.1%)	3 (0.1%)	6 (0.1%)
Dental implantation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dental prosthesis placement	1 (<0.1%)	0	1 (<0.1%)
Dialysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug delivery device placement	0	1 (<0.1%)	1 (<0.1%)
Duodenal sphincterotomy	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer repair	2 (<0.1%)	0	2 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ear tube insertion	1 (<0.1%)	0	1 (<0.1%)
Elbow operation	1 (<0.1%)	0	1 (<0.1%)
Endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Endodontic procedure	1 (<0.1%)	0	1 (<0.1%)
Endometrial ablation	0	1 (<0.1%)	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	0	1 (<0.1%)
Enterostomy	1 (<0.1%)	0	1 (<0.1%)
Epidermoid cyst excision	0	2 (<0.1%)	2 (<0.1%)
Epididymal cyst removal	1 (<0.1%)	0	1 (<0.1%)
Ethmoid sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Eustachian tube operation	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Eventration repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Excision of ampulla of Vater	1 (<0.1%)	0	1 (<0.1%)
Explorative laparotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye excision	0	1 (<0.1%)	1 (<0.1%)
Eye laser surgery	17 (0.6%)	12 (0.5%)	29 (0.6%)
Eye operation	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Eye prosthesis insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facetectomy	0	1 (<0.1%)	1 (<0.1%)
Female sterilisation	23 (0.9%)	28 (1.1%)	51 (1.0%)
Finger amputation	5 (0.2%)	4 (0.2%)	9 (0.2%)
Fistula repair	1 (<0.1%)	0	1 (<0.1%)
Foot amputation	9 (0.3%)	11 (0.4%)	20 (0.4%)
Foot operation	0	1 (<0.1%)	1 (<0.1%)
Foraminotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gallbladder operation	4 (0.2%)	3 (0.1%)	7 (0.1%)
Gastrectomy	3 (0.1%)	4 (0.2%)	7 (0.1%)
Gastric banding	4 (0.2%)	3 (0.1%)	7 (0.1%)
Gastric bypass	9 (0.3%)	8 (0.3%)	17 (0.3%)
Gastric operation	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal endoscopic therapy	0	1 (<0.1%)	1 (<0.1%)
Gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Glaucoma surgery	6 (0.2%)	4 (0.2%)	10 (0.2%)
Haemodialysis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoid operation	10 (0.4%)	7 (0.3%)	17 (0.3%)
Hearing aid therapy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	0	1 (<0.1%)	1 (<0.1%)
Hepatectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatic embolisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hernia repair	12 (0.5%)	5 (0.2%)	17 (0.3%)
High frequency ablation	1 (<0.1%)	0	1 (<0.1%)
Hip arthroplasty	21 (0.8%)	25 (1.0%)	46 (0.9%)
Hip surgery	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hormone therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrocele operation	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Hysterectomy	74 (2.8%)	76 (2.9%)	150 (2.9%)
Hysterosalpingo-oophorectomy	10 (0.4%)	7 (0.3%)	17 (0.3%)
Ileectomy	1 (<0.1%)	0	1 (<0.1%)
Ileocaecal resection	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Ileocolectomy	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	3 (0.1%)	0	3 (<0.1%)
Ileostomy closure	4 (0.2%)	0	4 (<0.1%)
Implantable defibrillator insertion	7 (0.3%)	5 (0.2%)	12 (0.2%)
Incisional drainage	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Influenza immunisation	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	11 (0.4%)	27 (1.0%)	38 (0.7%)
Internal fixation of fracture	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Intervertebral disc operation	15 (0.6%)	16 (0.6%)	31 (0.6%)
Intestinal anastomosis	1 (<0.1%)	0	1 (<0.1%)
Intestinal operation	0	3 (0.1%)	3 (<0.1%)
Intestinal polypectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Intestinal resection	0	1 (<0.1%)	1 (<0.1%)
Intra-cerebral aneurysm operation	3 (0.1%)	0	3 (<0.1%)
Intra-ocular injection	4 (0.2%)	4 (0.2%)	8 (0.2%)
Intra-thoracic aortic aneurysm repair	1 (<0.1%)	0	1 (<0.1%)
Intraocular lens implant	40 (1.5%)	39 (1.5%)	79 (1.5%)
Iridectomy	2 (<0.1%)	0	2 (<0.1%)
Iridotomy	1 (<0.1%)	0	1 (<0.1%)
Jaw operation	1 (<0.1%)	0	1 (<0.1%)
Jejunocolostomy	1 (<0.1%)	0	1 (<0.1%)
Joint arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint injection	0	1 (<0.1%)	1 (<0.1%)
Joint resurfacing surgery	1 (<0.1%)	0	1 (<0.1%)
Keratomileusis	0	1 (<0.1%)	1 (<0.1%)
Knee arthroplasty	22 (0.8%)	44 (1.7%)	66 (1.3%)
Knee operation	13 (0.5%)	13 (0.5%)	26 (0.5%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	10 (0.4%)	15 (0.6%)	25 (0.5%)
Laryngeal operation	1 (<0.1%)	0	1 (<0.1%)
Laryngeal repair	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Leg amputation	17 (0.6%)	24 (0.9%)	41 (0.8%)
Lens capsulotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lens extraction	9 (0.3%)	5 (0.2%)	14 (0.3%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Limb amputation	1 (<0.1%)	0	1 (<0.1%)
Limb operation	3 (0.1%)	5 (0.2%)	8 (0.2%)
Lip lesion excision	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Lipoma excision	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Lithotripsy	4 (0.2%)	6 (0.2%)	10 (0.2%)
Liver operation	0	1 (<0.1%)	1 (<0.1%)
Liver transplant	0	1 (<0.1%)	1 (<0.1%)
Lung lobectomy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Lung operation	0	1 (<0.1%)	1 (<0.1%)
Lymphadenectomy	1 (<0.1%)	0	1 (<0.1%)
Mammoplasty	0	1 (<0.1%)	1 (<0.1%)
Mastectomy	6 (0.2%)	5 (0.2%)	11 (0.2%)
Mastoidectomy	1 (<0.1%)	0	1 (<0.1%)
Maxillofacial operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Medical device implantation	1 (<0.1%)	0	1 (<0.1%)
Medical device removal	0	1 (<0.1%)	1 (<0.1%)
Meningeal repair	0	1 (<0.1%)	1 (<0.1%)
Meniscus operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Meniscus removal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Metabolic surgery	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Metatarsal excision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mitral commissurotomy	0	1 (<0.1%)	1 (<0.1%)
Mitral valve repair	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Mitral valve replacement	0	3 (0.1%)	3 (<0.1%)
Mole excision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myomectomy	3 (0.1%)	5 (0.2%)	8 (0.2%)
Nail operation	0	1 (<0.1%)	1 (<0.1%)
Nasal polypectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nasal septal operation	6 (0.2%)	4 (0.2%)	10 (0.2%)
Nasopharyngeal surgery	0	1 (<0.1%)	1 (<0.1%)
Neck dissection	1 (<0.1%)	0	1 (<0.1%)
Neck surgery	0	2 (<0.1%)	2 (<0.1%)
Nephrectomy	29 (1.1%)	28 (1.1%)	57 (1.1%)
Nephrostomy	0	1 (<0.1%)	1 (<0.1%)
Nephroureterectomy	2 (<0.1%)	0	2 (<0.1%)
Neurectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurolysis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Oesophagoenterostomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	6 (0.2%)	4 (0.2%)	10 (0.2%)
Oophorectomy bilateral	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Orchidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Orchidopexy	0	1 (<0.1%)	1 (<0.1%)
Orthopaedic procedure	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Ostectomy	0	1 (<0.1%)	1 (<0.1%)
Osteotomy	3 (0.1%)	0	3 (<0.1%)
Otorhinolaryngological surgery	1 (<0.1%)	0	1 (<0.1%)
Ovarian cystectomy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Ovarian neoplasm surgery	0	3 (0.1%)	3 (<0.1%)
Ovarian operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreas transplant	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic operation	1 (<0.1%)	0	1 (<0.1%)
Pancreatobiliary sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Papilloma excision	0	1 (<0.1%)	1 (<0.1%)
Parathyroidectomy	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Parotidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Penile prosthesis insertion	5 (0.2%)	4 (0.2%)	9 (0.2%)
Percutaneous coronary intervention	20 (0.8%)	21 (0.8%)	41 (0.8%)
Pericardial drainage	0	2 (<0.1%)	2 (<0.1%)
Perineoplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral artery angioplasty	18 (0.7%)	12 (0.5%)	30 (0.6%)
Peripheral artery bypass	12 (0.5%)	13 (0.5%)	25 (0.5%)
Peripheral artery stent insertion	10 (0.4%)	8 (0.3%)	18 (0.3%)
Peripheral endarterectomy	3 (0.1%)	4 (0.2%)	7 (0.1%)
Peripheral nerve decompression	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral nerve destruction	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve neurostimulation	0	1 (<0.1%)	1 (<0.1%)
Peripheral nerve operation	0	2 (<0.1%)	2 (<0.1%)
Peripheral nerve transposition	1 (<0.1%)	0	1 (<0.1%)
Peripheral revascularisation	0	2 (<0.1%)	2 (<0.1%)
Phlebectomy	6 (0.2%)	7 (0.3%)	13 (0.2%)
Phlebotomy	1 (<0.1%)	0	1 (<0.1%)
Photocoagulation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Plastic surgery to the face	0	1 (<0.1%)	1 (<0.1%)
Pleurectomy	0	1 (<0.1%)	1 (<0.1%)
Pneumocentesis	0	1 (<0.1%)	1 (<0.1%)
Polypectomy	3 (0.1%)	11 (0.4%)	14 (0.3%)
Posterior lens capsulotomy	1 (<0.1%)	0	1 (<0.1%)
Proctectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Profundaplasty	0	1 (<0.1%)	1 (<0.1%)
Prophylaxis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Prostatectomy	17 (0.6%)	17 (0.6%)	34 (0.6%)
Prostatic operation	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Pterygium operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Ptosis repair	0	1 (<0.1%)	1 (<0.1%)
Pulmonary resection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pyelotomy	1 (<0.1%)	0	1 (<0.1%)
Pyloroplasty	1 (<0.1%)	0	1 (<0.1%)
Radical cystectomy	0	1 (<0.1%)	1 (<0.1%)
Radical hysterectomy	1 (<0.1%)	0	1 (<0.1%)
Radical mastectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	4 (0.2%)	1 (<0.1%)	5 (<0.1%)
Radiotherapy	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Rectal polypectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rectal prolapse repair	1 (<0.1%)	0	1 (<0.1%)
Renal artery angioplasty	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Renal artery stent placement	4 (0.2%)	5 (0.2%)	9 (0.2%)
Renal cyst aspiration	0	1 (<0.1%)	1 (<0.1%)
Renal cyst excision	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	17 (0.6%)	11 (0.4%)	28 (0.5%)
Renal surgery	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Renal sympathetic nerve ablation	3 (0.1%)	1 (<0.1%)	4 (<0.1%)
Renal transplant	0	1 (<0.1%)	1 (<0.1%)
Renal tumour excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal laser coagulation	24 (0.9%)	16 (0.6%)	40 (0.8%)
Retinal operation	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Retinopexy	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Revascularisation procedure	2 (<0.1%)	0	2 (<0.1%)
Rotator cuff repair	5 (0.2%)	6 (0.2%)	11 (0.2%)
Salpingectomy	0	2 (<0.1%)	2 (<0.1%)
Salpingo-oophorectomy	2 (<0.1%)	0	2 (<0.1%)
Salpingo-oophorectomy bilateral	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Salpingo-oophorectomy unilateral	1 (<0.1%)	0	1 (<0.1%)
Scar excision	0	1 (<0.1%)	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)
Sebaceous cyst excision	0	2 (<0.1%)	2 (<0.1%)
Shoulder arthroplasty	4 (0.2%)	3 (0.1%)	7 (0.1%)
Shoulder operation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Sigmoidectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sinus operation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin graft	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Skin lesion removal	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Skin neoplasm excision	9 (0.3%)	13 (0.5%)	22 (0.4%)
Small intestinal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Small intestinal resection	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Spinal decompression	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Spinal fusion surgery	6 (0.2%)	2 (<0.1%)	8 (0.2%)
Spinal laminectomy	7 (0.3%)	13 (0.5%)	20 (0.4%)
Spinal nerve stimulator implantation	2 (<0.1%)	0	2 (<0.1%)
Spinal operation	8 (0.3%)	9 (0.3%)	17 (0.3%)
Splenectomy	6 (0.2%)	5 (0.2%)	11 (0.2%)
Stent placement	11 (0.4%)	5 (0.2%)	16 (0.3%)
Sterilisation	5 (0.2%)	0	5 (<0.1%)
Steroid therapy	0	1 (<0.1%)	1 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Suprapubic prostatectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Surgery	2 (<0.1%)	0	2 (<0.1%)
Sympathectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Synovectomy	1 (<0.1%)	0	1 (<0.1%)
Synovial cyst removal	0	1 (<0.1%)	1 (<0.1%)
Tendon sheath incision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tenoplasty	0	3 (0.1%)	3 (<0.1%)
Tenotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tetralogy of Fallot repair	0	1 (<0.1%)	1 (<0.1%)
Therapeutic embolisation	1 (<0.1%)	0	1 (<0.1%)
Thoracotomy	0	1 (<0.1%)	1 (<0.1%)
Thromboembolectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid nodule removal	1 (<0.1%)	0	1 (<0.1%)
Thyroid operation	0	1 (<0.1%)	1 (<0.1%)
Thyroidectomy	25 (1.0%)	33 (1.3%)	58 (1.1%)
Toe amputation	53 (2.0%)	55 (2.1%)	108 (2.1%)
Toe operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tonsillectomy	30 (1.1%)	37 (1.4%)	67 (1.3%)
Tooth extraction	4 (0.2%)	6 (0.2%)	10 (0.2%)
Tooth repair	1 (<0.1%)	0	1 (<0.1%)
Trabeculectomy	2 (<0.1%)	0	2 (<0.1%)
Tracheostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transcatheter aortic valve implantation	0	1 (<0.1%)	1 (<0.1%)
Transfusion	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Transmyocardial revascularisation	0	1 (<0.1%)	1 (<0.1%)
Transurethral bladder resection	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Transurethral prostatectomy	14 (0.5%)	16 (0.6%)	30 (0.6%)
Tricuspid valve repair	0	1 (<0.1%)	1 (<0.1%)
Tumour excision	3 (0.1%)	0	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Turbinectomy	1 (<0.1%)	0	1 (<0.1%)
Turbinoplasty	0	1 (<0.1%)	1 (<0.1%)
Tympanoplasty	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia repair	17 (0.6%)	10 (0.4%)	27 (0.5%)
Umbilicoplasty	0	1 (<0.1%)	1 (<0.1%)
Ureter dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Ureteral stent insertion	5 (0.2%)	3 (0.1%)	8 (0.2%)
Ureteric calculus removal	5 (0.2%)	5 (0.2%)	10 (0.2%)
Ureteric operation	1 (<0.1%)	0	1 (<0.1%)
Ureteric repair	0	1 (<0.1%)	1 (<0.1%)
Ureterolithotomy	1 (<0.1%)	0	1 (<0.1%)
Urethral calculus removal	0	1 (<0.1%)	1 (<0.1%)
Urethral dilation procedure	2 (<0.1%)	0	2 (<0.1%)
Urethral meatotomy	0	1 (<0.1%)	1 (<0.1%)
Urethral operation	0	2 (<0.1%)	2 (<0.1%)
Urethral repair	1 (<0.1%)	0	1 (<0.1%)
Urethrotomy	3 (0.1%)	0	3 (<0.1%)
Urinary bladder suspension	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary control neurostimulator implantation	0	1 (<0.1%)	1 (<0.1%)
Urinary cystectomy	1 (<0.1%)	0	1 (<0.1%)
Uterine dilation and curettage	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Uterine operation	0	1 (<0.1%)	1 (<0.1%)
Uterine polypectomy	0	2 (<0.1%)	2 (<0.1%)
Uterine repair	1 (<0.1%)	0	1 (<0.1%)
Uterine tumour excision	1 (<0.1%)	0	1 (<0.1%)
Uvulectomy	0	1 (<0.1%)	1 (<0.1%)
Uvulopalatopharyngoplasty	1 (<0.1%)	0	1 (<0.1%)
Uvuloplasty	1 (<0.1%)	0	1 (<0.1%)
Vagotomy	2 (<0.1%)	0	2 (<0.1%)
Varicocele repair	1 (<0.1%)	0	1 (<0.1%)
Varicose vein operation	8 (0.3%)	5 (0.2%)	13 (0.2%)
Vascular graft	7 (0.3%)	5 (0.2%)	12 (0.2%)
Vascular operation	2 (<0.1%)	0	2 (<0.1%)
Vascular stent insertion	6 (0.2%)	7 (0.3%)	13 (0.2%)
Vasectomy	9 (0.3%)	6 (0.2%)	15 (0.3%)
Vena cava filter insertion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Venous angioplasty	0	1 (<0.1%)	1 (<0.1%)
Venous operation	0	1 (<0.1%)	1 (<0.1%)
Venous stent insertion	0	1 (<0.1%)	1 (<0.1%)
Vitamin supplementation	0	1 (<0.1%)	1 (<0.1%)
Vitrectomy	30 (1.1%)	29 (1.1%)	59 (1.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Vocal cord operation	1 (<0.1%)	0	1 (<0.1%)
Vocal cord polypectomy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Wrist surgery	1 (<0.1%)	0	1 (<0.1%)
Vascular disorders	2562 (97.7%)	2570 (98.1%)	5132 (97.9%)
Angiopathy	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	18 (0.7%)	23 (0.9%)	41 (0.8%)
Aortic arteriosclerosis	38 (1.4%)	29 (1.1%)	67 (1.3%)
Aortic dilatation	5 (0.2%)	5 (0.2%)	10 (0.2%)
Aortic disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic dissection	1 (<0.1%)	0	1 (<0.1%)
Aortic stenosis	27 (1.0%)	16 (0.6%)	43 (0.8%)
Aortic thrombosis	0	1 (<0.1%)	1 (<0.1%)
Arterial insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	2 (<0.1%)	3 (0.1%)	5 (<0.1%)
Arteriosclerosis	43 (1.6%)	54 (2.1%)	97 (1.9%)
Arteriosclerosis Moenckeberg-type	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arteritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atheroembolism	0	1 (<0.1%)	1 (<0.1%)
Brachiocephalic arteriosclerosis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Brachiocephalic artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Circulatory collapse	1 (<0.1%)	0	1 (<0.1%)
Cryoglobulinaemia	2 (<0.1%)	0	2 (<0.1%)
Deep vein thrombosis	24 (0.9%)	29 (1.1%)	53 (1.0%)
Diabetic macroangiopathy	11 (0.4%)	10 (0.4%)	21 (0.4%)
Diabetic microangiopathy	4 (0.2%)	5 (0.2%)	9 (0.2%)
Diabetic vascular disorder	48 (1.8%)	34 (1.3%)	82 (1.6%)
Diastolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Dry gangrene	2 (<0.1%)	0	2 (<0.1%)
Embolism venous	0	1 (<0.1%)	1 (<0.1%)
Essential hypertension	85 (3.2%)	91 (3.5%)	176 (3.4%)
Extremity necrosis	2 (<0.1%)	0	2 (<0.1%)
Giant cell arteritis	0	1 (<0.1%)	1 (<0.1%)
Granulomatosis with polyangiitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haematoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hot flush	1 (<0.1%)	0	1 (<0.1%)
Hypertension	2446 (93.3%)	2463 (94.0%)	4909 (93.6%)
Hypertensive angiopathy	7 (0.3%)	5 (0.2%)	12 (0.2%)
Hypertensive crisis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Hypertensive end-organ damage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypertensive urgency	2 (<0.1%)	0	2 (<0.1%)
Hypotension	4 (0.2%)	9 (0.3%)	13 (0.2%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Infarction	0	1 (<0.1%)	1 (<0.1%)
Intermittent claudication	21 (0.8%)	29 (1.1%)	50 (1.0%)
Labile hypertension	1 (<0.1%)	0	1 (<0.1%)
Leriche syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphocele	0	1 (<0.1%)	1 (<0.1%)
Lymphoedema	9 (0.3%)	7 (0.3%)	16 (0.3%)
Lymphostasis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Macroangiopathy	3 (0.1%)	3 (0.1%)	6 (0.1%)
Malignant hypertension	1 (<0.1%)	0	1 (<0.1%)
Microangiopathy	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	4 (0.2%)	8 (0.3%)	12 (0.2%)
Pallor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	436 (16.6%)	424 (16.2%)	860 (16.4%)
Peripheral artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery occlusion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral artery stenosis	5 (0.2%)	4 (0.2%)	9 (0.2%)
Peripheral artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Peripheral coldness	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral ischaemia	4 (0.2%)	2 (<0.1%)	6 (0.1%)
Peripheral vascular disorder	15 (0.6%)	27 (1.0%)	42 (0.8%)
Peripheral venous disease	63 (2.4%)	60 (2.3%)	123 (2.3%)
Phlebitis	3 (0.1%)	2 (<0.1%)	5 (<0.1%)
Poor peripheral circulation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post thrombotic syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Postpartum venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Raynaud's phenomenon	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renovascular hypertension	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Secondary hypertension	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery stenosis	5 (0.2%)	1 (<0.1%)	6 (0.1%)
Subclavian steal syndrome	2 (<0.1%)	0	2 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Thromboangiitis obliterans	0	2 (<0.1%)	2 (<0.1%)
Thrombophlebitis	5 (0.2%)	7 (0.3%)	12 (0.2%)
Thrombophlebitis superficial	1 (<0.1%)	0	1 (<0.1%)
Thrombosis	1 (<0.1%)	3 (0.1%)	4 (<0.1%)
Varicose vein	81 (3.1%)	57 (2.2%)	138 (2.6%)
Vasodilatation	0	1 (<0.1%)	1 (<0.1%)
Vein disorder	3 (0.1%)	0	3 (<0.1%)
Venous thrombosis	1 (<0.1%)	4 (0.2%)	5 (<0.1%)
Venous thrombosis in pregnancy	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis limb	0	4 (0.2%)	4 (<0.1%)
White coat hypertension	5 (0.2%)	6 (0.2%)	11 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 26JAN2023 15:21
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4.6 Concomitant medication

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

Drug grouping	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	2157 (82.3%)	2176 (83.1%)	4333 (82.7%)
ACEI	396 (15.1%)	404 (15.4%)	800 (15.3%)
ARB	699 (26.7%)	771 (29.4%)	1470 (28.0%)
RAS-inhibitors	1012 (38.6%)	1049 (40.0%)	2061 (39.3%)
Beta-blocker	715 (27.3%)	800 (30.5%)	1515 (28.9%)
Diuretics	1145 (43.7%)	1209 (46.1%)	2354 (44.9%)
Loop diuretics	883 (33.7%)	934 (35.6%)	1817 (34.7%)
Thiazide diuretics	269 (10.3%)	296 (11.3%)	565 (10.8%)
Potassium supplements	180 (6.9%)	233 (8.9%)	413 (7.9%)
Potassium lowering agents (including binders)	293 (11.2%)	181 (6.9%)	474 (9.0%)
Alpha blocking agents	751 (28.6%)	821 (31.3%)	1572 (30.0%)
Calcium channel blockers	939 (35.8%)	1110 (42.4%)	2049 (39.1%)
Centrally acting antihypertensives	186 (7.1%)	240 (9.2%)	426 (8.1%)
Strong CYP3A4 inhibitors	151 (5.8%)	138 (5.3%)	289 (5.5%)
Moderate CYP3A4 inhibitors	335 (12.8%)	346 (13.2%)	681 (13.0%)
Weak CYP3A4 inhibitors	1069 (40.8%)	1129 (43.1%)	2198 (41.9%)
Unclassified CYP3A4 inhibitors	117 (4.5%)	130 (5.0%)	247 (4.7%)
Strong CYP3A4 inducers	32 (1.2%)	31 (1.2%)	63 (1.2%)
Moderate CYP3A4 inducers	163 (6.2%)	196 (7.5%)	359 (6.8%)
Weak CYP3A4 inducers	183 (7.0%)	198 (7.6%)	381 (7.3%)
Unclassified CYP3A4 inducers	124 (4.7%)	115 (4.4%)	239 (4.6%)
Oral anticoagulants	201 (7.7%)	209 (8.0%)	410 (7.8%)
Acetylsalycylic acid and its salts	413 (15.8%)	443 (16.9%)	856 (16.3%)
Statins	775 (29.6%)	797 (30.4%)	1572 (30.0%)
Erythropoeitin stimulating agents	175 (6.7%)	203 (7.7%)	378 (7.2%)
NSAIDS (excluding acetylsalicylic acid)	676 (25.8%)	701 (26.8%)	1377 (26.3%)
ARNIs	6 (0.2%)	11 (0.4%)	17 (0.3%)
Potassium-sparing diuretics	125 (4.8%)	155 (5.9%)	280 (5.3%)
Platelet aggregation inhibitors (excluding heparin)	623 (23.8%)	637 (24.3%)	1260 (24.0%)
Trimethoprim and derivatives	69 (2.6%)	78 (3.0%)	147 (2.8%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:22
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=2622 (100%)	Placebo N=2620 (100%)	Total N=5242 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1669 (63.7%)	1708 (65.2%)	3377 (64.4%)
Insulins and analogues	1247 (47.6%)	1290 (49.2%)	2537 (48.4%)
Dipeptidyl peptidase 4 inhibitors	442 (16.9%)	450 (17.2%)	892 (17.0%)
Glucagon-like peptide-1(GLP1) agonists	239 (9.1%)	241 (9.2%)	480 (9.2%)
SGLT-2 inhibitors	161 (6.1%)	189 (7.2%)	350 (6.7%)
Biguanides	460 (17.5%)	443 (16.9%)	903 (17.2%)
Sulfonylureas	272 (10.4%)	311 (11.9%)	583 (11.1%)
Alpha glucosidase inhibitors	111 (4.2%)	106 (4.0%)	217 (4.1%)
Meglitinides	119 (4.5%)	138 (5.3%)	257 (4.9%)
Thiazolidinediones	76 (2.9%)	77 (2.9%)	153 (2.9%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:22
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1.2.1 Study duration

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

		BAY 94-8862 (N=2622)	Placebo (N=2620)	Total (N=5242)
Study duration (months)	n	2622	2620	5242
	Nmiss	0	0	0
	Mean	31.619	31.451	31.535
	SD	9.946	10.018	9.981
	Min	0.03	0.03	0.03
	Median	31.195	31.310	31.310
	Max	51.48	51.52	51.52

Study duration is defined as time from randomization to the EOS visit (or to last contact date if no EOS visit took place).
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl_study_duration_s.sas 06FEB2023 14:54
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1.2.2 Time-to-event analyses

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

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	202 (7.7%)	230 (8.8%)
Number (%) of subjects censored	2420 (92.3%)	2390 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.72; 1.05]	
two-sided p-value from stratified logrank test	0.1571	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	202 (7.7%)	230 (8.8%)
Number (%) of subjects censored	2420 (92.3%)	2390 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.72; 1.05]	
two-sided p-value from unstratified logrank test	0.1585	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	470 (17.9%)	564 (21.5%)
Number (%) of subjects censored	2152 (82.1%)	2056 (78.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.72; 0.92]	
two-sided p-value from stratified logrank test	0.0010	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 4: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	245 (9.3%)	310 (11.8%)
Number (%) of subjects censored	2377 (90.7%)	2310 (88.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.66; 0.92]	
two-sided p-value from stratified logrank test	0.0037	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 5: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	245 (9.3%)	310 (11.8%)
Number (%) of subjects censored	2377 (90.7%)	2310 (88.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.66; 0.93]	
two-sided p-value from unstratified logrank test	0.0041	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 6: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	140 (5.3%)	214 (8.2%)
Number (%) of subjects censored	2482 (94.7%)	2406 (91.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.53; 0.81]	
two-sided p-value from stratified logrank test	0.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 7: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	206 (7.9%)	227 (8.7%)
Number (%) of subjects censored	2416 (92.1%)	2393 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.74; 1.08]	
two-sided p-value from stratified logrank test	0.2279	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 8: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	206 (7.9%)	227 (8.7%)
Number (%) of subjects censored	2416 (92.1%)	2393 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.75; 1.09]	
two-sided p-value from unstratified logrank test	0.2822	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 9: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	110 (4.2%)	145 (5.5%)
Number (%) of subjects censored	2512 (95.8%)	2475 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.59; 0.97]	
two-sided p-value from stratified logrank test	0.0255	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 10: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	118 (4.5%)	134 (5.1%)
Number (%) of subjects censored	2504 (95.5%)	2486 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.69; 1.13]	
two-sided p-value from stratified logrank test	0.3163	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 11: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	166 (6.3%)	193 (7.4%)
Number (%) of subjects censored	2456 (93.7%)	2427 (92.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.69; 1.04]	
two-sided p-value from stratified logrank test	0.1080	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 12: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	161 (6.1%)	229 (8.7%)
Number (%) of subjects censored	2461 (93.9%)	2391 (91.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.57; 0.85]	
two-sided p-value from stratified logrank test	0.0004	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 13: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	2 (<0.1%)	2 (<0.1%)
Number (%) of subjects censored	2620 (>99.9%)	2618 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.14; 7.24]	
two-sided p-value from stratified logrank test	0.9851	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 14: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	386 (14.7%)	445 (17.0%)
Number (%) of subjects censored	2236 (85.3%)	2175 (83.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.75; 0.98]	
two-sided p-value from stratified logrank test	0.0244	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 15: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	333 (12.7%)	387 (14.8%)
Number (%) of subjects censored	2289 (87.3%)	2233 (85.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.73; 0.97]	
two-sided p-value from stratified logrank test	0.0204	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 16: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	333 (12.7%)	387 (14.8%)
Number (%) of subjects censored	2289 (87.3%)	2233 (85.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.73; 0.98]	
two-sided p-value from unstratified logrank test	0.0229	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 17: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	230 (8.8%)	310 (11.8%)
Number (%) of subjects censored	2392 (91.2%)	2310 (88.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.63; 0.88]	
two-sided p-value from stratified logrank test	0.0006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 18: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	115 (4.4%)	138 (5.3%)
Number (%) of subjects censored	2507 (95.6%)	2482 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.65; 1.06]	
two-sided p-value from stratified logrank test	0.1403	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 19: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	62 (2.4%)	78 (3.0%)
Number (%) of subjects censored	2560 (97.6%)	2542 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.56; 1.09]	
two-sided p-value from stratified logrank test	0.1457	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 20: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	82 (3.1%)	76 (2.9%)
Number (%) of subjects censored	2540 (96.9%)	2544 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.78; 1.45]	
two-sided p-value from stratified logrank test	0.6999	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 21: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	130 (5.0%)	149 (5.7%)
Number (%) of subjects censored	2492 (95.0%)	2471 (94.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.69; 1.10]	
two-sided p-value from stratified logrank test	0.2419	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 22: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	70 (2.7%)	83 (3.2%)
Number (%) of subjects censored	2552 (97.3%)	2537 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.60; 1.14]	
two-sided p-value from stratified logrank test	0.2481	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 23: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	70 (2.7%)	83 (3.2%)
Number (%) of subjects censored	2552 (97.3%)	2537 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.61; 1.15]	
two-sided p-value from unstratified logrank test	0.2634	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 24: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	52 (2.0%)	66 (2.5%)
Number (%) of subjects censored	2570 (98.0%)	2554 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.55; 1.13]	
two-sided p-value from stratified logrank test	0.2000	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 25: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	90 (3.4%)	87 (3.3%)
Number (%) of subjects censored	2532 (96.6%)	2533 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.76; 1.37]	
two-sided p-value from stratified logrank test	0.8968	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 26: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	90 (3.4%)	87 (3.3%)
Number (%) of subjects censored	2532 (96.6%)	2533 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.03 [0.76; 1.38]	
two-sided p-value from unstratified logrank test	0.8696	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 27: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	73 (2.8%)	73 (2.8%)
Number (%) of subjects censored	2549 (97.2%)	2547 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.73; 1.40]	
two-sided p-value from stratified logrank test	0.9336	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 28: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	132 (5.0%)	157 (6.0%)
Number (%) of subjects censored	2490 (95.0%)	2463 (94.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.66; 1.06]	
two-sided p-value from stratified logrank test	0.1325	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 29: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	132 (5.0%)	157 (6.0%)
Number (%) of subjects censored	2490 (95.0%)	2463 (94.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.66; 1.05]	
two-sided p-value from unstratified logrank test	0.1173	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 30: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	83 (3.2%)	134 (5.1%)
Number (%) of subjects censored	2539 (96.8%)	2486 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.63 [0.48; 0.82]	
two-sided p-value from stratified logrank test	0.0008	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 31: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	1176 (44.9%)	1227 (46.8%)
Number (%) of subjects censored	1446 (55.1%)	1393 (53.2%)
Median Time to event (month) [95 % CI]	38.867 [36.467;41.100]	34.867 [32.667;37.933]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.87; 1.03]	
two-sided p-value from stratified logrank test	0.1838	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 32: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	1176 (44.9%)	1227 (46.8%)
Number (%) of subjects censored	1446 (55.1%)	1393 (53.2%)
Median Time to event (month) [95 % CI]	38.867 [36.467;41.100]	34.867 [32.667;37.933]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.87; 1.02]	
two-sided p-value from unstratified logrank test	0.1673	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
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Table 1.2.2 / 33: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	2622 (100.0%)	2620 (100.0%)
Number (%) of subjects with event	1034 (39.4%)	1100 (42.0%)
Number (%) of subjects censored	1588 (60.6%)	1520 (58.0%)
Median Time to event (month) [95 % CI]	39.667 [37.667;42.267]	35.967 [33.500;39.267]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.87; 1.03]	
two-sided p-value from stratified logrank test	0.2228	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / type of albuminuria at screening /screening eGFR.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fid_s1.sas 06FEB2023 14:55
End of table

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

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.88; 1.06]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.4688

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 06FEB2023 15:01
End of table

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

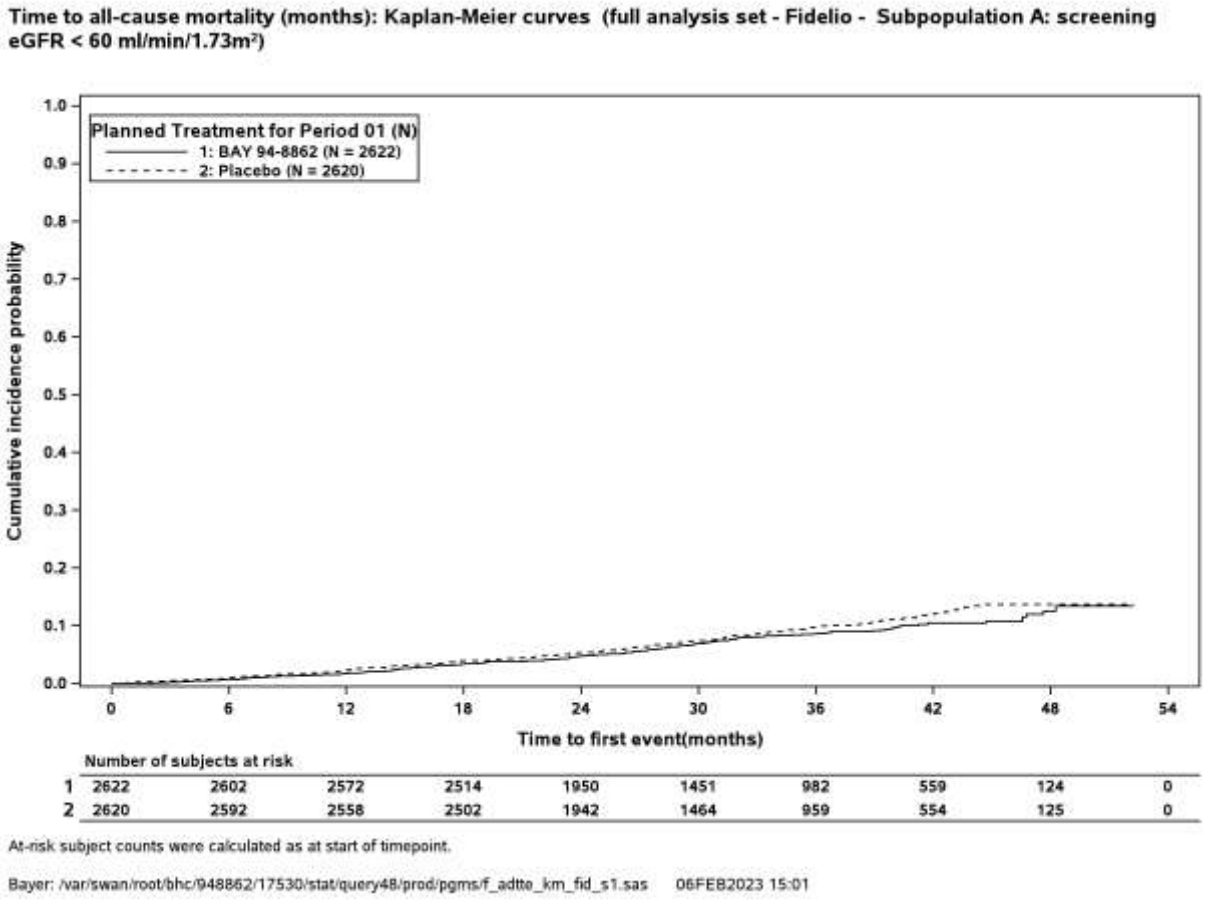


Figure 1.2.2 / 2: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

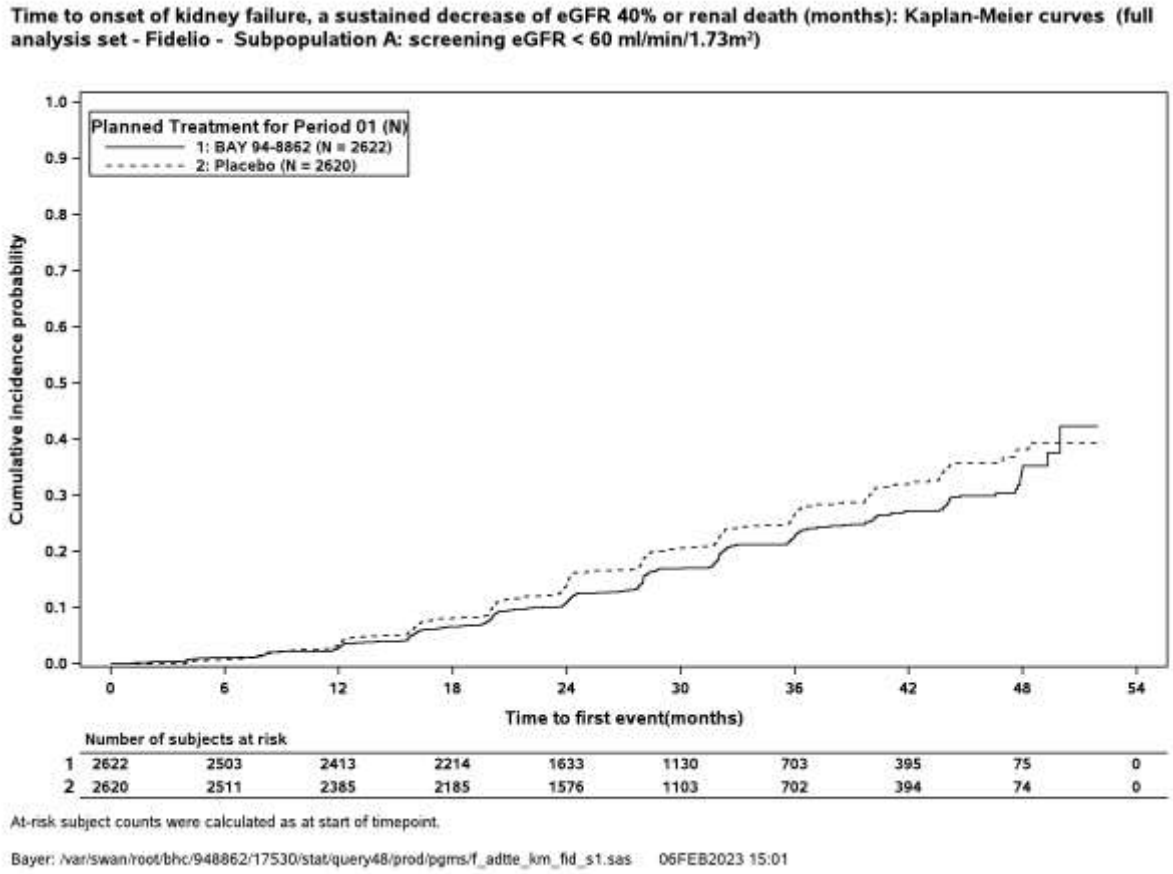


Figure 1.2.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

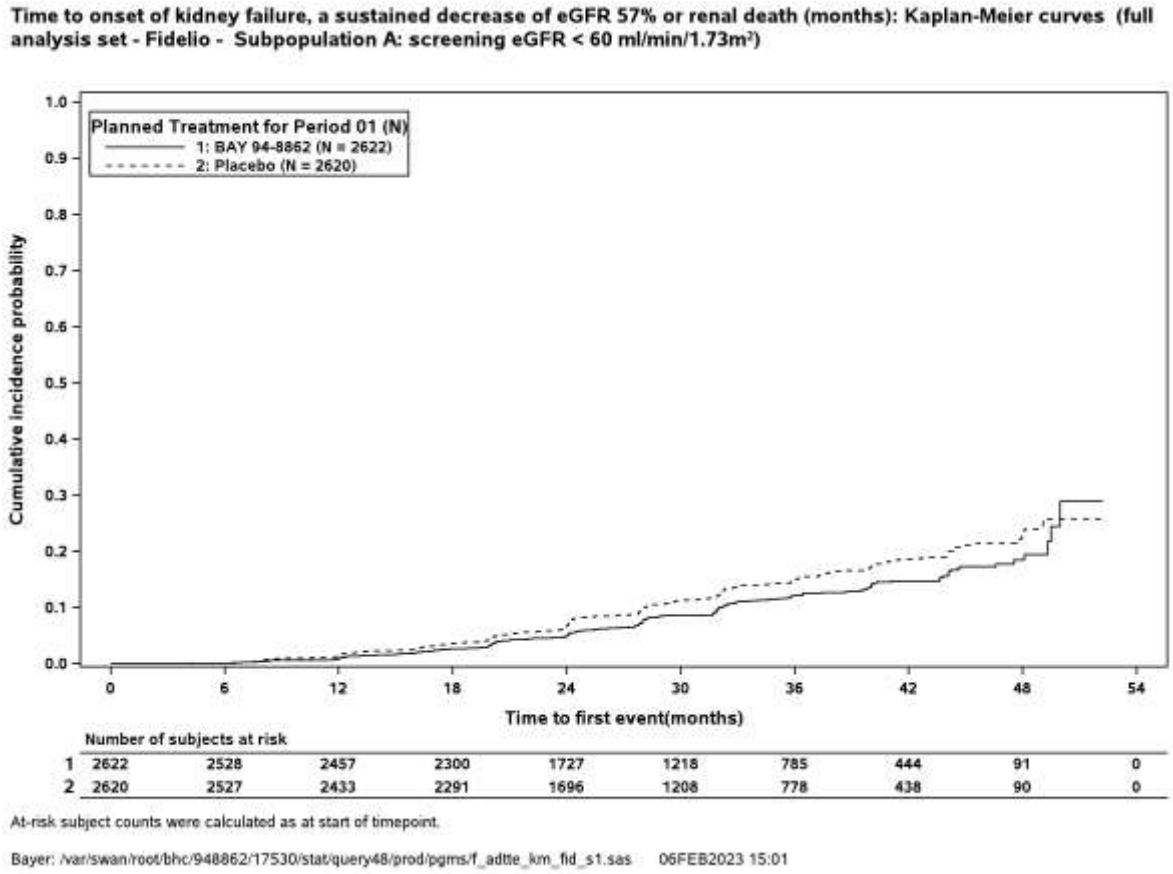


Figure 1.2.2 / 4: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

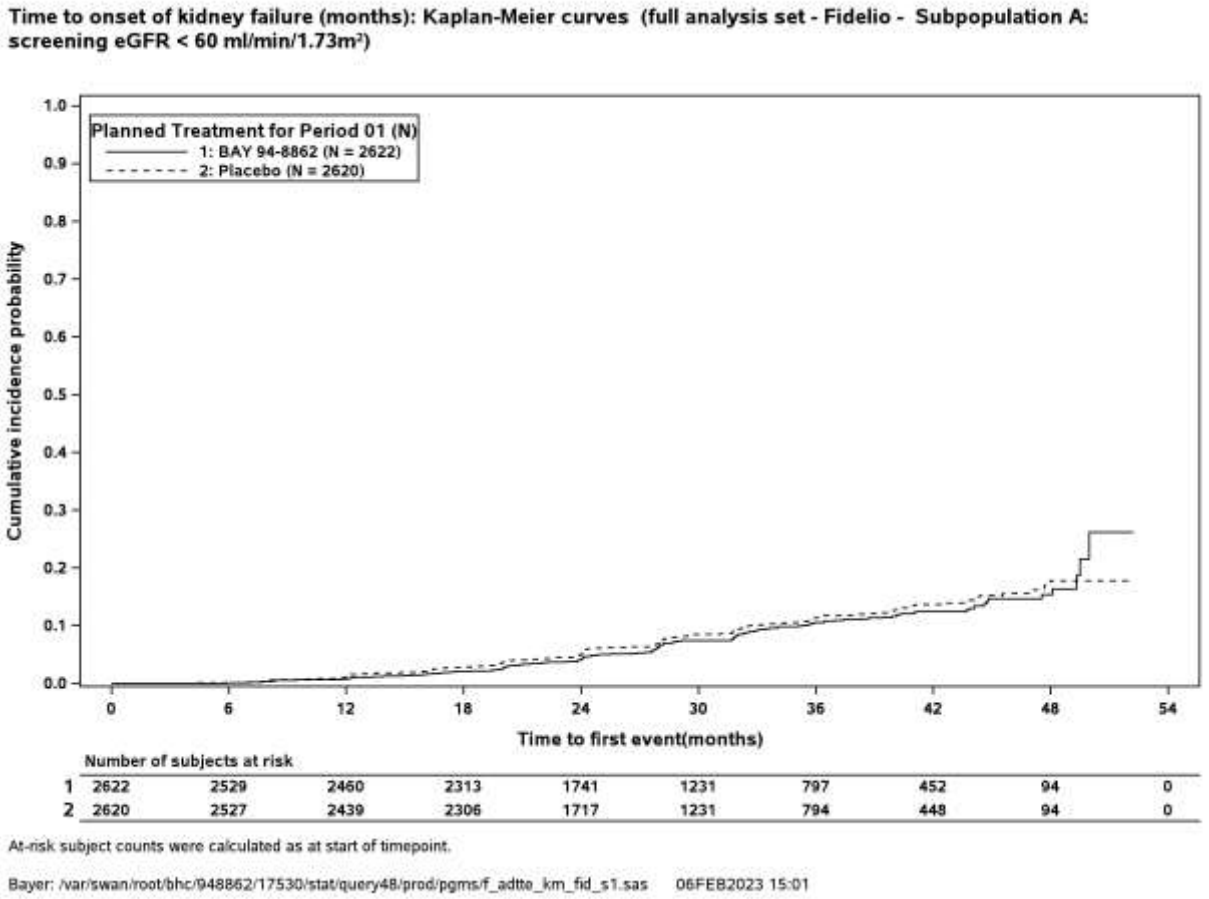


Figure 1.2.2 / 5: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

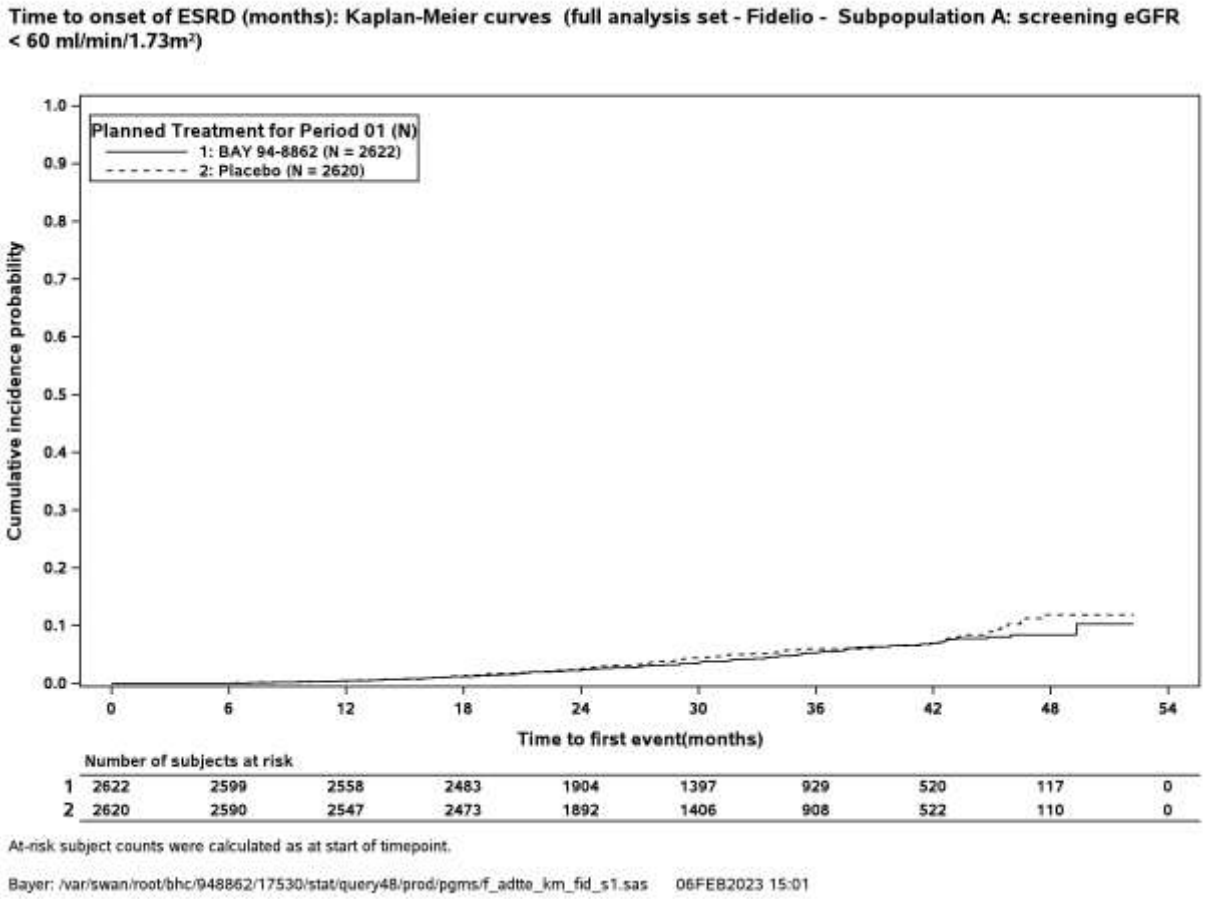


Figure 1.2.2 / 6: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

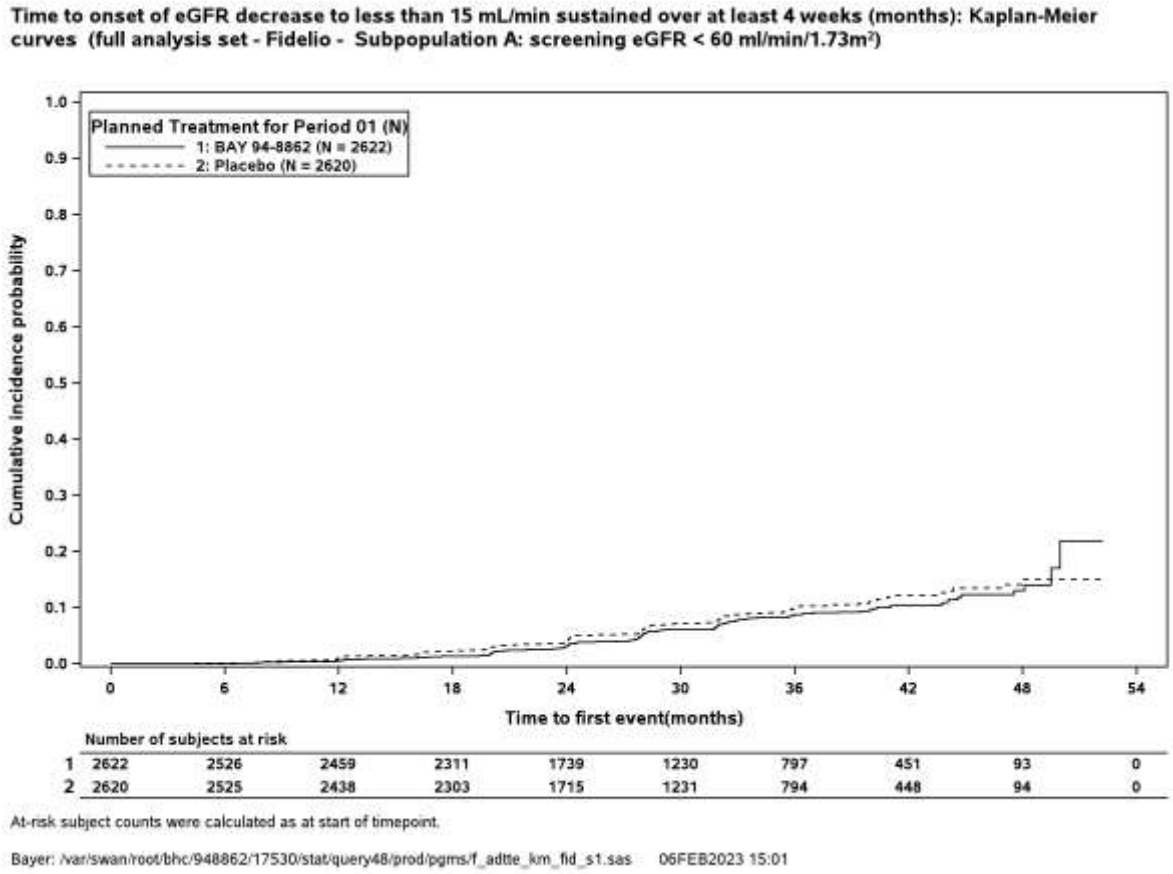


Figure 1.2.2 / 7: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

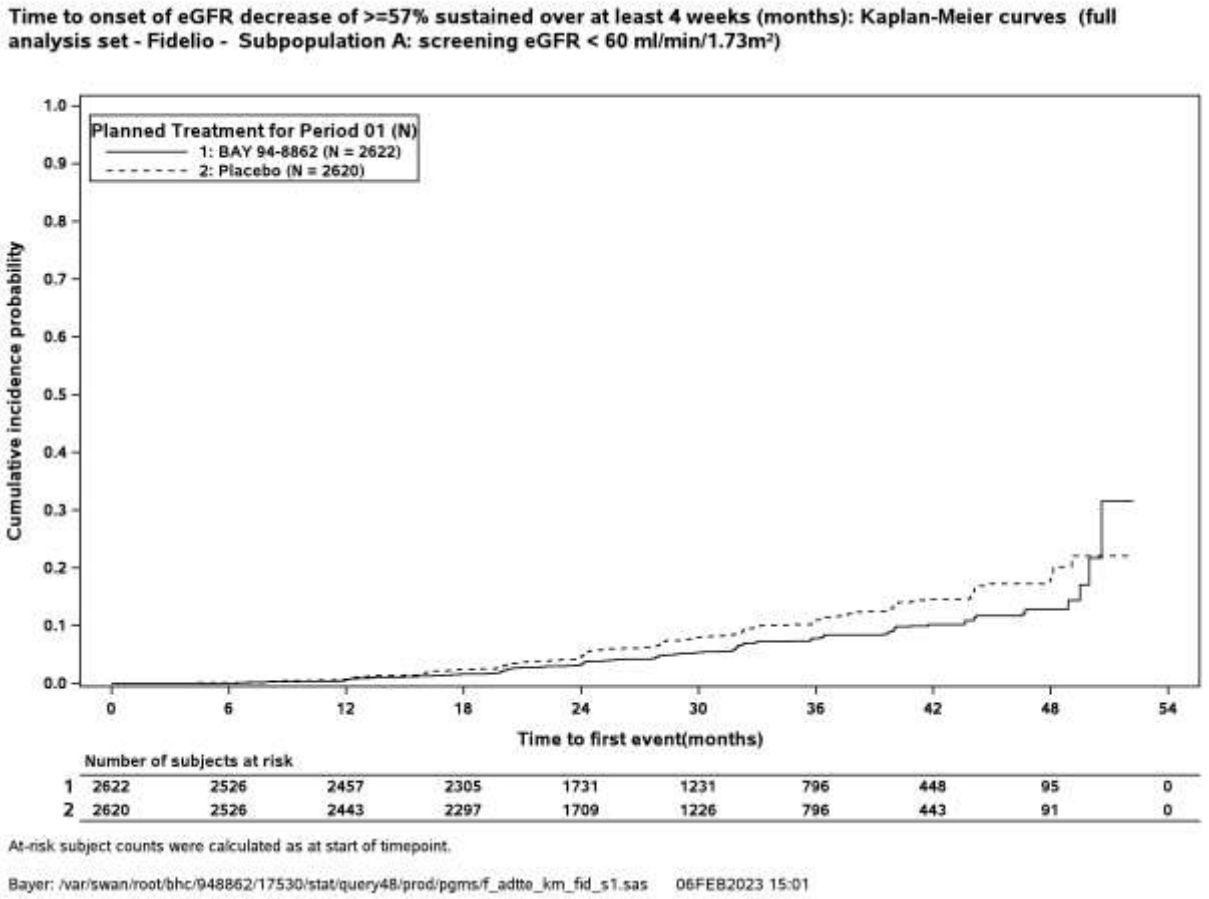


Figure 1.2.2 / 8: Time to renal death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

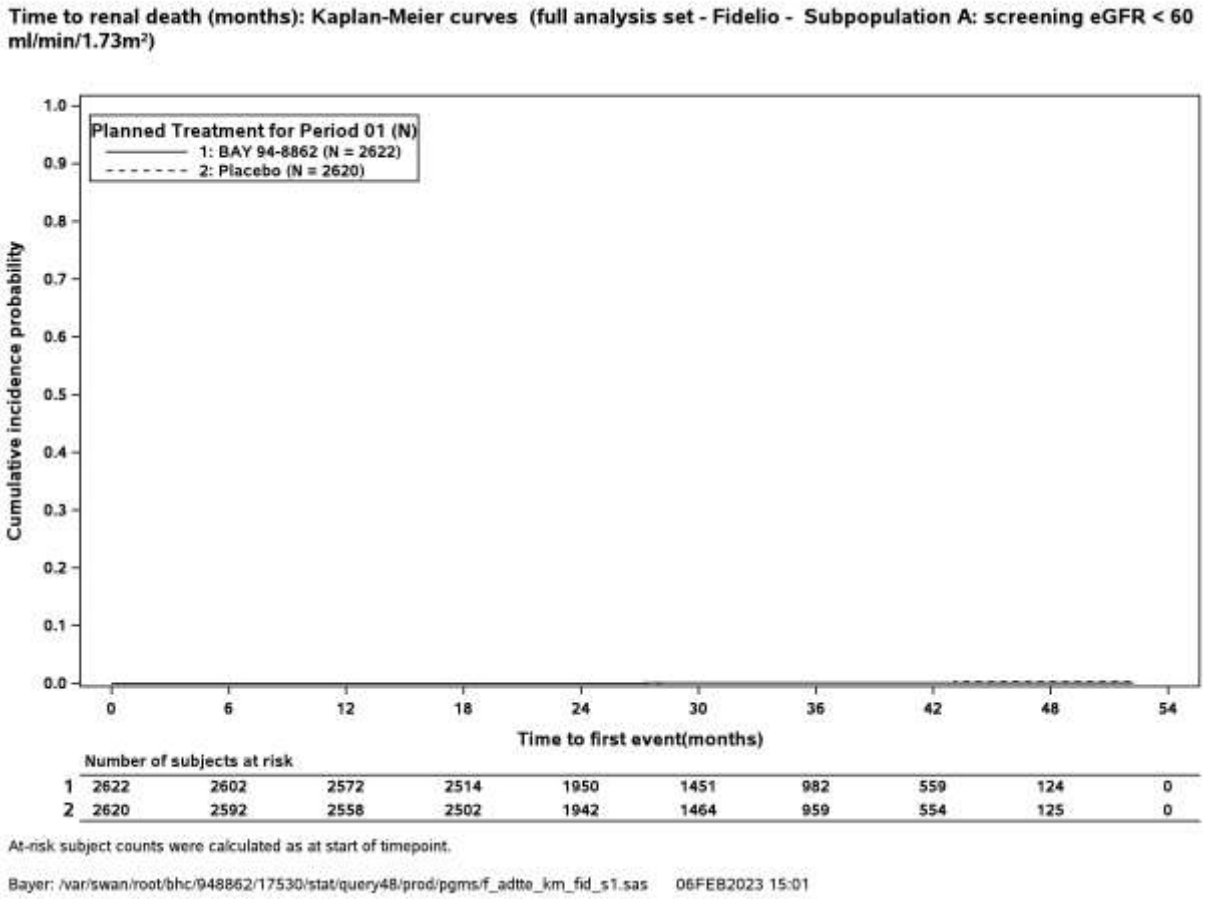


Figure 1.2.2 / 9: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

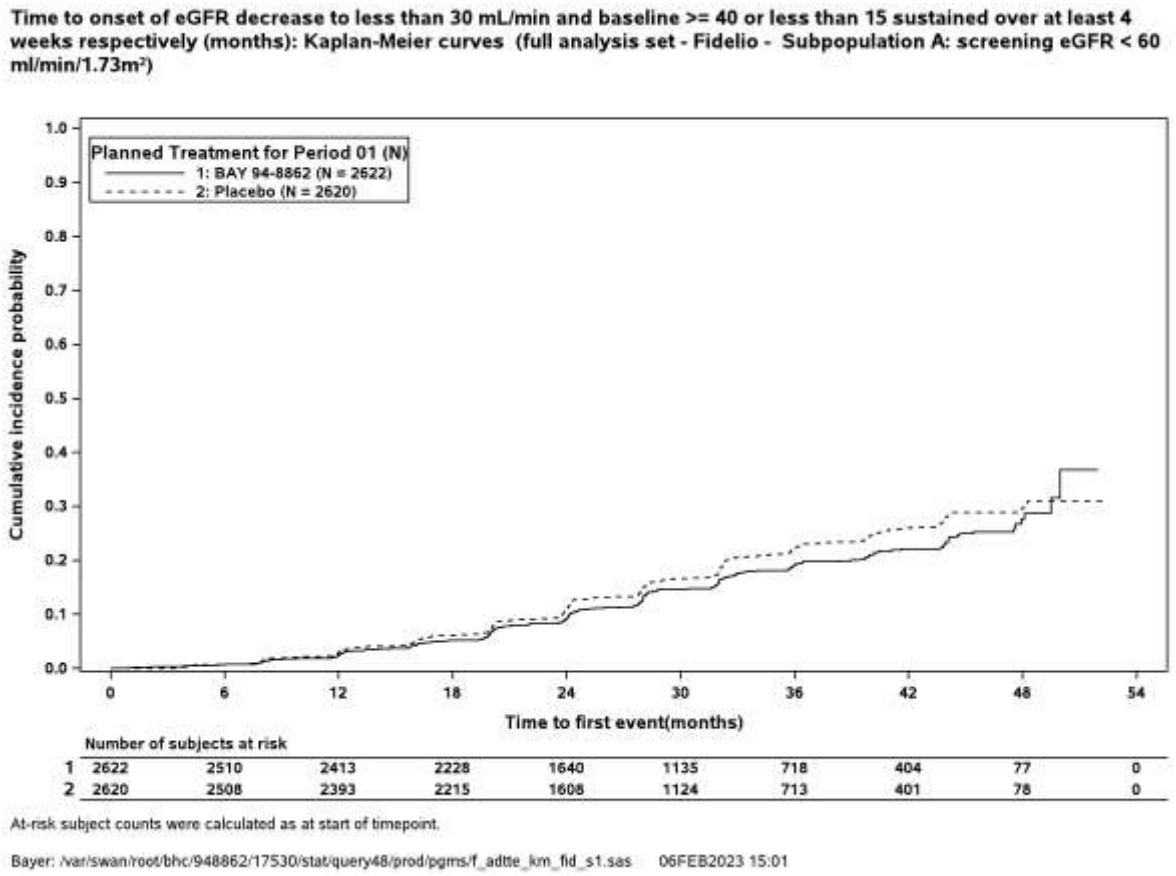


Figure 1.2.2 / 10: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

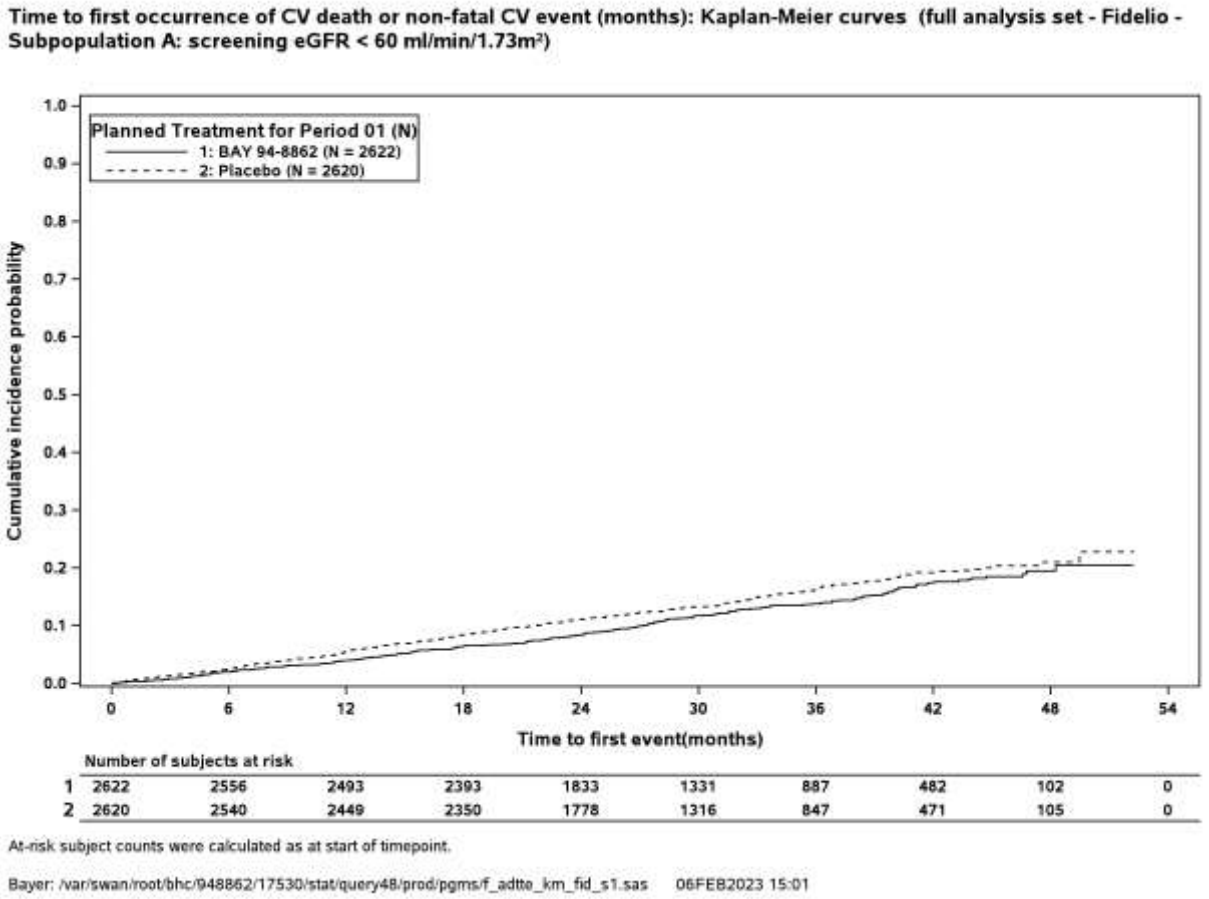


Figure 1.2.2 / 11: Time to CV death (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

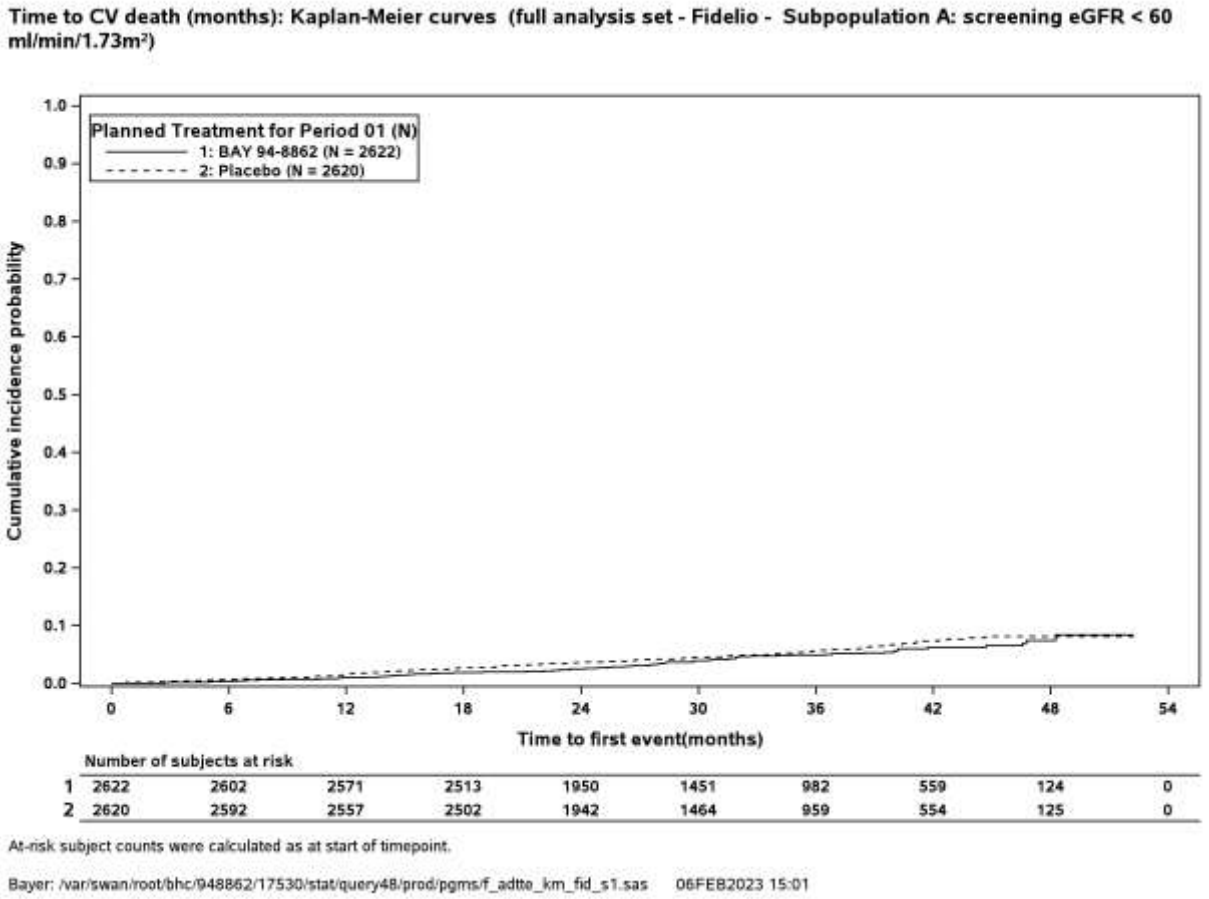


Figure 1.2.2 / 12: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

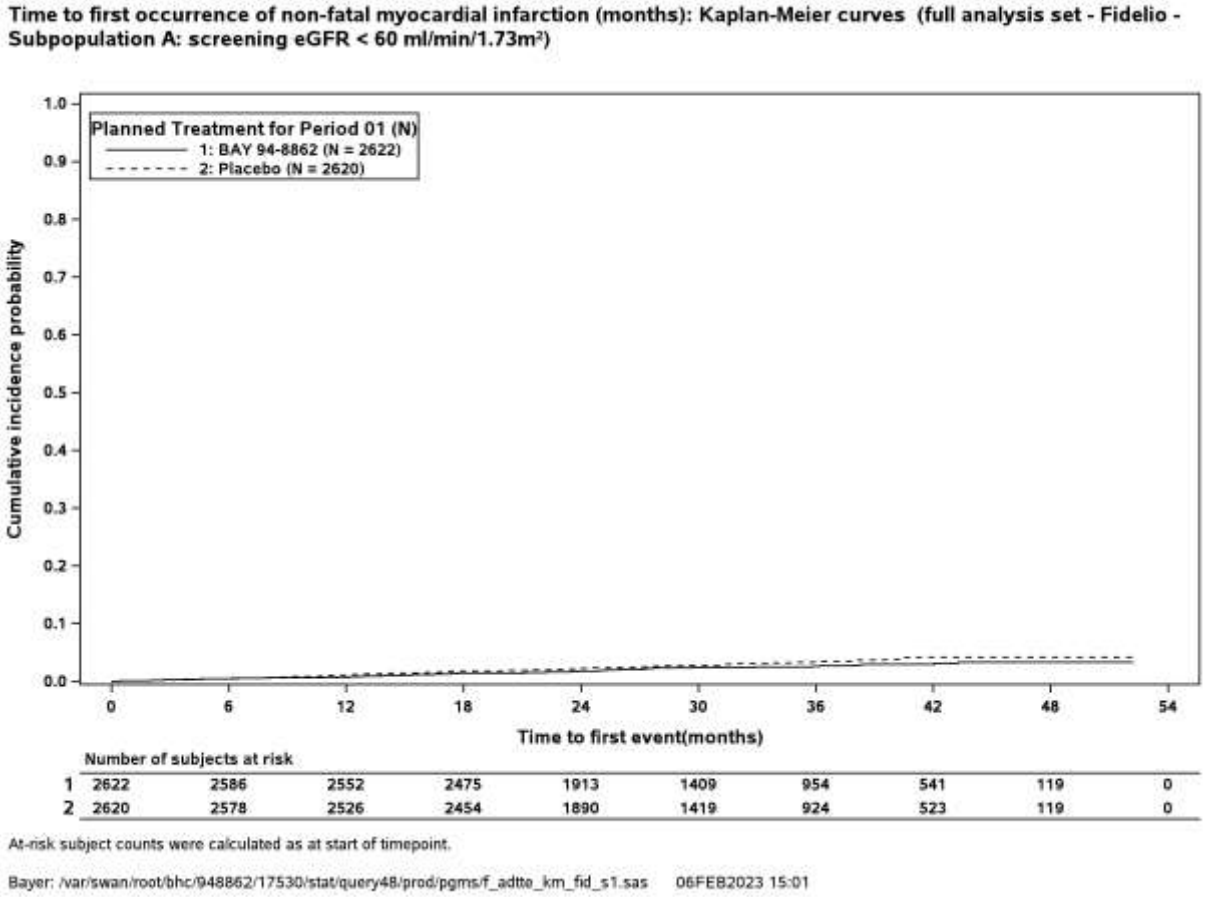


Figure 1.2.2 / 13: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

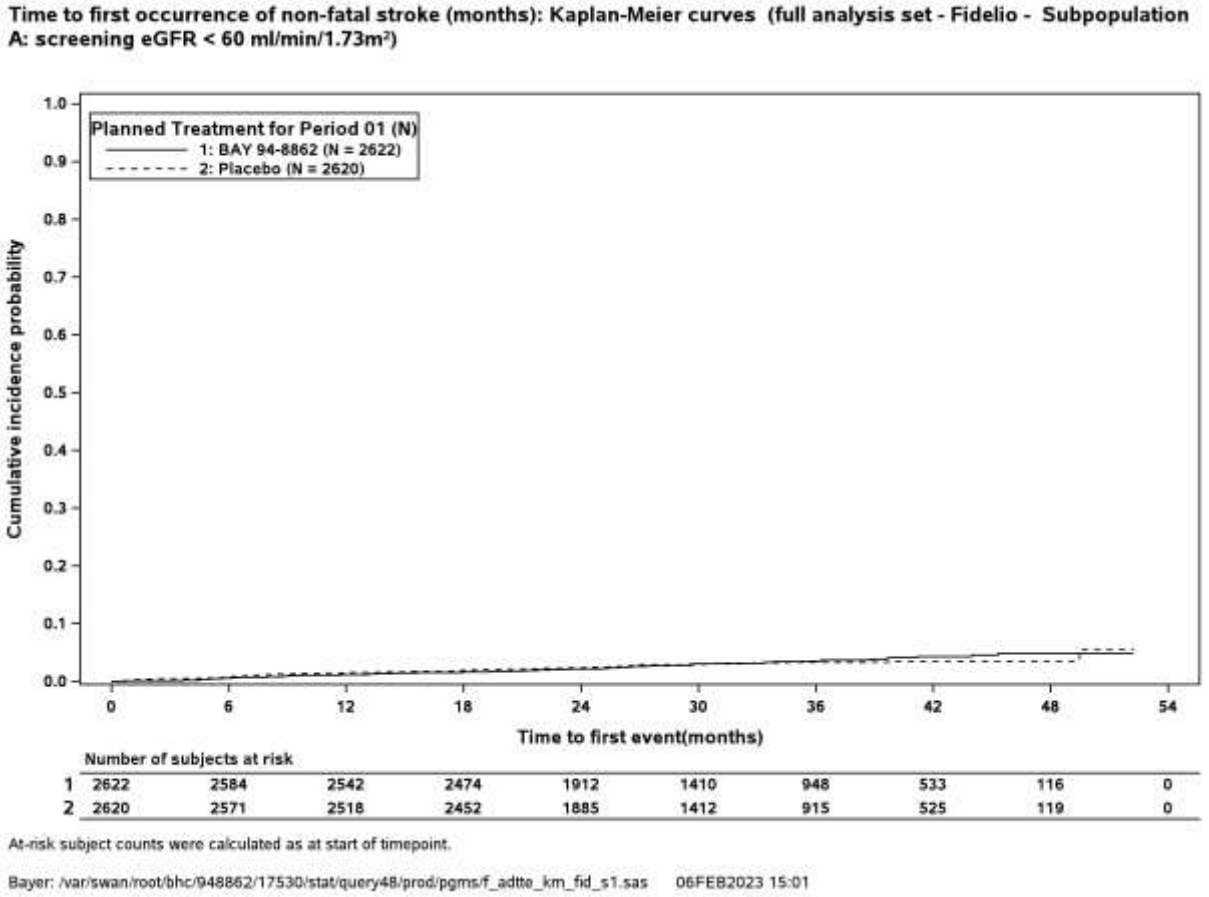


Figure 1.2.2 / 14: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

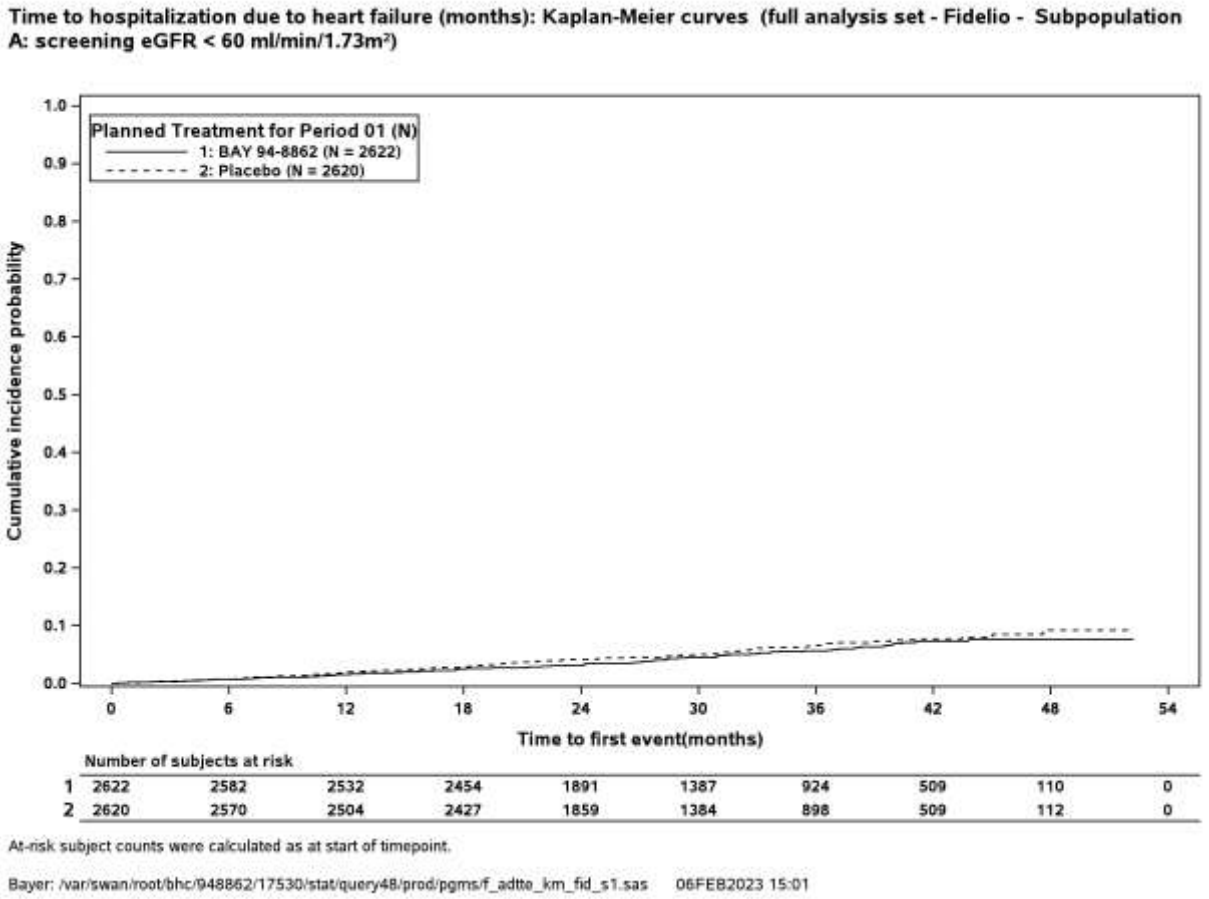


Figure 1.2.2 / 15: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

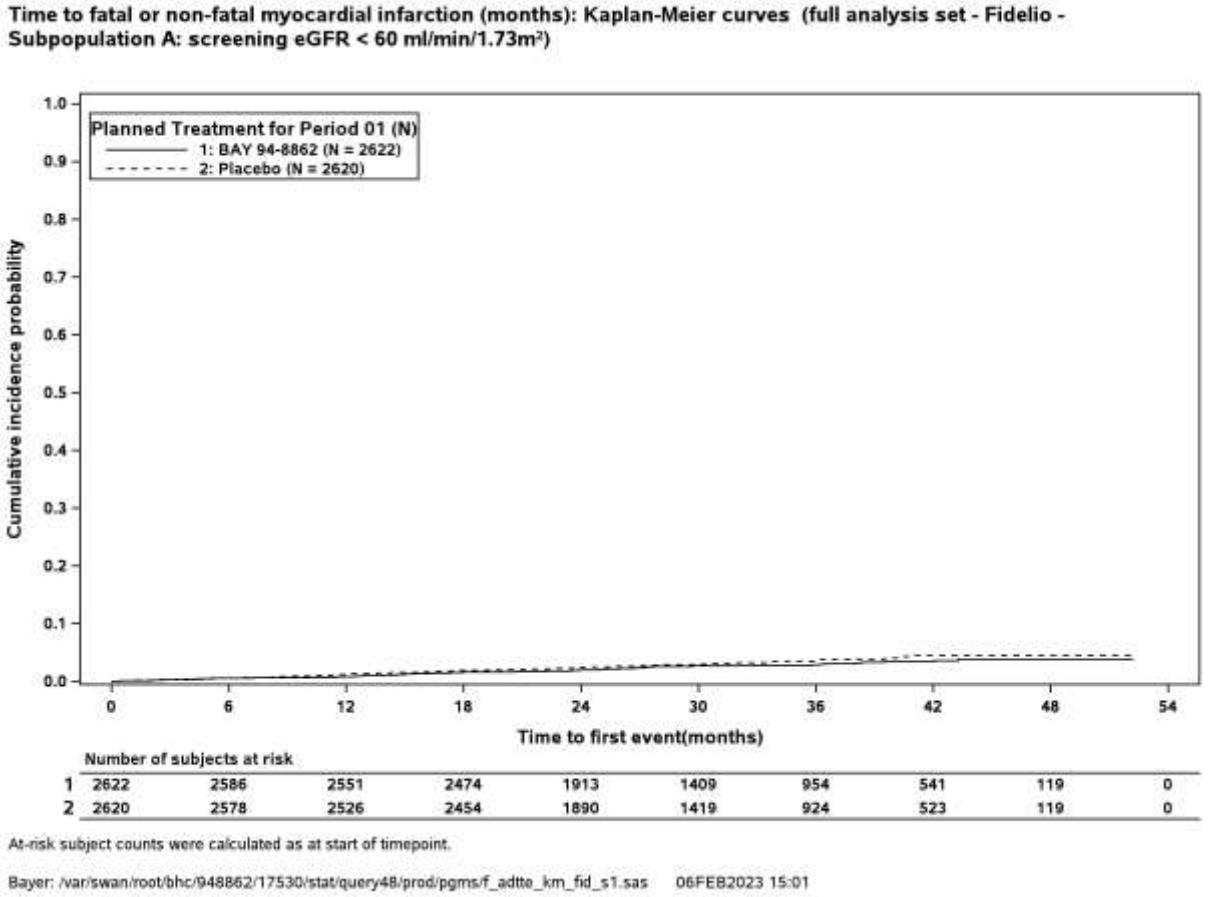


Figure 1.2.2 / 16: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

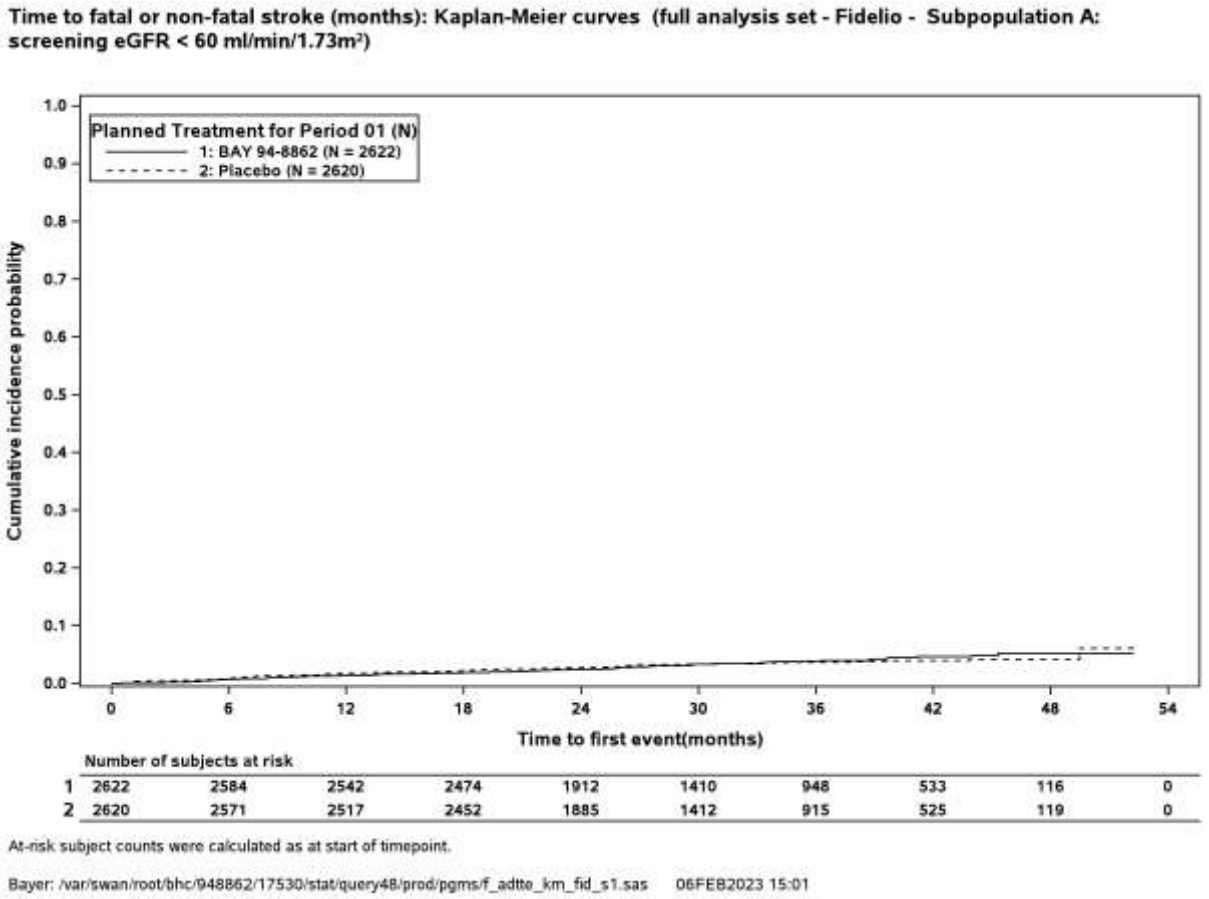


Figure 1.2.2 / 17: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

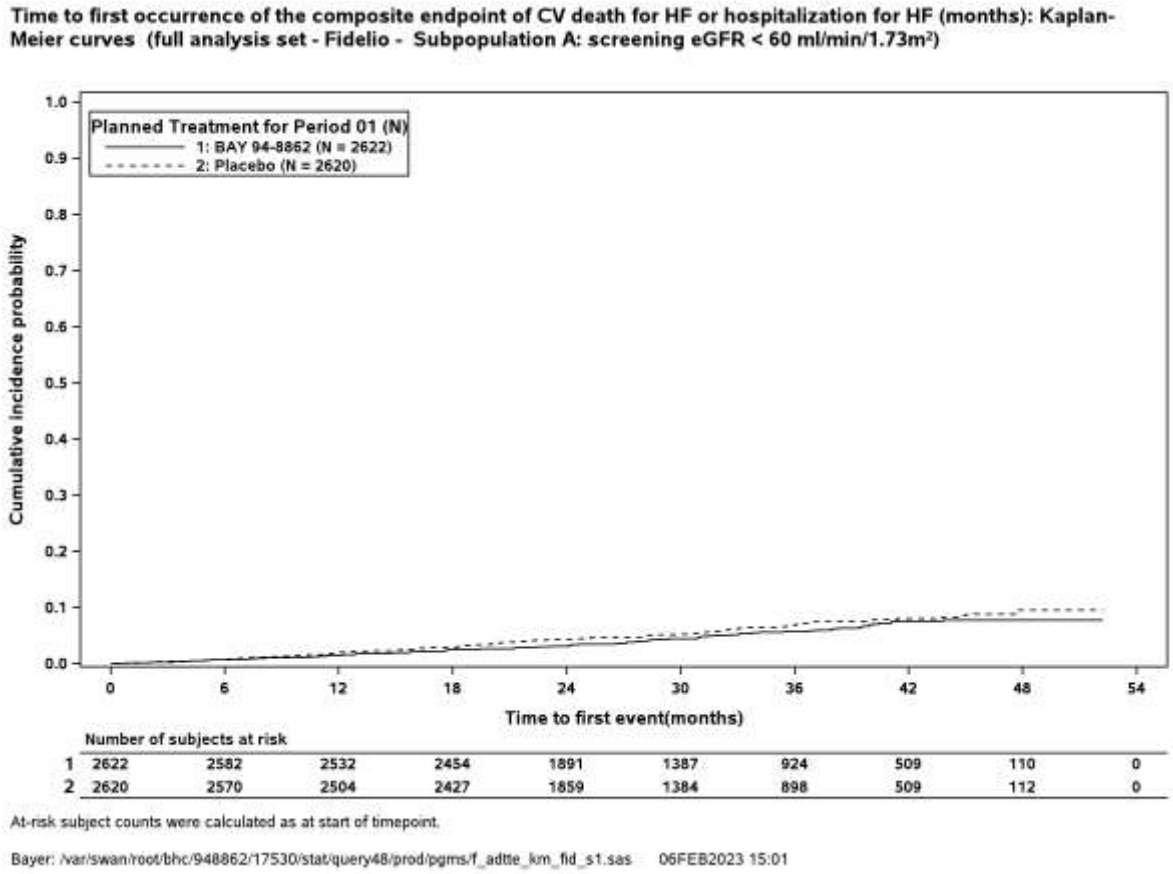


Figure 1.2.2 / 18: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Fidelio - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

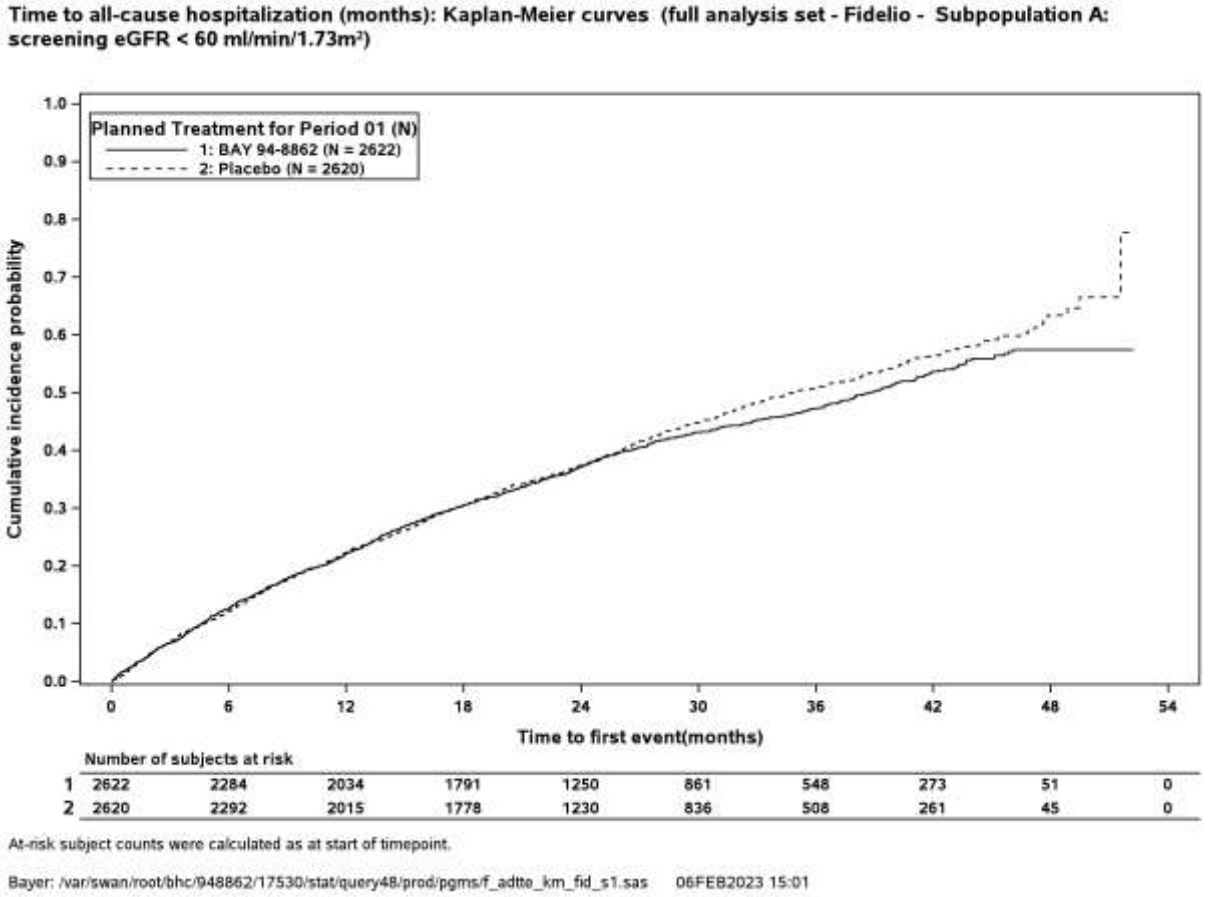


Table A3.1.1: EQ-5D VAS - Return Rate - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2567	2622	97.9%	2551	2620	97.4%	5118	5242	97.6%
Baseline	2567	2622	97.9%	2551	2620	97.4%	5118	5242	97.6%
Visit 5	2369	2622	90.4%	2371	2620	90.5%	4740	5242	90.4%
Visit 8	1668	2622	63.6%	1653	2620	63.1%	3321	5242	63.4%
Visit 11	791	2622	30.2%	771	2620	29.4%	1562	5242	29.8%
Visit 14	66	2622	2.5%	57	2620	2.2%	123	5242	2.3%
Last on-treatment	2237	2622	85.3%	2269	2620	86.6%	4506	5242	86.0%
Premature discontinuation	134	2622	5.1%	104	2620	4.0%	238	5242	4.5%
End of Study Visit	2001	2622	76.3%	1982	2620	75.6%	3983	5242	76.0%

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

Table A3.1.2: KDQoL-36 - Return Rate of Physical Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2541	2622	96.9%	2526	2620	96.4%	5067	5242	96.7%
Baseline	2541	2622	96.9%	2526	2620	96.4%	5067	5242	96.7%
Visit 5	2351	2622	89.7%	2357	2620	90.0%	4708	5242	89.8%
Visit 8	1660	2622	63.3%	1647	2620	62.9%	3307	5242	63.1%
Visit 11	776	2622	29.6%	763	2620	29.1%	1539	5242	29.4%
Visit 14	65	2622	2.5%	57	2620	2.2%	122	5242	2.3%
Last on-treatment	2234	2622	85.2%	2263	2620	86.4%	4497	5242	85.8%
Premature discontinuation	131	2622	5.0%	102	2620	3.9%	233	5242	4.4%
End of Study Visit	1983	2622	75.6%	1964	2620	75.0%	3947	5242	75.3%

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

Table A3.1.3: KDQoL-36 - Return Rate of Mental Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2541	2622	96.9%	2526	2620	96.4%	5067	5242	96.7%
Baseline	2541	2622	96.9%	2526	2620	96.4%	5067	5242	96.7%
Visit 5	2351	2622	89.7%	2357	2620	90.0%	4708	5242	89.8%
Visit 8	1660	2622	63.3%	1647	2620	62.9%	3307	5242	63.1%
Visit 11	776	2622	29.6%	763	2620	29.1%	1539	5242	29.4%
Visit 14	65	2622	2.5%	57	2620	2.2%	122	5242	2.3%
Last on-treatment	2234	2622	85.2%	2263	2620	86.4%	4497	5242	85.8%
Premature discontinuation	131	2622	5.0%	102	2620	3.9%	233	5242	4.4%
End of Study Visit	1983	2622	75.6%	1964	2620	75.0%	3947	5242	75.3%

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

Table A3.1.4: KDQoL-36 - Return Rate of Burden of Kidney Disease - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2561	2622	97.7%	2552	2620	97.4%	5113	5242	97.5%
Baseline	2561	2622	97.7%	2552	2620	97.4%	5113	5242	97.5%
Visit 5	2366	2622	90.2%	2368	2620	90.4%	4734	5242	90.3%
Visit 8	1666	2622	63.5%	1647	2620	62.9%	3313	5242	63.2%
Visit 11	787	2622	30.0%	769	2620	29.4%	1556	5242	29.7%
Visit 14	66	2622	2.5%	57	2620	2.2%	123	5242	2.3%
Last on-treatment	2236	2622	85.3%	2268	2620	86.6%	4504	5242	85.9%
Premature discontinuation	133	2622	5.1%	103	2620	3.9%	236	5242	4.5%
End of Study Visit	1997	2622	76.2%	1980	2620	75.6%	3977	5242	75.9%

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

Table A3.1.5: KDQoL-36 - Return Rate of Symptoms and Problems - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2562	2622	97.7%	2553	2620	97.4%	5115	5242	97.6%
Baseline	2562	2622	97.7%	2553	2620	97.4%	5115	5242	97.6%
Visit 5	2372	2622	90.5%	2372	2620	90.5%	4744	5242	90.5%
Visit 8	1664	2622	63.5%	1650	2620	63.0%	3314	5242	63.2%
Visit 11	789	2622	30.1%	771	2620	29.4%	1560	5242	29.8%
Visit 14	66	2622	2.5%	56	2620	2.1%	122	5242	2.3%
Last on-treatment	2237	2622	85.3%	2271	2620	86.7%	4508	5242	86.0%
Premature discontinuation	133	2622	5.1%	102	2620	3.9%	235	5242	4.5%
End of Study Visit	1998	2622	76.2%	1986	2620	75.8%	3984	5242	76.0%

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

Table A3.1.6: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	2554	2622	97.4%	2549	2620	97.3%	5103	5242	97.3%
Baseline	2554	2622	97.4%	2549	2620	97.3%	5103	5242	97.3%
Visit 5	2369	2622	90.4%	2369	2620	90.4%	4738	5242	90.4%
Visit 8	1669	2622	63.7%	1647	2620	62.9%	3316	5242	63.3%
Visit 11	784	2622	29.9%	767	2620	29.3%	1551	5242	29.6%
Visit 14	65	2622	2.5%	56	2620	2.1%	121	5242	2.3%
Last on-treatment	2237	2622	85.3%	2269	2620	86.6%	4506	5242	86.0%
Premature discontinuation	132	2622	5.0%	102	2620	3.9%	234	5242	4.5%
End of Study Visit	1996	2622	76.1%	1983	2620	75.7%	3979	5242	75.9%

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

Table A3.1.7: EQ-5D VAS - Return Rate (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2567	2620	98.0%	2551	2618	97.4%	5118	5238	97.7%
Visit 5	2369	2499	94.8%	2371	2497	95.0%	4740	4996	94.9%
Visit 8	1668	1817	91.8%	1653	1811	91.3%	3321	3628	91.5%
Visit 11	791	879	90.0%	771	861	89.5%	1562	1740	89.8%
Visit 14	66	73	90.4%	57	65	87.7%	123	138	89.1%
Premature discontinuation	134	158	84.8%	104	119	87.4%	238	277	85.9%
End of Study Visit	2001	2333	85.8%	1982	2301	86.1%	3983	4634	86.0%

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

Table A3.1.8: KDQoL-36 - Return Rate of Physical Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2541	2620	97.0%	2526	2618	96.5%	5067	5238	96.7%
Visit 5	2351	2499	94.1%	2357	2497	94.4%	4708	4996	94.2%
Visit 8	1660	1817	91.4%	1647	1811	90.9%	3307	3628	91.2%
Visit 11	776	879	88.3%	763	861	88.6%	1539	1740	88.4%
Visit 14	65	73	89.0%	57	65	87.7%	122	138	88.4%
Premature discontinuation	131	158	82.9%	102	119	85.7%	233	277	84.1%
End of Study Visit	1983	2333	85.0%	1964	2301	85.4%	3947	4634	85.2%

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

Table A3.1.9: KDQoL-36 - Return Rate of Mental Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2541	2620	97.0%	2526	2618	96.5%	5067	5238	96.7%
Visit 5	2351	2499	94.1%	2357	2497	94.4%	4708	4996	94.2%
Visit 8	1660	1817	91.4%	1647	1811	90.9%	3307	3628	91.2%
Visit 11	776	879	88.3%	763	861	88.6%	1539	1740	88.4%
Visit 14	65	73	89.0%	57	65	87.7%	122	138	88.4%
Premature discontinuation	131	158	82.9%	102	119	85.7%	233	277	84.1%
End of Study Visit	1983	2333	85.0%	1964	2301	85.4%	3947	4634	85.2%

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

Table A3.1.10: KDQoL-36 - Return Rate of Burden of Kidney Disease (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2561	2620	97.7%	2552	2618	97.5%	5113	5238	97.6%
Visit 5	2366	2499	94.7%	2368	2497	94.8%	4734	4996	94.8%
Visit 8	1666	1817	91.7%	1647	1811	90.9%	3313	3628	91.3%
Visit 11	787	879	89.5%	769	861	89.3%	1556	1740	89.4%
Visit 14	66	73	90.4%	57	65	87.7%	123	138	89.1%
Premature discontinuation	133	158	84.2%	103	119	86.6%	236	277	85.2%
End of Study Visit	1997	2333	85.6%	1980	2301	86.0%	3977	4634	85.8%

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

Table A3.1.11: KDQoL-36 - Return Rate of Symptoms and Problems (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2562	2620	97.8%	2553	2618	97.5%	5115	5238	97.7%
Visit 5	2372	2499	94.9%	2372	2497	95.0%	4744	4996	95.0%
Visit 8	1664	1817	91.6%	1650	1811	91.1%	3314	3628	91.3%
Visit 11	789	879	89.8%	771	861	89.5%	1560	1740	89.7%
Visit 14	66	73	90.4%	56	65	86.2%	122	138	88.4%
Premature discontinuation	133	158	84.2%	102	119	85.7%	235	277	84.8%
End of Study Visit	1998	2333	85.6%	1986	2301	86.3%	3984	4634	86.0%

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

Table A3.1.12: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	2554	2620	97.5%	2549	2618	97.4%	5103	5238	97.4%
Visit 5	2369	2499	94.8%	2369	2497	94.9%	4738	4996	94.8%
Visit 8	1669	1817	91.9%	1647	1811	90.9%	3316	3628	91.4%
Visit 11	784	879	89.2%	767	861	89.1%	1551	1740	89.1%
Visit 14	65	73	89.0%	56	65	86.2%	121	138	87.7%
Premature discontinuation	132	158	83.5%	102	119	85.7%	234	277	84.5%
End of Study Visit	1996	2333	85.6%	1983	2301	86.2%	3979	4634	85.9%

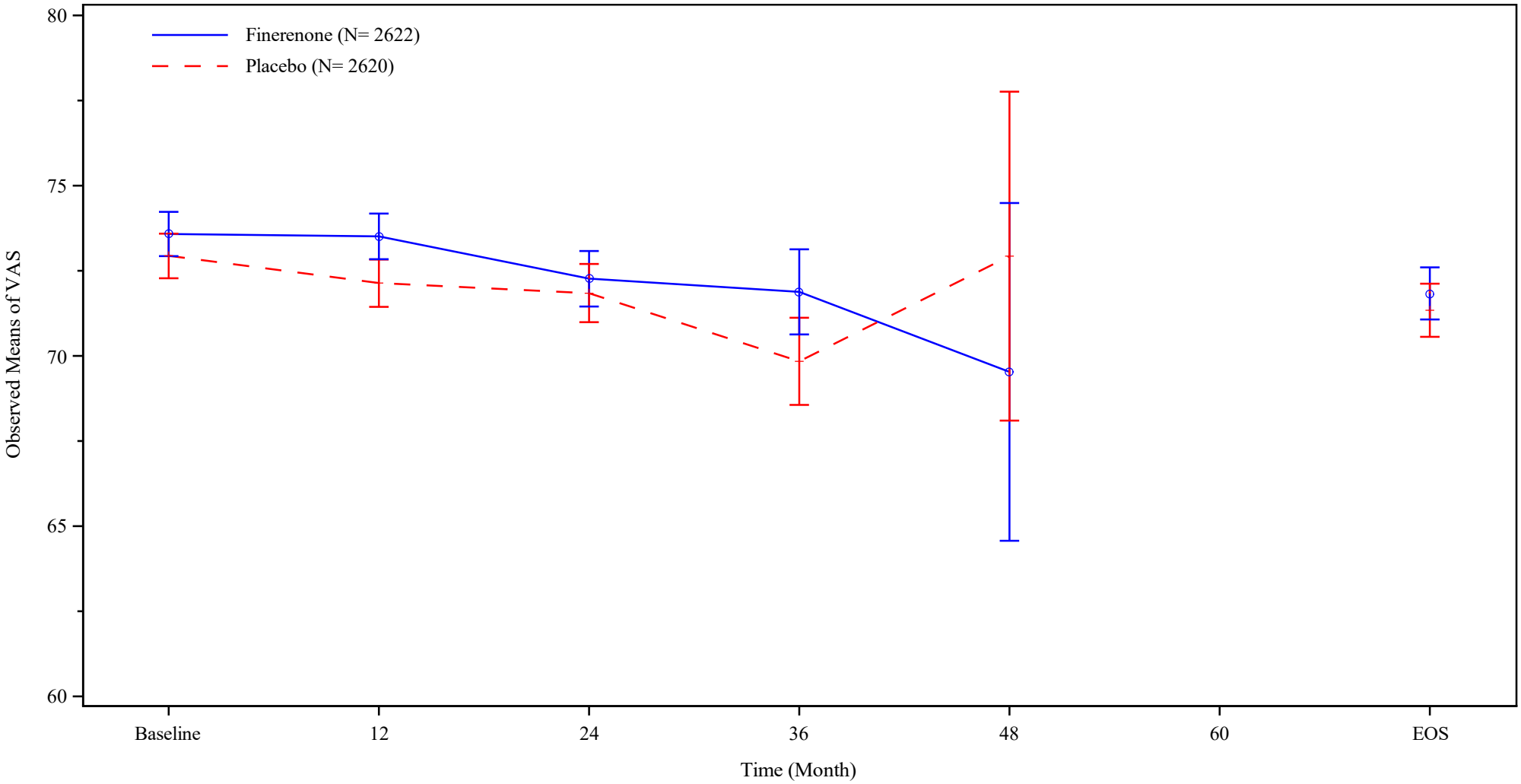
Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table A3.2.1: EQ-5D VAS - Observed Means and Change from Baseline - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2567	73.58(16.77)	(72.93, 74.23)	75.00	(0.0, 100.0)	2551	72.94(16.80)	(72.28, 73.59)	75.00	(0.0, 100.0)
Baseline	2567	73.58(16.77)	(72.93, 74.23)	75.00	(0.0, 100.0)	2551	72.94(16.80)	(72.28, 73.59)	75.00	(0.0, 100.0)
Visit 5	2369	73.51(16.61)	(72.84, 74.18)	75.00	(10.0, 100.0)	2371	72.14(17.23)	(71.44, 72.83)	75.00	(1.0, 100.0)
Visit 8	1668	72.27(16.97)	(71.45, 73.08)	75.00	(0.0, 100.0)	1653	71.84(17.73)	(70.99, 72.70)	75.00	(0.0, 100.0)
Visit 11	791	71.88(17.86)	(70.63, 73.13)	75.00	(5.0, 100.0)	771	69.84(18.11)	(68.56, 71.12)	70.00	(0.0, 100.0)
Visit 14	66	69.53(20.16)	(64.57, 74.49)	72.00	(5.0, 95.0)	57	72.93(18.20)	(68.10, 77.76)	80.00	(30.0, 100.0)
Last On-Treatment	2237	72.46(17.22)	(71.74, 73.17)	75.00	(0.0, 100.0)	2269	71.87(17.42)	(71.15, 72.58)	75.00	(0.0, 100.0)
Premature Discontinuation	134	71.46(17.45)	(68.48, 74.44)	75.00	(20.0, 100.0)	104	63.95(20.39)	(59.99, 67.92)	60.00	(12.0, 100.0)
End Of Study Visit	2001	71.83(17.41)	(71.07, 72.60)	75.00	(0.0, 100.0)	1982	71.34(17.76)	(70.56, 72.12)	75.00	(0.0, 100.0)
Change from Baseline										
Visit 5	2343	-0.42(15.18)	(-1.04, 0.19)	0.00	(-88.0, 70.0)	2329	-1.16(15.62)	(-1.79, -0.52)	0.00	(-85.0, 65.0)
Visit 8	1652	-2.14(16.40)	(-2.93, -1.35)	0.00	(-90.0, 55.0)	1630	-1.74(16.84)	(-2.56, -0.92)	0.00	(-90.0, 70.0)
Visit 11	785	-3.48(17.04)	(-4.67, -2.28)	0.00	(-90.0, 60.0)	762	-2.59(17.88)	(-3.86, -1.32)	0.00	(-90.0, 60.0)
Visit 14	66	-7.30(16.98)	(-11.48, -3.13)	-5.00	(-60.0, 30.0)	57	-3.04(13.86)	(-6.71, 0.64)	0.00	(-40.0, 21.0)
Last On-Treatment	2211	-1.57(16.35)	(-2.25, -0.88)	0.00	(-85.0, 85.0)	2229	-1.36(16.53)	(-2.05, -0.67)	0.00	(-83.0, 70.0)
Premature Discontinuation	133	-3.11(19.07)	(-6.38, 0.17)	0.00	(-70.0, 50.0)	101	-8.55(20.31)	(-12.56, -4.55)	-5.00	(-73.0, 40.0)
End Of Study Visit	1977	-2.10(16.68)	(-2.83, -1.36)	0.00	(-85.0, 70.0)	1945	-1.94(16.89)	(-2.69, -1.19)	0.00	(-80.0, 70.0)

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

Figure A3.2.1: EQ-5D VAS - Time Profile Curve
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



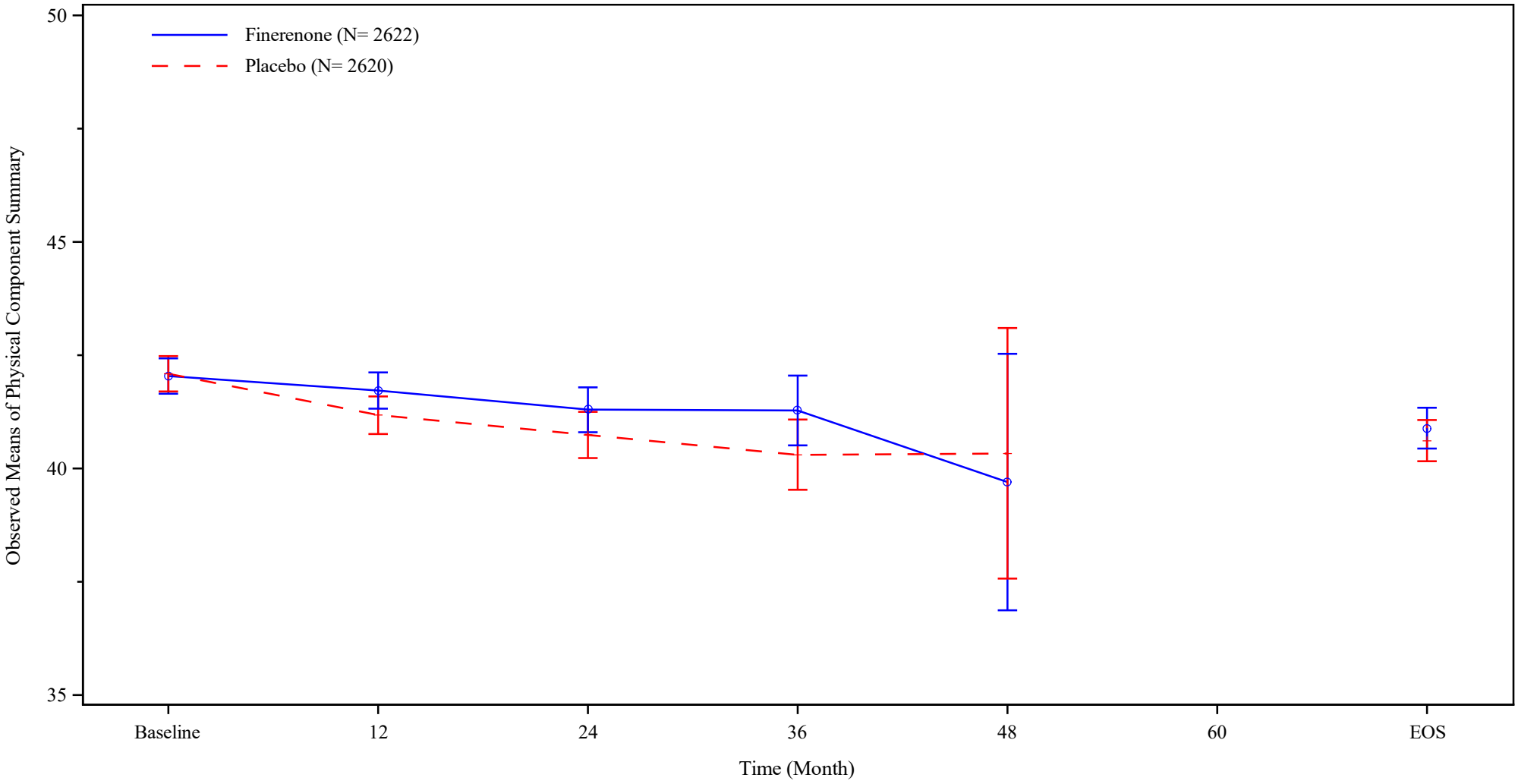
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, EQ-5D=EuroQOL group 5-dimension, N=number of patients, VAS=Visual analog scale.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.2: KDQoL-36 - Observed Means and Change from Baseline of Physical Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2541	42.04(10.09)	(41.65, 42.43)	43.19	(11.9, 62.3)	2526	42.09(9.99)	(41.70, 42.48)	43.13	(15.1, 62.5)
Baseline	2541	42.04(10.09)	(41.65, 42.43)	43.19	(11.9, 62.3)	2526	42.09(9.99)	(41.70, 42.48)	43.13	(15.1, 62.5)
Visit 5	2351	41.72(9.89)	(41.32, 42.12)	42.67	(11.4, 62.4)	2357	41.18(10.30)	(40.76, 41.59)	42.14	(11.8, 62.1)
Visit 8	1660	41.30(10.20)	(40.80, 41.79)	41.87	(11.4, 61.5)	1647	40.74(10.55)	(40.23, 41.25)	41.02	(14.0, 64.2)
Visit 11	776	41.28(10.91)	(40.51, 42.05)	42.63	(13.8, 62.3)	763	40.30(10.87)	(39.53, 41.08)	40.11	(13.9, 67.0)
Visit 14	65	39.70(11.42)	(36.87, 42.53)	39.24	(14.2, 60.2)	57	40.33(10.42)	(37.57, 43.10)	41.18	(15.5, 55.9)
Last On-Treatment	2234	41.15(10.13)	(40.72, 41.57)	41.91	(11.4, 62.4)	2263	40.57(10.39)	(40.15, 41.00)	40.90	(11.8, 63.7)
Premature Discontinuation	131	40.11(10.62)	(38.28, 41.95)	40.73	(18.1, 60.3)	102	37.30(10.04)	(35.33, 39.27)	35.63	(20.6, 55.9)
End Of Study Visit	1983	40.89(10.25)	(40.44, 41.34)	41.90	(13.5, 62.4)	1964	40.61(10.30)	(40.16, 41.07)	40.88	(13.8, 63.7)
Change from Baseline										
Visit 5	2303	-0.55(8.46)	(-0.90, -0.20)	-0.24	(-39.6, 32.6)	2294	-1.01(8.48)	(-1.36, -0.67)	-0.47	(-34.1, 28.6)
Visit 8	1629	-1.20(9.12)	(-1.64, -0.76)	-0.79	(-31.8, 33.3)	1603	-1.77(8.92)	(-2.20, -1.33)	-0.99	(-35.8, 34.2)
Visit 11	765	-2.20(9.53)	(-2.88, -1.52)	-1.43	(-31.8, 26.2)	743	-2.61(9.11)	(-3.26, -1.95)	-2.03	(-30.6, 30.5)
Visit 14	64	-3.13(10.50)	(-5.76, -0.51)	-1.86	(-26.7, 18.4)	57	-2.81(9.41)	(-5.31, -0.31)	-1.59	(-30.3, 25.5)
Last On-Treatment	2187	-1.22(9.23)	(-1.61, -0.83)	-0.66	(-34.5, 28.4)	2199	-1.64(8.88)	(-2.01, -1.27)	-0.96	(-34.1, 33.4)
Premature Discontinuation	128	-2.42(9.86)	(-4.15, -0.70)	-0.79	(-30.0, 17.9)	98	-4.34(9.39)	(-6.22, -2.46)	-2.48	(-28.7, 12.0)
End Of Study Visit	1940	-1.51(9.68)	(-1.94, -1.08)	-1.01	(-36.2, 28.5)	1912	-2.01(9.06)	(-2.42, -1.60)	-1.22	(-37.4, 31.8)

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

Figure A3.2.2: KDQoL-36 - Time Profile Curve of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



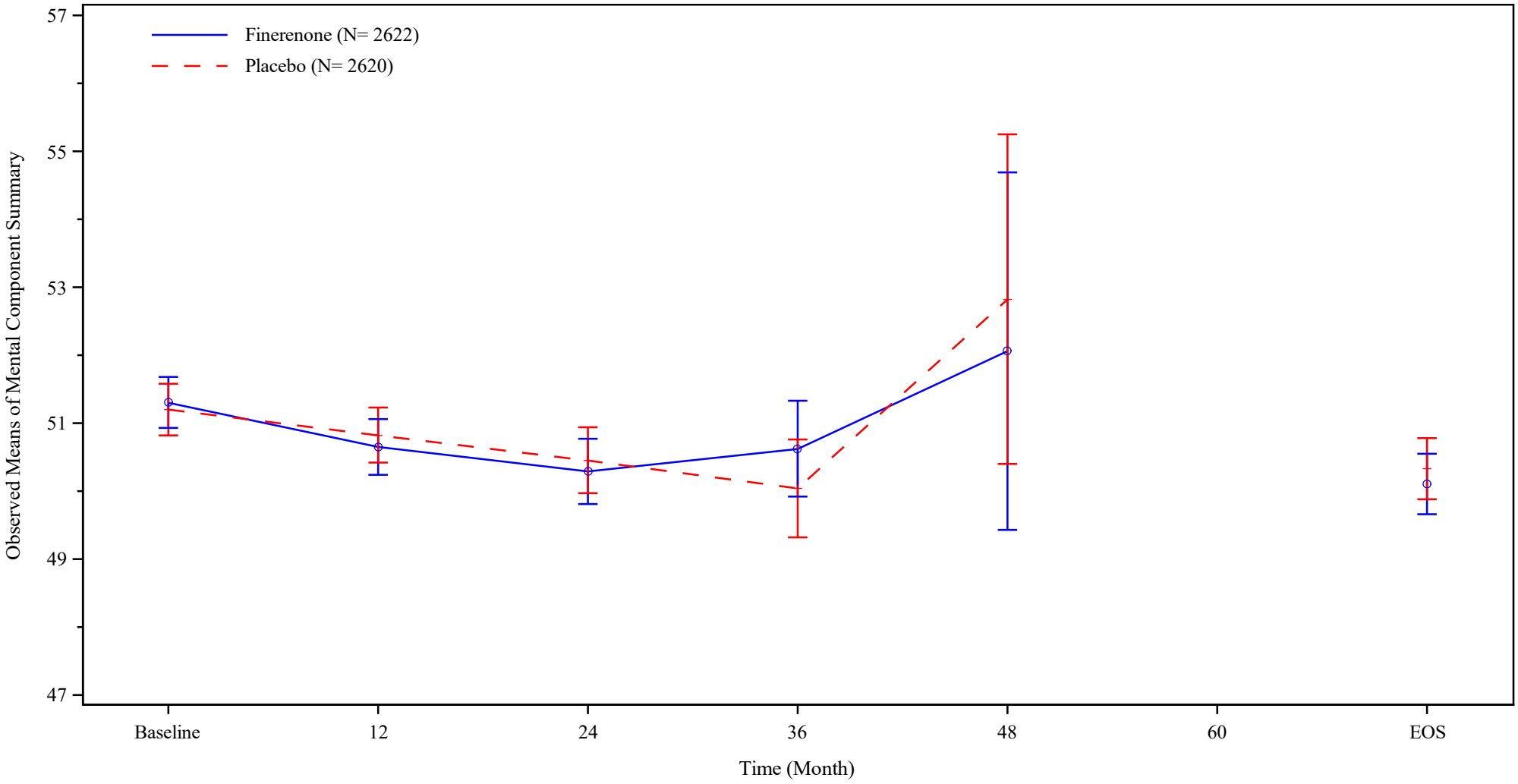
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.3: KDQoL-36 - Observed Means and Change from Baseline of Mental Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2541	51.30(9.66)	(50.93, 51.68)	53.72	(11.0, 70.3)	2526	51.20(9.70)	(50.82, 51.58)	53.76	(15.3, 70.2)
Baseline	2541	51.30(9.66)	(50.93, 51.68)	53.72	(11.0, 70.3)	2526	51.20(9.70)	(50.82, 51.58)	53.76	(15.3, 70.2)
Visit 5	2351	50.65(10.09)	(50.24, 51.06)	53.20	(8.5, 72.1)	2357	50.82(10.03)	(50.42, 51.23)	53.01	(15.4, 71.8)
Visit 8	1660	50.29(10.04)	(49.81, 50.77)	52.36	(15.3, 72.1)	1647	50.45(9.99)	(49.97, 50.94)	52.95	(18.3, 69.7)
Visit 11	776	50.62(10.00)	(49.92, 51.33)	53.07	(17.4, 72.1)	763	50.04(10.10)	(49.32, 50.76)	52.60	(15.0, 67.8)
Visit 14	65	52.06(10.62)	(49.43, 54.69)	55.61	(21.3, 67.0)	57	52.82(9.14)	(50.40, 55.25)	56.45	(25.6, 64.3)
Last On-Treatment	2234	50.07(10.13)	(49.65, 50.49)	52.25	(15.5, 72.1)	2263	50.34(10.13)	(49.92, 50.76)	52.82	(13.3, 70.9)
Premature Discontinuation	131	48.11(10.54)	(46.29, 49.93)	50.25	(20.7, 64.7)	102	47.49(12.23)	(45.08, 49.89)	52.00	(17.4, 67.0)
End Of Study Visit	1983	50.10(10.11)	(49.66, 50.55)	52.28	(15.8, 69.2)	1964	50.33(10.19)	(49.88, 50.78)	53.16	(13.3, 70.5)
Change from Baseline										
Visit 5	2303	-0.79(9.93)	(-1.19, -0.38)	0.00	(-41.1, 41.1)	2294	-0.50(9.81)	(-0.90, -0.10)	-0.08	(-40.5, 37.4)
Visit 8	1629	-1.45(10.46)	(-1.95, -0.94)	-0.84	(-41.6, 33.8)	1603	-0.96(9.79)	(-1.44, -0.48)	-0.61	(-34.6, 34.9)
Visit 11	765	-1.88(10.85)	(-2.65, -1.11)	-1.33	(-39.2, 33.7)	743	-1.34(10.41)	(-2.09, -0.59)	-0.72	(-49.9, 34.6)
Visit 14	64	-2.91(12.13)	(-5.94, 0.12)	-1.10	(-38.8, 23.0)	57	-1.63(8.91)	(-4.00, 0.73)	-0.50	(-34.3, 17.4)
Last On-Treatment	2187	-1.33(10.37)	(-1.77, -0.90)	-0.70	(-39.5, 41.1)	2199	-0.98(10.36)	(-1.42, -0.55)	-0.77	(-40.5, 35.6)
Premature Discontinuation	128	-2.92(11.16)	(-4.87, -0.96)	-2.86	(-32.8, 32.4)	98	-2.68(12.08)	(-5.10, -0.26)	-0.86	(-43.2, 22.8)
End Of Study Visit	1940	-1.37(10.71)	(-1.85, -0.90)	-0.87	(-39.2, 46.8)	1912	-1.15(10.80)	(-1.64, -0.67)	-0.78	(-41.0, 36.1)

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

Figure A3.2.3: KDQoL-36 - Time Profile Curve of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



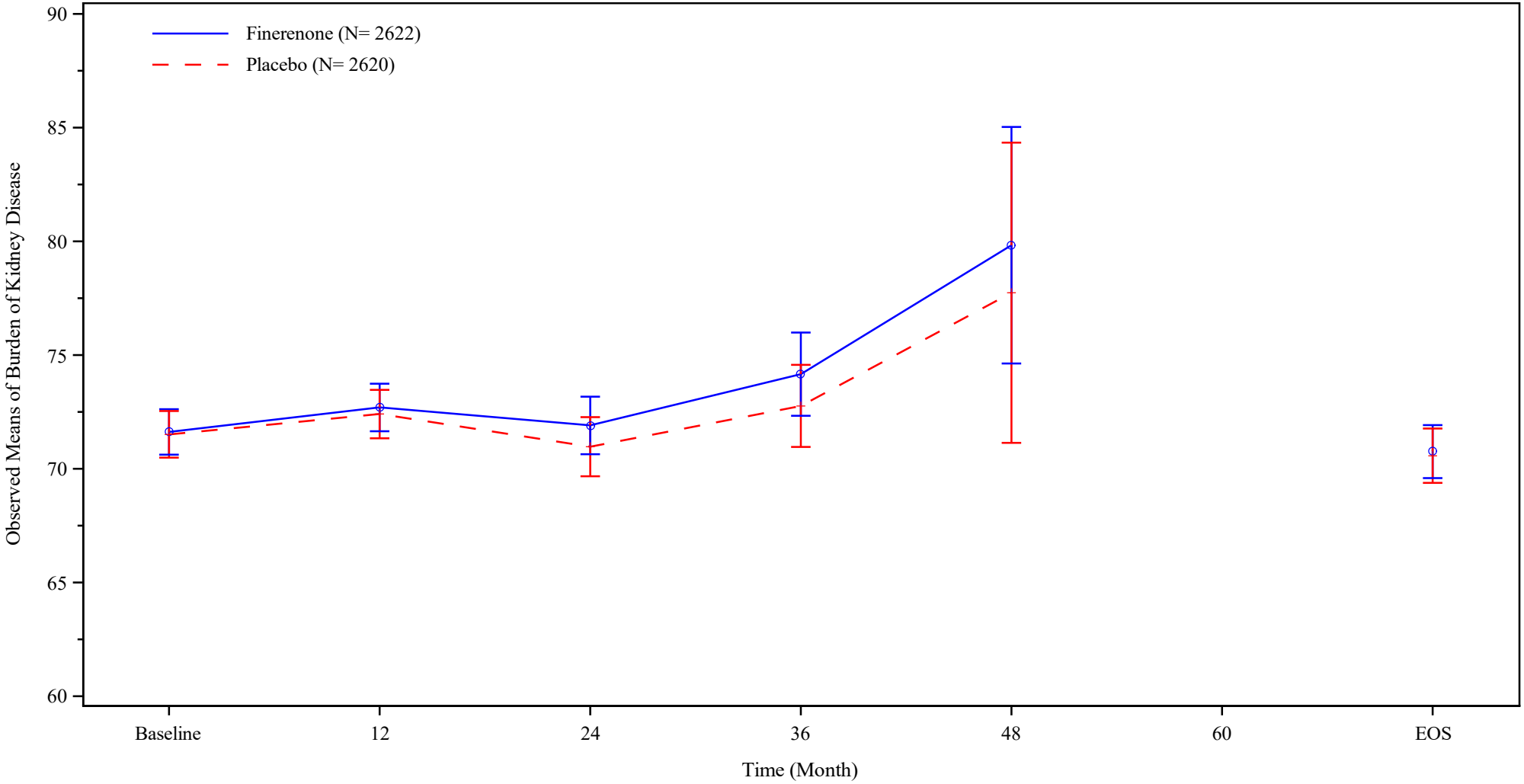
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.4: KDQoL-36 - Observed Means and Change from Baseline of Burden of Kidney Disease - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2561	71.62(25.77)	(70.62, 72.62)	75.00	(0.0, 100.0)	2552	71.51(26.46)	(70.49, 72.54)	75.00	(0.0, 100.0)
Baseline	2561	71.62(25.77)	(70.62, 72.62)	75.00	(0.0, 100.0)	2552	71.51(26.46)	(70.49, 72.54)	75.00	(0.0, 100.0)
Visit 5	2366	72.70(25.95)	(71.65, 73.74)	75.00	(0.0, 100.0)	2368	72.41(26.47)	(71.34, 73.47)	75.00	(0.0, 100.0)
Visit 8	1666	71.91(26.31)	(70.64, 73.17)	75.00	(0.0, 100.0)	1647	70.97(26.91)	(69.67, 72.27)	75.00	(0.0, 100.0)
Visit 11	787	74.16(26.16)	(72.33, 75.99)	81.25	(0.0, 100.0)	769	72.76(25.54)	(70.96, 74.57)	75.00	(0.0, 100.0)
Visit 14	66	79.83(21.14)	(74.63, 85.03)	87.50	(25.0, 100.0)	57	77.74(24.86)	(71.14, 84.34)	81.25	(6.3, 100.0)
Last On-Treatment	2236	71.71(25.71)	(70.65, 72.78)	75.00	(0.0, 100.0)	2268	70.75(26.53)	(69.66, 71.84)	75.00	(0.0, 100.0)
Premature Discontinuation	133	65.93(28.10)	(61.11, 70.75)	68.75	(0.0, 100.0)	103	64.81(28.36)	(59.26, 70.35)	68.75	(0.0, 100.0)
End Of Study Visit	1997	70.76(26.52)	(69.59, 71.92)	75.00	(0.0, 100.0)	1980	70.57(27.07)	(69.38, 71.77)	75.00	(0.0, 100.0)
Change from Baseline										
Visit 5	2335	0.75(25.28)	(-0.28, 1.77)	0.00	(-100.0, 93.8)	2324	0.82(24.91)	(-0.19, 1.83)	0.00	(-100.0, 100.0)
Visit 8	1646	-0.17(26.54)	(-1.45, 1.11)	0.00	(-100.0, 100.0)	1620	-1.01(26.40)	(-2.30, 0.28)	0.00	(-100.0, 100.0)
Visit 11	779	-2.63(26.82)	(-4.52, -0.75)	0.00	(-100.0, 87.5)	755	-1.73(25.79)	(-3.57, 0.11)	0.00	(-93.8, 93.8)
Visit 14	65	-2.69(22.43)	(-8.25, 2.86)	0.00	(-50.0, 75.0)	56	-3.24(24.40)	(-9.77, 3.30)	0.00	(-68.8, 56.3)
Last On-Treatment	2204	-0.43(26.39)	(-1.54, 0.67)	0.00	(-100.0, 100.0)	2227	-0.86(27.08)	(-1.99, 0.26)	0.00	(-93.8, 100.0)
Premature Discontinuation	131	-6.30(28.80)	(-11.28, -1.32)	-6.25	(-100.0, 81.3)	102	-9.25(28.48)	(-14.85, -3.66)	-6.25	(-75.0, 75.0)
End Of Study Visit	1969	-2.52(27.62)	(-3.74, -1.30)	0.00	(-100.0, 93.8)	1944	-2.84(28.87)	(-4.12, -1.55)	0.00	(-100.0, 100.0)

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

Figure A3.2.4: KDQoL-36 - Time Profile Curve of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



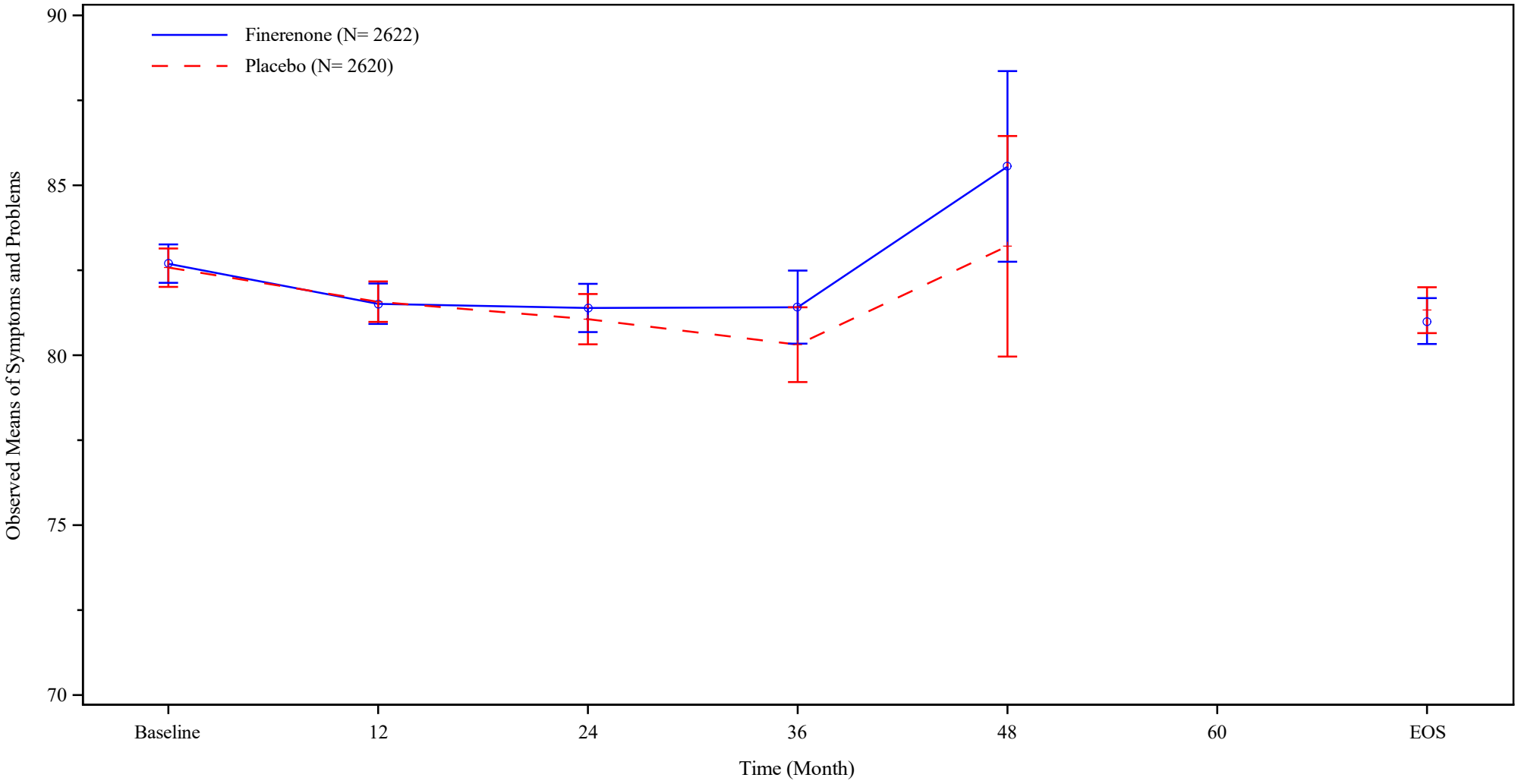
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.5: KDQoL-36 - Observed Means and Change from Baseline of Symptoms and Problems - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2562	82.69(14.54)	(82.13, 83.26)	86.36	(15.9, 100.0)	2553	82.58(14.56)	(82.01, 83.14)	86.36	(0.0, 100.0)
Baseline	2562	82.69(14.54)	(82.13, 83.26)	86.36	(15.9, 100.0)	2553	82.58(14.56)	(82.01, 83.14)	86.36	(0.0, 100.0)
Visit 5	2372	81.51(14.82)	(80.92, 82.11)	84.09	(15.9, 100.0)	2372	81.57(14.75)	(80.98, 82.17)	84.09	(11.4, 100.0)
Visit 8	1664	81.39(14.76)	(80.68, 82.10)	84.09	(0.0, 100.0)	1650	81.06(15.31)	(80.32, 81.80)	84.09	(18.2, 100.0)
Visit 11	789	81.41(15.37)	(80.34, 82.49)	84.09	(18.2, 100.0)	771	80.31(15.59)	(79.21, 81.41)	84.09	(11.4, 100.0)
Visit 14	66	85.55(11.42)	(82.75, 88.36)	86.36	(50.0, 100.0)	56	83.21(12.11)	(79.96, 86.45)	85.23	(47.7, 100.0)
Last On-Treatment	2237	81.24(14.94)	(80.62, 81.86)	84.09	(11.4, 100.0)	2271	81.18(15.13)	(80.56, 81.81)	84.09	(13.6, 100.0)
Premature Discontinuation	133	81.69(15.27)	(79.07, 84.31)	84.09	(29.5, 100.0)	102	75.70(16.86)	(72.39, 79.01)	79.55	(34.1, 100.0)
End Of Study Visit	1998	81.00(15.28)	(80.33, 81.68)	84.09	(6.8, 100.0)	1986	81.33(15.37)	(80.65, 82.00)	84.09	(0.0, 100.0)
Change from Baseline										
Visit 5	2342	-1.51(11.96)	(-2.00, -1.03)	0.00	(-77.3, 79.5)	2330	-1.17(12.10)	(-1.67, -0.68)	0.00	(-75.0, 81.8)
Visit 8	1647	-1.96(13.09)	(-2.59, -1.32)	-2.27	(-77.3, 70.5)	1626	-1.93(12.60)	(-2.54, -1.32)	0.00	(-63.6, 75.0)
Visit 11	781	-3.42(13.32)	(-4.36, -2.49)	-2.27	(-56.8, 72.7)	758	-2.38(12.01)	(-3.23, -1.52)	-2.27	(-43.2, 52.3)
Visit 14	65	-2.19(9.72)	(-4.59, 0.22)	0.00	(-30.7, 20.5)	56	-0.46(10.99)	(-3.41, 2.48)	0.00	(-25.0, 31.8)
Last On-Treatment	2206	-1.94(13.17)	(-2.49, -1.39)	-2.27	(-81.8, 79.5)	2231	-1.63(13.10)	(-2.17, -1.08)	0.00	(-75.0, 93.2)
Premature Discontinuation	131	-1.09(14.16)	(-3.54, 1.36)	0.00	(-59.1, 47.7)	101	-5.85(16.20)	(-9.05, -2.65)	-4.55	(-54.5, 47.7)
End Of Study Visit	1971	-2.14(13.89)	(-2.76, -1.53)	-2.27	(-88.6, 79.5)	1951	-1.52(13.69)	(-2.13, -0.92)	0.00	(-95.5, 93.2)

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

Figure A3.2.5: KDQoL-36 - Time Profile Curve of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



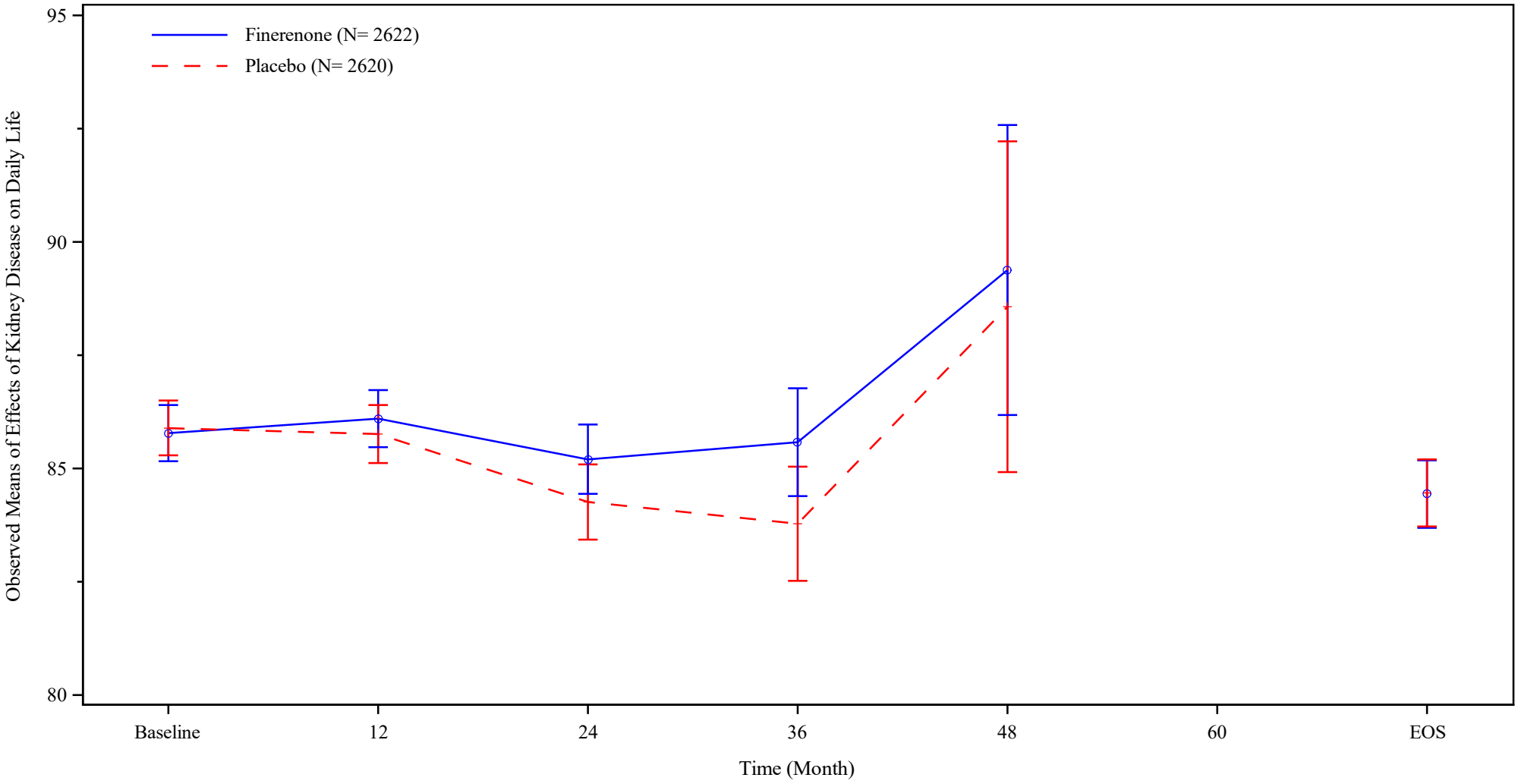
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.6: KDQoL-36 - Observed Means and Change from Baseline of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)					Placebo (N=2620)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	2554	85.78(15.94)	(85.16, 86.40)	90.63	(6.3, 100.0)	2549	85.89(15.60)	(85.29, 86.50)	90.63	(0.0, 100.0)
Baseline	2554	85.78(15.94)	(85.16, 86.40)	90.63	(6.3, 100.0)	2549	85.89(15.60)	(85.29, 86.50)	90.63	(0.0, 100.0)
Visit 5	2369	86.10(15.62)	(85.47, 86.73)	90.63	(0.0, 100.0)	2369	85.76(15.87)	(85.12, 86.40)	90.63	(9.4, 100.0)
Visit 8	1669	85.20(15.92)	(84.44, 85.97)	90.63	(3.1, 100.0)	1647	84.26(17.20)	(83.43, 85.09)	90.63	(12.5, 100.0)
Visit 11	784	85.58(16.97)	(84.39, 86.77)	90.63	(0.0, 100.0)	767	83.78(17.75)	(82.52, 85.04)	90.63	(12.5, 100.0)
Visit 14	65	89.38(12.91)	(86.18, 92.58)	96.88	(43.8, 100.0)	56	88.57(13.62)	(84.92, 92.22)	93.75	(50.0, 100.0)
Last On-Treatment	2237	85.25(16.05)	(84.58, 85.91)	90.63	(0.0, 100.0)	2269	84.61(16.40)	(83.93, 85.28)	90.63	(9.4, 100.0)
Premature Discontinuation	132	83.97(19.03)	(80.70, 87.25)	93.30	(18.8, 100.0)	102	81.74(20.75)	(77.66, 85.82)	87.50	(0.0, 100.0)
End Of Study Visit	1996	84.44(17.00)	(83.69, 85.18)	90.63	(3.1, 100.0)	1983	84.46(16.89)	(83.72, 85.20)	90.63	(0.0, 100.0)
Change from Baseline										
Visit 5	2330	-0.24(14.31)	(-0.82, 0.35)	0.00	(-75.0, 65.6)	2322	-0.25(13.96)	(-0.82, 0.32)	0.00	(-90.6, 78.1)
Visit 8	1645	-1.20(15.10)	(-1.93, -0.47)	0.00	(-87.5, 81.3)	1618	-1.88(15.86)	(-2.65, -1.11)	0.00	(-84.4, 81.3)
Visit 11	774	-2.52(16.09)	(-3.65, -1.38)	0.00	(-75.0, 68.8)	753	-2.72(16.68)	(-3.91, -1.52)	0.00	(-68.8, 71.9)
Visit 14	64	-0.92(15.35)	(-4.75, 2.91)	0.00	(-34.4, 71.9)	56	-1.52(16.04)	(-5.81, 2.78)	0.00	(-46.9, 59.4)
Last On-Treatment	2198	-1.12(15.98)	(-1.79, -0.45)	0.00	(-100.0, 81.3)	2224	-1.40(15.47)	(-2.05, -0.76)	0.00	(-90.6, 81.3)
Premature Discontinuation	131	-1.98(19.11)	(-5.28, 1.32)	0.00	(-68.8, 62.5)	100	-5.79(18.73)	(-9.51, -2.08)	-3.13	(-87.5, 56.3)
End Of Study Visit	1960	-2.13(16.49)	(-2.86, -1.40)	0.00	(-84.4, 68.8)	1945	-2.15(16.55)	(-2.88, -1.41)	0.00	(-100.0, 81.3)

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

Figure A3.2.6: KDQoL-36 - Time Profile Curve of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



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

Table A3.3.1: EQ-5D VAS - Summary and MMRM of Change from Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2343	-	[- , -]	2329	-	[- , -]	-	[- , -]	-
Visit 8	1652	-	[- , -]	1630	-	[- , -]	-	[- , -]	-
Visit 11	785	-	[- , -]	762	-	[- , -]	-	[- , -]	-
Overall	2386	-	[- , -]	2366	-	[- , -]	-	[- , -]	-
Hedges' g							-	[- , -]	-

Convergence Status of MMRM:
WARNING: Stopped because of infinite likelihood.

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

Table A3.3.2: KDQoL-36 - Summary and MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2303	-0.57	[-0.88 , -0.26]	2294	-1.03	[-1.34 , -0.71]	0.46	[0.02 , 0.90]	0.0426
Visit 8	1629	-1.28	[-1.67 , -0.90]	1603	-1.86	[-2.25 , -1.47]	0.58	[0.03 , 1.12]	0.0391
Visit 11	765	-2.44	[-3.01 , -1.87]	743	-2.61	[-3.17 , -2.05]	0.17	[-0.63 , 0.96]	0.6840
Overall	2360	-0.81	[-1.26 , -0.35]	2333	-1.29	[-1.75 , -0.83]	0.49	[0.04 , 0.93]	0.0323
Hedges' g							0.04	[-0.01 , 0.10]	0.1439

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.3: KDQoL-36 - Summary and MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2303	-0.78	[-1.14 , -0.42]	2294	-0.50	[-0.85 , -0.14]	-0.29	[-0.79 , 0.22]	0.2679
Visit 8	1629	-1.55	[-1.98 , -1.12]	1603	-1.05	[-1.46 , -0.63]	-0.50	[-1.10 , 0.09]	0.0986
Visit 11	765	-2.02	[-2.64 , -1.41]	743	-1.55	[-2.15 , -0.94]	-0.48	[-1.34 , 0.38]	0.2777
Overall	2360	-1.14	[-1.64 , -0.64]	2333	-1.03	[-1.52 , -0.53]	-0.11	[-0.59 , 0.37]	0.6499
Hedges' g							-0.01	[-0.07 , 0.05]	0.7576

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.4: KDQoL-36 - Summary and MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2335	0.69	[-0.21 , 1.59]	2324	0.78	[-0.11 , 1.67]	-0.09	[-1.35 , 1.18]	0.8926
Visit 8	1646	-0.68	[-1.77 , 0.41]	1620	-0.99	[-2.08 , 0.09]	0.31	[-1.22 , 1.85]	0.6886
Visit 11	779	-3.67	[-5.23 , -2.11]	755	-2.90	[-4.41 , -1.40]	-0.77	[-2.93 , 1.39]	0.4864
Overall	2381	0.93	[-0.34 , 2.21]	2361	0.67	[-0.59 , 1.94]	0.26	[-0.96 , 1.48]	0.6741
Hedges' g							0.01	[-0.05 , 0.07]	0.7753

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.5: KDQoL-36 - Summary and MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2342	-1.53	[-1.98 , -1.08]	2330	-1.18	[-1.64 , -0.73]	-0.34	[-0.98 , 0.29]	0.2914
Visit 8	1647	-2.10	[-2.66 , -1.54]	1626	-2.03	[-2.60 , -1.47]	-0.07	[-0.86 , 0.73]	0.8675
Visit 11	781	-3.61	[-4.41 , -2.82]	758	-2.44	[-3.19 , -1.68]	-1.18	[-2.27 , -0.09]	0.0343
Overall	2383	-2.15	[-2.82 , -1.49]	2366	-1.93	[-2.59 , -1.26]	-0.23	[-0.87 , 0.41]	0.4853
Hedges' g							-0.01	[-0.07 , 0.04]	0.6358

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.6: KDQoL-36 - Summary and MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2622)			Placebo (N=2620)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	2330	-0.26	[-0.78 , 0.26]	2322	-0.28	[-0.79 , 0.24]	0.01	[-0.72 , 0.75]	0.9729
Visit 8	1645	-1.41	[-2.05 , -0.76]	1618	-2.12	[-2.82 , -1.43]	0.72	[-0.23 , 1.66]	0.1363
Visit 11	774	-3.11	[-4.07 , -2.16]	753	-3.47	[-4.48 , -2.47]	0.36	[-1.02 , 1.74]	0.6117
Overall	2375	-0.40	[-1.17 , 0.38]	2358	-1.04	[-1.83 , -0.24]	0.64	[-0.13 , 1.41]	0.1019
Hedges' g							0.03	[-0.02 , 0.09]	0.2575

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.4.1: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		840 (32.0%)	865 (33.0%)	1705 (32.5%)
Number of subjects without events		1782 (68.0%)	1755 (67.0%)	3537 (67.5%)
Odds Ratio [a]				
OR, 95% CI	0.956 [0.851, 1.073]			
p-value	0.4454			
Relative Risk [b]				
RR, 95% CI	0.969 [0.897, 1.048]			
p-value	0.4334			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.035, 0.016]			
p-value	0.4525			

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

Table A3.4.2: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		600 (22.9%)	597 (22.8%)	1197 (22.8%)
Number of subjects without events		2022 (77.1%)	2023 (77.2%)	4045 (77.2%)
Odds Ratio [a]				
OR, 95% CI	1.006 [0.884, 1.145]			
p-value	0.9235			
Relative Risk [b]				
RR, 95% CI	1.005 [0.910, 1.110]			
p-value	0.9193			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.022, 0.024]			
p-value	0.9403			

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

Table A3.4.3: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		836 (31.9%)	876 (33.4%)	1712 (32.7%)
Number of subjects without events		1786 (68.1%)	1744 (66.6%)	3530 (67.3%)
Odds Ratio [a]				
OR, 95% CI	0.931 [0.830, 1.045]			
p-value	0.2268			
Relative Risk [b]				
RR, 95% CI	0.951 [0.880, 1.028]			
p-value	0.2085			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.040, 0.011]			
p-value	0.2526			

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

Table A3.4.4: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		873 (33.3%)	800 (30.5%)	1673 (31.9%)
Number of subjects without events		1749 (66.7%)	1820 (69.5%)	3569 (68.1%)
Odds Ratio [a]				
OR, 95% CI	1.136 [1.011, 1.277]			
p-value	0.0316			
Relative Risk [b]				
RR, 95% CI	1.094 [1.011, 1.184]			
p-value	0.0258			
Risk Difference [c]				
RD, 95% CI	0.027 [0.002, 0.052]			
p-value	0.0360			

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

Table A3.4.5: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		973 (37.1%)	955 (36.5%)	1928 (36.8%)
Number of subjects without events		1649 (62.9%)	1665 (63.5%)	3314 (63.2%)
Odds Ratio [a]				
OR, 95% CI	1.029 [0.919, 1.151]			
p-value	0.6204			
Relative Risk [b]				
RR, 95% CI	1.016 [0.946, 1.091]			
p-value	0.6609			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.019, 0.033]			
p-value	0.5897			

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

Table A3.4.6: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		578 (22.0%)	568 (21.7%)	1146 (21.9%)
Number of subjects without events		2044 (78.0%)	2052 (78.3%)	4096 (78.1%)
Odds Ratio [a]				
OR, 95% CI	1.022 [0.897, 1.166]			
p-value	0.7399			
Relative Risk [b]				
RR, 95% CI	1.017 [0.918, 1.127]			
p-value	0.7429			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.018, 0.026]			
p-value	0.7307			

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

Table A3.4.7: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		677 (25.8%)	692 (26.4%)	1369 (26.1%)
Number of subjects without events		1945 (74.2%)	1928 (73.6%)	3873 (73.9%)
Odds Ratio [a]				
OR, 95% CI	0.969 [0.857, 1.096]			
p-value	0.6182			
Relative Risk [b]				
RR, 95% CI	0.976 [0.892, 1.069]			
p-value	0.6077			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.030, 0.018]			
p-value	0.6348			

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

Table A3.4.8: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		574 (21.9%)	532 (20.3%)	1106 (21.1%)
Number of subjects without events		2048 (78.1%)	2088 (79.7%)	4136 (78.9%)
Odds Ratio [a]				
OR, 95% CI	1.103 [0.966, 1.261]			
p-value	0.1484			
Relative Risk [b]				
RR, 95% CI	1.078 [0.971, 1.196]			
p-value	0.1601			
Risk Difference [c]				
RD, 95% CI	0.017 [-0.004, 0.039]			
p-value	0.1181			

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

Table A3.4.9: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		533 (20.3%)	540 (20.6%)	1073 (20.5%)
Number of subjects without events		2089 (79.7%)	2080 (79.4%)	4169 (79.5%)
Odds Ratio [a]				
OR, 95% CI	0.983 [0.859, 1.124]			
p-value	0.7991			
Relative Risk [b]				
RR, 95% CI	0.988 [0.888, 1.099]			
p-value	0.8229			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.026, 0.018]			
p-value	0.7381			

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

Table A3.4.10: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		803 (30.6%)	778 (29.7%)	1581 (30.2%)
Number of subjects without events		1819 (69.4%)	1842 (70.3%)	3661 (69.8%)
Odds Ratio [a]				
OR, 95% CI	1.045 [0.929, 1.176]			
p-value	0.4642			
Relative Risk [b]				
RR, 95% CI	1.030 [0.949, 1.119]			
p-value	0.4740			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.015, 0.034]			
p-value	0.4519			

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

Table A3.4.11: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		314 (12.0%)	303 (11.6%)	617 (11.8%)
Number of subjects without events		2308 (88.0%)	2317 (88.4%)	4625 (88.2%)
Odds Ratio [a]				
OR, 95% CI	1.040 [0.879, 1.231]			
p-value	0.6454			
Relative Risk [b]				
RR, 95% CI	1.035 [0.893, 1.200]			
p-value	0.6486			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.013, 0.021]			
p-value	0.6638			

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

Table A3.4.12: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2622)	Placebo (N=2620)	Total (N=5242)
Number of subjects at risk		2622 (100.0%)	2620 (100.0%)	5242 (100.0%)
Number of subjects with events		422 (16.1%)	395 (15.1%)	817 (15.6%)
Number of subjects without events		2200 (83.9%)	2225 (84.9%)	4425 (84.4%)
Odds Ratio [a]				
OR, 95% CI	1.081 [0.931, 1.255]			
p-value	0.3096			
Relative Risk [b]				
RR, 95% CI	1.067 [0.941, 1.211]			
p-value	0.3113			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.009, 0.030]			
p-value	0.3017			

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Any TEAE	2287(87.4%)	2300(88.1%)
Infections And Infestations	1139(43.5%)	1165(44.6%)
Nasopharyngitis	227(8.7%)	232(8.9%)
Upper respiratory tract infection	170(6.5%)	171(6.6%)
Urinary tract infection	165(6.3%)	177(6.8%)
Bronchitis	129(4.9%)	143(5.5%)
Pneumonia	118(4.5%)	175(6.7%)
Influenza	104(4.0%)	98(3.8%)
Cellulitis	71(2.7%)	55(2.1%)
Gastroenteritis	44(1.7%)	50(1.9%)
Respiratory tract infection	43(1.6%)	37(1.4%)
Conjunctivitis	37(1.4%)	37(1.4%)
Pharyngitis	32(1.2%)	31(1.2%)
Herpes zoster	31(1.2%)	29(1.1%)
Sinusitis	28(1.1%)	28(1.1%)
Cystitis	24(0.9%)	22(0.8%)
Erysipelas	22(0.8%)	18(0.7%)
Localised infection	22(0.8%)	17(0.7%)
Sepsis	18(0.7%)	17(0.7%)
Osteomyelitis	17(0.6%)	13(0.5%)
Viral infection	16(0.6%)	25(1.0%)
Periodontitis	15(0.6%)	25(1.0%)
Helicobacter infection	13(0.5%)	9(0.3%)
Tooth abscess	13(0.5%)	8(0.3%)
Lower respiratory tract infection	12(0.5%)	23(0.9%)
Rhinitis	12(0.5%)	17(0.7%)
Gingivitis	12(0.5%)	14(0.5%)
Wound infection	12(0.5%)	7(0.3%)
Fungal skin infection	12(0.5%)	6(0.2%)
Skin infection	11(0.4%)	11(0.4%)
Pyelonephritis	11(0.4%)	10(0.4%)
Ear infection	11(0.4%)	6(0.2%)
Paronychia	10(0.4%)	8(0.3%)
Gastroenteritis viral	9(0.3%)	8(0.3%)
Tooth infection	9(0.3%)	8(0.3%)
Subcutaneous abscess	9(0.3%)	7(0.3%)
Viral upper respiratory tract infection	9(0.3%)	7(0.3%)
Pyelonephritis chronic	9(0.3%)	5(0.2%)
Tinea pedis	8(0.3%)	17(0.7%)
Respiratory tract infection viral	8(0.3%)	13(0.5%)
Otitis externa	8(0.3%)	10(0.4%)
Infected skin ulcer	8(0.3%)	7(0.3%)
Epididymitis	8(0.3%)	6(0.2%)
Otitis media	7(0.3%)	9(0.3%)
Folliculitis	7(0.3%)	6(0.2%)
Abscess limb	7(0.3%)	5(0.2%)
Hordeolum	7(0.3%)	3(0.1%)
Onychomycosis	6(0.2%)	17(0.7%)
Acarodermatitis	6(0.2%)	6(0.2%)
Acute sinusitis	6(0.2%)	6(0.2%)
Gangrene	6(0.2%)	5(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Oral candidiasis	6(0.2%)	4(0.2%)
Pharyngotonsillitis	6(0.2%)	2(0.1%)
Pulmonary sepsis	6(0.2%)	2(0.1%)
Pyelonephritis acute	6(0.2%)	1(0.0%)
Diabetic foot infection	5(0.2%)	10(0.4%)
Diverticulitis	5(0.2%)	9(0.3%)
Eye infection	5(0.2%)	7(0.3%)
Postoperative wound infection	5(0.2%)	5(0.2%)
Tonsillitis	4(0.2%)	6(0.2%)
Urosepsis	4(0.2%)	6(0.2%)
Septic shock	4(0.2%)	5(0.2%)
Laryngitis	4(0.2%)	4(0.2%)
Infection	4(0.2%)	3(0.1%)
Oral herpes	4(0.2%)	2(0.1%)
Soft tissue infection	4(0.2%)	2(0.1%)
Urinary tract infection bacterial	4(0.2%)	2(0.1%)
Asymptomatic bacteriuria	4(0.2%)	1(0.0%)
Febrile infection	4(0.2%)	1(0.0%)
Groin abscess	4(0.2%)	1(0.0%)
Arthritis bacterial	4(0.2%)	0
Tracheobronchitis	3(0.1%)	6(0.2%)
Escherichia urinary tract infection	3(0.1%)	4(0.2%)
Helicobacter gastritis	3(0.1%)	3(0.1%)
Orchitis	3(0.1%)	3(0.1%)
Pulmonary tuberculosis	3(0.1%)	3(0.1%)
Abdominal abscess	3(0.1%)	1(0.0%)
Herpes ophthalmic	3(0.1%)	1(0.0%)
Vaginal infection	3(0.1%)	0
Furuncle	2(0.1%)	8(0.3%)
Liver abscess	2(0.1%)	6(0.2%)
Dermatophytosis of nail	2(0.1%)	5(0.2%)
Appendicitis	2(0.1%)	4(0.2%)
Labyrinthitis	2(0.1%)	4(0.2%)
Chronic sinusitis	2(0.1%)	3(0.1%)
Fungal infection	2(0.1%)	3(0.1%)
Otitis media acute	2(0.1%)	3(0.1%)
Vulvovaginal candidiasis	2(0.1%)	3(0.1%)
Anal abscess	2(0.1%)	2(0.1%)
Bacteraemia	2(0.1%)	2(0.1%)
Body tinea	2(0.1%)	2(0.1%)
Herpes dermatitis	2(0.1%)	2(0.1%)
Infected bite	2(0.1%)	2(0.1%)
Oral fungal infection	2(0.1%)	2(0.1%)
Pneumonia bacterial	2(0.1%)	2(0.1%)
Pulpitis dental	2(0.1%)	2(0.1%)
Abscess	2(0.1%)	1(0.0%)
Clostridium difficile infection	2(0.1%)	1(0.0%)
Hepatitis C	2(0.1%)	1(0.0%)
Pharyngitis streptococcal	2(0.1%)	1(0.0%)
Sialoadenitis	2(0.1%)	1(0.0%)
Staphylococcal sepsis	2(0.1%)	1(0.0%)
Viral diarrhoea	2(0.1%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Appendicitis perforated	2(0.1%)	0
Bacteriuria	2(0.1%)	0
Diarrhoea infectious	2(0.1%)	0
Gastritis viral	2(0.1%)	0
Kidney infection	2(0.1%)	0
Peritonitis bacterial	2(0.1%)	0
Pneumonia streptococcal	2(0.1%)	0
Pyelocystitis	2(0.1%)	0
Pyuria	2(0.1%)	0
Tinea versicolour	2(0.1%)	0
Atypical pneumonia	1(0.0%)	4(0.2%)
Herpes simplex	1(0.0%)	4(0.2%)
Otitis media chronic	1(0.0%)	4(0.2%)
Infected dermal cyst	1(0.0%)	3(0.1%)
COVID-19	1(0.0%)	2(0.1%)
Carbuncle	1(0.0%)	2(0.1%)
Clostridium difficile colitis	1(0.0%)	2(0.1%)
Conjunctivitis bacterial	1(0.0%)	2(0.1%)
Conjunctivitis viral	1(0.0%)	2(0.1%)
Groin infection	1(0.0%)	2(0.1%)
Impetigo	1(0.0%)	2(0.1%)
Large intestine infection	1(0.0%)	2(0.1%)
Mastoiditis	1(0.0%)	2(0.1%)
Post procedural infection	1(0.0%)	2(0.1%)
Tinea cruris	1(0.0%)	2(0.1%)
Tracheitis	1(0.0%)	2(0.1%)
Abdominal wall abscess	1(0.0%)	1(0.0%)
Abscess oral	1(0.0%)	1(0.0%)
Bronchitis viral	1(0.0%)	1(0.0%)
Candida infection	1(0.0%)	1(0.0%)
Dacryocystitis	1(0.0%)	1(0.0%)
Dengue fever	1(0.0%)	1(0.0%)
Endocarditis	1(0.0%)	1(0.0%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	1(0.0%)
Nail infection	1(0.0%)	1(0.0%)
Oesophageal candidiasis	1(0.0%)	1(0.0%)
Osteomyelitis chronic	1(0.0%)	1(0.0%)
Pericoronitis	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Pharyngitis bacterial	1(0.0%)	1(0.0%)
Respiratory syncytial virus infection	1(0.0%)	1(0.0%)
Urethritis	1(0.0%)	1(0.0%)
Ascariasis	1(0.0%)	0
Bacterial vaginosis	1(0.0%)	0
Bladder diverticulitis	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Bronchiolitis	1(0.0%)	0
Campylobacter gastroenteritis	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Cystitis bacterial	1(0.0%)	0
Dermatitis infected	1(0.0%)	0
Device related sepsis	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Enteritis infectious	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
Eye infection bacterial	1(0.0%)	0
Eye infection viral	1(0.0%)	0
Eyelid folliculitis	1(0.0%)	0
Fournier's gangrene	1(0.0%)	0
Gastroenteritis bacterial	1(0.0%)	0
Genital herpes	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Helminthic infection	1(0.0%)	0
Hepatic infection	1(0.0%)	0
Herpes zoster infection neurological	1(0.0%)	0
Incision site abscess	1(0.0%)	0
Infective spondylitis	1(0.0%)	0
Infusion site infection	1(0.0%)	0
Keratitis bacterial	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Lymphangitis	1(0.0%)	0
Meningitis	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oral infection	1(0.0%)	0
Otitis externa fungal	1(0.0%)	0
Otosalpingitis	1(0.0%)	0
Parotitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pharyngeal abscess	1(0.0%)	0
Prostate infection	1(0.0%)	0
Prostatic abscess	1(0.0%)	0
Pseudomonas infection	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Scrotal cellulitis	1(0.0%)	0
Septic rash	1(0.0%)	0
Skin candida	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Staphylococcal bacteraemia	1(0.0%)	0
Staphylococcal infection	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Tongue fungal infection	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Vestibular neuronitis	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral labyrinthitis	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Viral pharyngitis	1(0.0%)	0
Vulvitis	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Tinea infection	0	6(0.2%)
Intervertebral discitis	0	3(0.1%)
Myringitis	0	3(0.1%)
Acute hepatitis B	0	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Fungal pharyngitis	0	2(0.1%)
Gastroenteritis salmonella	0	2(0.1%)
Gastrointestinal infection	0	2(0.1%)
Genitourinary tract infection	0	2(0.1%)
Hepatitis B	0	2(0.1%)
Infective exacerbation of bronchiectasis	0	2(0.1%)
Penile infection	0	2(0.1%)
Root canal infection	0	2(0.1%)
Skin bacterial infection	0	2(0.1%)
Vulvovaginal mycotic infection	0	2(0.1%)
American trypanosomiasis	0	1(0.0%)
Bacterial sepsis	0	1(0.0%)
Bacterial vulvovaginitis	0	1(0.0%)
Beta haemolytic streptococcal infection	0	1(0.0%)
Blister infected	0	1(0.0%)
Breast abscess	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Burn infection	0	1(0.0%)
Chronic hepatitis B	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Dental fistula	0	1(0.0%)
Dermatophytosis	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Ear infection fungal	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Eye abscess	0	1(0.0%)
Fungal oesophagitis	0	1(0.0%)
Gastrointestinal viral infection	0	1(0.0%)
Genital infection female	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
HIV infection	0	1(0.0%)
Haemophilus infection	0	1(0.0%)
Infected seroma	0	1(0.0%)
Joint abscess	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Laryngitis viral	0	1(0.0%)
Latent tuberculosis	0	1(0.0%)
Lower respiratory tract infection viral	0	1(0.0%)
Lyme disease	0	1(0.0%)
Mastitis	0	1(0.0%)
Medical device site infection	0	1(0.0%)
Medical device site joint infection	0	1(0.0%)
Nasal herpes	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Omphalitis	0	1(0.0%)
Ophthalmic herpes simplex	0	1(0.0%)
Ophthalmic herpes zoster	0	1(0.0%)
Parasitic gastroenteritis	0	1(0.0%)
Perineal abscess	0	1(0.0%)
Periorbital cellulitis	0	1(0.0%)
Peritonitis	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pertussis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Pustule	0	1(0.0%)
Renal abscess	0	1(0.0%)
Rotavirus infection	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Streptococcal bacteraemia	0	1(0.0%)
Tinea blanca	0	1(0.0%)
Trichomoniasis	0	1(0.0%)
Upper respiratory tract infection bacterial	0	1(0.0%)
Urinary tract candidiasis	0	1(0.0%)
Urinary tract infection enterococcal	0	1(0.0%)
Urinary tract infection fungal	0	1(0.0%)
Varicella	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	971(37.1%)	894(34.3%)
Hyperkalaemia	428(16.4%)	208(8.0%)
Hypoglycaemia	143(5.5%)	177(6.8%)
Hyperuricaemia	111(4.2%)	108(4.1%)
Hyperglycaemia	68(2.6%)	73(2.8%)
Gout	61(2.3%)	74(2.8%)
Diabetes mellitus inadequate control	54(2.1%)	68(2.6%)
Vitamin D deficiency	48(1.8%)	56(2.1%)
Diabetes mellitus	45(1.7%)	72(2.8%)
Hyponatraemia	36(1.4%)	18(0.7%)
Dehydration	35(1.3%)	28(1.1%)
Metabolic acidosis	32(1.2%)	26(1.0%)
Type 2 diabetes mellitus	31(1.2%)	36(1.4%)
Decreased appetite	28(1.1%)	30(1.1%)
Hypokalaemia	26(1.0%)	58(2.2%)
Hypertriglyceridaemia	25(1.0%)	20(0.8%)
Dyslipidaemia	23(0.9%)	28(1.1%)
Hyperlipidaemia	23(0.9%)	27(1.0%)
Hypomagnesaemia	17(0.6%)	14(0.5%)
Diabetic metabolic decompensation	15(0.6%)	24(0.9%)
Fluid overload	14(0.5%)	13(0.5%)
Iron deficiency	12(0.5%)	22(0.8%)
Hyperphosphataemia	11(0.4%)	11(0.4%)
Hypocalcaemia	10(0.4%)	16(0.6%)
Hypercalcaemia	9(0.3%)	5(0.2%)
Vitamin B12 deficiency	9(0.3%)	3(0.1%)
Acidosis	8(0.3%)	6(0.2%)
Diabetic ketoacidosis	7(0.3%)	7(0.3%)
Folate deficiency	7(0.3%)	2(0.1%)
Hypercholesterolaemia	6(0.2%)	9(0.3%)
Fluid retention	6(0.2%)	5(0.2%)
Obesity	5(0.2%)	8(0.3%)
Hypovolaemia	5(0.2%)	2(0.1%)
Hypervolaemia	4(0.2%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Hypoproteinaemia	3(0.1%)	6(0.2%)
Metabolic disorder	3(0.1%)	3(0.1%)
Vitamin B complex deficiency	3(0.1%)	2(0.1%)
Ketosis	3(0.1%)	0
Overweight	3(0.1%)	0
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.1%)	5(0.2%)
Hypernatraemia	2(0.1%)	5(0.2%)
Hypoalbuminaemia	2(0.1%)	4(0.2%)
Ketoacidosis	2(0.1%)	1(0.0%)
Hypoglycaemia unawareness	2(0.1%)	0
Hypophosphataemia	2(0.1%)	0
Polydipsia	2(0.1%)	0
Hyperhomocysteinaemia	1(0.0%)	4(0.2%)
Magnesium deficiency	1(0.0%)	2(0.1%)
Hypovitaminosis	1(0.0%)	1(0.0%)
Malnutrition	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Calcium metabolism disorder	1(0.0%)	0
Decreased insulin requirement	1(0.0%)	0
Diabetic complication	1(0.0%)	0
Food aversion	1(0.0%)	0
Hyperferritinaemia	1(0.0%)	0
Hyperlipasaemia	1(0.0%)	0
Hyperphagia	1(0.0%)	0
Hypervitaminosis D	1(0.0%)	0
Hypometabolism	1(0.0%)	0
Lactose intolerance	1(0.0%)	0
Lipid metabolism disorder	1(0.0%)	0
Metabolic syndrome	1(0.0%)	0
Phosphorus metabolism disorder	1(0.0%)	0
Shock hypoglycaemic	1(0.0%)	0
Vitamin B1 deficiency	1(0.0%)	0
Hypermagnesaemia	0	2(0.1%)
Hypochloraemia	0	2(0.1%)
Increased appetite	0	2(0.1%)
Metabolic alkalosis	0	2(0.1%)
Tumour lysis syndrome	0	2(0.1%)
Abnormal loss of weight	0	1(0.0%)
Cachexia	0	1(0.0%)
Calcium deficiency	0	1(0.0%)
Central obesity	0	1(0.0%)
Food intolerance	0	1(0.0%)
Hyperalbuminaemia	0	1(0.0%)
Hyperosmolar state	0	1(0.0%)
Hyperproteinaemia	0	1(0.0%)
Pancreatogenous diabetes	0	1(0.0%)
Pseudohyponatraemia	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	720(27.5%)	739(28.3%)
Arthralgia	184(7.0%)	186(7.1%)
Back pain	160(6.1%)	163(6.2%)
Pain in extremity	100(3.8%)	101(3.9%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Muscle spasms	100(3.8%)	90(3.4%)
Osteoarthritis	67(2.6%)	75(2.9%)
Myalgia	49(1.9%)	39(1.5%)
Spinal osteoarthritis	28(1.1%)	42(1.6%)
Arthritis	27(1.0%)	19(0.7%)
Neck pain	25(1.0%)	32(1.2%)
Gouty arthritis	20(0.8%)	17(0.7%)
Intervertebral disc protrusion	17(0.6%)	35(1.3%)
Flank pain	15(0.6%)	15(0.6%)
Osteoporosis	15(0.6%)	14(0.5%)
Trigger finger	13(0.5%)	9(0.3%)
Tendonitis	12(0.5%)	11(0.4%)
Bursitis	11(0.4%)	18(0.7%)
Lumbar spinal stenosis	11(0.4%)	17(0.7%)
Rotator cuff syndrome	11(0.4%)	14(0.5%)
Joint swelling	11(0.4%)	12(0.5%)
Muscular weakness	10(0.4%)	11(0.4%)
Exostosis	10(0.4%)	7(0.3%)
Periarthritis	9(0.3%)	8(0.3%)
Plantar fasciitis	9(0.3%)	8(0.3%)
Rhabdomyolysis	8(0.3%)	6(0.2%)
Musculoskeletal pain	8(0.3%)	5(0.2%)
Musculoskeletal stiffness	8(0.3%)	4(0.2%)
Musculoskeletal chest pain	7(0.3%)	12(0.5%)
Spinal pain	7(0.3%)	6(0.2%)
Tenosynovitis	6(0.2%)	6(0.2%)
Intervertebral disc disorder	6(0.2%)	5(0.2%)
Tendon disorder	6(0.2%)	4(0.2%)
Arthropathy	6(0.2%)	1(0.0%)
Intervertebral disc degeneration	4(0.2%)	5(0.2%)
Spinal stenosis	4(0.2%)	4(0.2%)
Spondylolisthesis	4(0.2%)	4(0.2%)
Foot deformity	4(0.2%)	3(0.1%)
Scoliosis	4(0.2%)	3(0.1%)
Dupuytren's contracture	4(0.2%)	1(0.0%)
Bone pain	3(0.1%)	5(0.2%)
Polymyalgia rheumatica	3(0.1%)	4(0.2%)
Synovial cyst	3(0.1%)	3(0.1%)
Limb discomfort	3(0.1%)	2(0.1%)
Limb mass	3(0.1%)	2(0.1%)
Tenosynovitis stenosans	3(0.1%)	2(0.1%)
Facet joint syndrome	3(0.1%)	0
Groin pain	2(0.1%)	6(0.2%)
Neuropathic arthropathy	2(0.1%)	5(0.2%)
Joint effusion	2(0.1%)	4(0.2%)
Spondylitis	2(0.1%)	3(0.1%)
Chondrocalcinosis pyrophosphate	2(0.1%)	2(0.1%)
Mobility decreased	2(0.1%)	2(0.1%)
Myalgia intercostal	2(0.1%)	2(0.1%)
Osteolysis	2(0.1%)	2(0.1%)
Rheumatoid arthritis	2(0.1%)	2(0.1%)
Chondrocalcinosis	2(0.1%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Muscle fatigue	2(0.1%)	1(0.0%)
Musculoskeletal disorder	2(0.1%)	1(0.0%)
Osteosclerosis	2(0.1%)	1(0.0%)
Bone swelling	2(0.1%)	0
Periostitis	2(0.1%)	0
Muscle contracture	1(0.0%)	6(0.2%)
Osteopenia	1(0.0%)	5(0.2%)
Cervical spinal stenosis	1(0.0%)	3(0.1%)
Osteitis	1(0.0%)	3(0.1%)
Joint contracture	1(0.0%)	2(0.1%)
Muscle atrophy	1(0.0%)	2(0.1%)
Musculoskeletal discomfort	1(0.0%)	2(0.1%)
Polyarthritis	1(0.0%)	2(0.1%)
Back disorder	1(0.0%)	1(0.0%)
Chronic kidney disease-mineral and bone disorder	1(0.0%)	1(0.0%)
Costochondritis	1(0.0%)	1(0.0%)
Fistula	1(0.0%)	1(0.0%)
Fracture pain	1(0.0%)	1(0.0%)
Joint stiffness	1(0.0%)	1(0.0%)
Muscle twitching	1(0.0%)	1(0.0%)
Myopathy	1(0.0%)	1(0.0%)
Osteochondrosis	1(0.0%)	1(0.0%)
Rheumatic disorder	1(0.0%)	1(0.0%)
Synovitis	1(0.0%)	1(0.0%)
Tendon calcification	1(0.0%)	1(0.0%)
Tendon pain	1(0.0%)	1(0.0%)
Vertebral osteophyte	1(0.0%)	1(0.0%)
Chest wall mass	1(0.0%)	0
Clubbing	1(0.0%)	0
Connective tissue inflammation	1(0.0%)	0
Fasciitis	1(0.0%)	0
Finger deformity	1(0.0%)	0
Haematoma muscle	1(0.0%)	0
Hypercreatinaemia	1(0.0%)	0
Kyphosis	1(0.0%)	0
Ligament pain	1(0.0%)	0
Ligamentitis	1(0.0%)	0
Metatarsalgia	1(0.0%)	0
Myofascial pain syndrome	1(0.0%)	0
Myositis	1(0.0%)	0
Neuropathic muscular atrophy	1(0.0%)	0
Pain in jaw	1(0.0%)	0
Sacroiliitis	1(0.0%)	0
Spinal flattening	1(0.0%)	0
Torticollis	1(0.0%)	0
Osteoarthropathy	0	3(0.1%)
Spondyloarthropathy	0	3(0.1%)
Bone formation increased	0	2(0.1%)
Joint range of motion decreased	0	2(0.1%)
Psoriatic arthropathy	0	2(0.1%)
Spinal instability	0	2(0.1%)
Temporomandibular joint syndrome	0	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Arthritis reactive	0	1(0.0%)
Articular calcification	0	1(0.0%)
Axillary mass	0	1(0.0%)
Bone callus excessive	0	1(0.0%)
Chondropathy	0	1(0.0%)
Coccydynia	0	1(0.0%)
Connective tissue disorder	0	1(0.0%)
Crystal arthropathy	0	1(0.0%)
Diastasis recti abdominis	0	1(0.0%)
Fibromyalgia	0	1(0.0%)
Gouty tophus	0	1(0.0%)
Jaw cyst	0	1(0.0%)
Nodal osteoarthritis	0	1(0.0%)
Osteonecrosis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Patellofemoral pain syndrome	0	1(0.0%)
Sjogren's syndrome	0	1(0.0%)
Soft tissue mass	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal fusion acquired	0	1(0.0%)
Systemic lupus erythematosus	0	1(0.0%)
Trismus	0	1(0.0%)
Vertebral foraminal stenosis	0	1(0.0%)
Gastrointestinal Disorders	693(26.5%)	728(27.9%)
Diarrhoea	170(6.5%)	181(6.9%)
Constipation	124(4.7%)	156(6.0%)
Nausea	83(3.2%)	82(3.1%)
Vomiting	72(2.8%)	59(2.3%)
Abdominal pain upper	47(1.8%)	49(1.9%)
Abdominal pain	41(1.6%)	44(1.7%)
Gastritis	40(1.5%)	34(1.3%)
Gastrooesophageal reflux disease	35(1.3%)	56(2.1%)
Dyspepsia	30(1.1%)	35(1.3%)
Haemorrhoids	30(1.1%)	29(1.1%)
Large intestine polyp	27(1.0%)	43(1.6%)
Chronic gastritis	21(0.8%)	16(0.6%)
Dental caries	19(0.7%)	11(0.4%)
Diverticulum intestinal	18(0.7%)	16(0.6%)
Toothache	17(0.6%)	24(0.9%)
Abdominal distension	14(0.5%)	9(0.3%)
Gastrointestinal haemorrhage	12(0.5%)	10(0.4%)
Gastritis erosive	12(0.5%)	7(0.3%)
Umbilical hernia	11(0.4%)	9(0.3%)
Rectal haemorrhage	11(0.4%)	7(0.3%)
Abdominal discomfort	9(0.3%)	14(0.5%)
Haematochezia	8(0.3%)	7(0.3%)
Flatulence	8(0.3%)	6(0.2%)
Periodontal disease	8(0.3%)	5(0.2%)
Gastric polyps	8(0.3%)	4(0.2%)
Gastric ulcer	7(0.3%)	10(0.4%)
Dry mouth	7(0.3%)	8(0.3%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Colitis	7(0.3%)	6(0.2%)
Enteritis	7(0.3%)	3(0.1%)
Hiatus hernia	6(0.2%)	14(0.5%)
Irritable bowel syndrome	6(0.2%)	11(0.4%)
Pancreatitis acute	6(0.2%)	9(0.3%)
Lower gastrointestinal haemorrhage	6(0.2%)	3(0.1%)
Melaena	6(0.2%)	2(0.1%)
Inguinal hernia	5(0.2%)	12(0.5%)
Duodenal ulcer	5(0.2%)	10(0.4%)
Dysphagia	5(0.2%)	9(0.3%)
Oesophagitis	5(0.2%)	4(0.2%)
Haemorrhoidal haemorrhage	5(0.2%)	1(0.0%)
Diverticulum	4(0.2%)	13(0.5%)
Abdominal pain lower	4(0.2%)	8(0.3%)
Upper gastrointestinal haemorrhage	4(0.2%)	6(0.2%)
Pancreatitis chronic	4(0.2%)	5(0.2%)
Gastrointestinal disorder	4(0.2%)	4(0.2%)
Intestinal obstruction	4(0.2%)	2(0.1%)
Anal fissure	3(0.1%)	3(0.1%)
Duodenal polyp	3(0.1%)	2(0.1%)
Enterocolitis	3(0.1%)	2(0.1%)
Food poisoning	3(0.1%)	2(0.1%)
Gingival pain	3(0.1%)	2(0.1%)
Mouth ulceration	3(0.1%)	2(0.1%)
Pancreatic cyst	3(0.1%)	2(0.1%)
Haematemesis	3(0.1%)	1(0.0%)
Ileus	3(0.1%)	0
Duodenitis	2(0.1%)	8(0.3%)
Peptic ulcer	2(0.1%)	6(0.2%)
Ascites	2(0.1%)	5(0.2%)
Abdominal hernia	2(0.1%)	3(0.1%)
Change of bowel habit	2(0.1%)	3(0.1%)
Pancreatitis	2(0.1%)	3(0.1%)
Rectal polyp	2(0.1%)	3(0.1%)
Faecaloma	2(0.1%)	2(0.1%)
Intestinal metaplasia	2(0.1%)	2(0.1%)
Angular cheilitis	2(0.1%)	1(0.0%)
Barrett's oesophagus	2(0.1%)	1(0.0%)
Colitis microscopic	2(0.1%)	1(0.0%)
Epigastric discomfort	2(0.1%)	1(0.0%)
Gingival bleeding	2(0.1%)	1(0.0%)
Small intestinal obstruction	2(0.1%)	1(0.0%)
Defaecation urgency	2(0.1%)	0
Diverticulum intestinal haemorrhagic	2(0.1%)	0
Functional gastrointestinal disorder	2(0.1%)	0
Gastric ulcer haemorrhage	2(0.1%)	0
Proctalgia	2(0.1%)	0
Stomatitis	1(0.0%)	4(0.2%)
Tooth disorder	1(0.0%)	4(0.2%)
Colon dysplasia	1(0.0%)	3(0.1%)
Gastrointestinal motility disorder	1(0.0%)	3(0.1%)
Gingival swelling	1(0.0%)	3(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Intestinal polyp	1(0.0%)	3(0.1%)
Frequent bowel movements	1(0.0%)	2(0.1%)
Odynophagia	1(0.0%)	2(0.1%)
Pancreatolithiasis	1(0.0%)	2(0.1%)
Rectal prolapse	1(0.0%)	2(0.1%)
Salivary gland calculus	1(0.0%)	2(0.1%)
Abnormal faeces	1(0.0%)	1(0.0%)
Anal incontinence	1(0.0%)	1(0.0%)
Anal pruritus	1(0.0%)	1(0.0%)
Diaphragmatic hernia	1(0.0%)	1(0.0%)
Diarrhoea haemorrhagic	1(0.0%)	1(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Faeces discoloured	1(0.0%)	1(0.0%)
Gastric mucosal lesion	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Gastritis haemorrhagic	1(0.0%)	1(0.0%)
Gastroduodenal ulcer	1(0.0%)	1(0.0%)
Gastrointestinal dysplasia	1(0.0%)	1(0.0%)
Incarcerated umbilical hernia	1(0.0%)	1(0.0%)
Pancreatic disorder	1(0.0%)	1(0.0%)
Peptic ulcer haemorrhage	1(0.0%)	1(0.0%)
Abdominal rigidity	1(0.0%)	0
Abdominal symptom	1(0.0%)	0
Aerophagia	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Anal haemorrhage	1(0.0%)	0
Anorectal swelling	1(0.0%)	0
Aptyalism	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Dyschezia	1(0.0%)	0
Gastric dilatation	1(0.0%)	0
Gastric disorder	1(0.0%)	0
Gastric haemorrhage	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Glossitis	1(0.0%)	0
Glossodynia	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids thrombosed	1(0.0%)	0
Hyperaesthesia teeth	1(0.0%)	0
Hypoaesthesia oral	1(0.0%)	0
Ileal ulcer	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Intra-abdominal fluid collection	1(0.0%)	0
Large intestinal stenosis	1(0.0%)	0
Lip pruritus	1(0.0%)	0
Lip swelling	1(0.0%)	0
Mouth cyst	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Oesophageal ulcer haemorrhage	1(0.0%)	0
Oral pain	1(0.0%)	0
Paraesthesia oral	1(0.0%)	0
Parotid gland enlargement	1(0.0%)	0
Proctitis	1(0.0%)	0
Pyloric sphincter insufficiency	1(0.0%)	0
Rectal ulcer	1(0.0%)	0
Reflux gastritis	1(0.0%)	0
Retching	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Salivary gland mass	1(0.0%)	0
Salivary hypersecretion	1(0.0%)	0
Small intestinal haemorrhage	1(0.0%)	0
Splenic artery aneurysm	1(0.0%)	0
Swollen tongue	1(0.0%)	0
Tongue haemorrhage	1(0.0%)	0
Varices oesophageal	0	4(0.2%)
Colitis ischaemic	0	3(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Eructation	0	2(0.1%)
Gastric mucosa erythema	0	2(0.1%)
Impaired gastric emptying	0	2(0.1%)
Intestinal mass	0	2(0.1%)
Mesenteric panniculitis	0	2(0.1%)
Subileus	0	2(0.1%)
Abdominal adhesions	0	1(0.0%)
Abdominal strangulated hernia	0	1(0.0%)
Abdominal tenderness	0	1(0.0%)
Acquired oesophageal web	0	1(0.0%)
Anal fistula	0	1(0.0%)
Bowel movement irregularity	0	1(0.0%)
Erosive duodenitis	0	1(0.0%)
Erosive oesophagitis	0	1(0.0%)
Faeces hard	0	1(0.0%)
Faeces soft	0	1(0.0%)
Gastrointestinal angiodysplasia	0	1(0.0%)
Gastrointestinal hypomotility	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal mucosa hyperaemia	0	1(0.0%)
Gastrointestinal oedema	0	1(0.0%)
Gastrointestinal tract mucosal pigmentation	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Gastrooesophageal sphincter insufficiency	0	1(0.0%)
Gingival hypertrophy	0	1(0.0%)
Hyperchlorhydria	0	1(0.0%)
Intestinal ischaemia	0	1(0.0%)
Lip blister	0	1(0.0%)
Malabsorption	0	1(0.0%)
Mesenteric artery stenosis	0	1(0.0%)
Mouth haemorrhage	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Oesophageal stenosis	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Oral disorder	0	1(0.0%)
Palatal polyp	0	1(0.0%)
Pancreatic duct stenosis	0	1(0.0%)
Pancreatic failure	0	1(0.0%)
Periodontal inflammation	0	1(0.0%)
Pneumoperitoneum	0	1(0.0%)
Rectal dysplasia	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland cyst	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Tooth deposit	0	1(0.0%)
Investigations	598(22.9%)	630(24.1%)
Glomerular filtration rate decreased	167(6.4%)	126(4.8%)
Blood creatinine increased	100(3.8%)	82(3.1%)
Blood potassium increased	72(2.8%)	37(1.4%)
Blood creatine phosphokinase increased	56(2.1%)	94(3.6%)
Blood pressure increased	51(1.9%)	66(2.5%)
C-reactive protein increased	46(1.8%)	55(2.1%)
Glycosylated haemoglobin increased	35(1.3%)	25(1.0%)
Gamma-glutamyltransferase increased	30(1.1%)	19(0.7%)
Blood urea increased	25(1.0%)	11(0.4%)
Weight decreased	19(0.7%)	30(1.1%)
Blood glucose increased	19(0.7%)	20(0.8%)
Blood uric acid increased	18(0.7%)	20(0.8%)
Blood triglycerides increased	13(0.5%)	10(0.4%)
Haemoglobin decreased	11(0.4%)	16(0.6%)
Alanine aminotransferase increased	10(0.4%)	12(0.5%)
Weight increased	9(0.3%)	20(0.8%)
Blood pressure decreased	9(0.3%)	5(0.2%)
Aspartate aminotransferase increased	7(0.3%)	7(0.3%)
Blood alkaline phosphatase increased	6(0.2%)	7(0.3%)
Blood potassium decreased	6(0.2%)	4(0.2%)
White blood cell count increased	6(0.2%)	1(0.0%)
Prostatic specific antigen increased	5(0.2%)	7(0.3%)
Occult blood positive	5(0.2%)	4(0.2%)
Helicobacter test positive	5(0.2%)	3(0.1%)
Hepatic enzyme increased	4(0.2%)	8(0.3%)
Troponin increased	4(0.2%)	8(0.3%)
Cardiac murmur	4(0.2%)	4(0.2%)
Liver function test increased	4(0.2%)	3(0.1%)
Blood glucose decreased	4(0.2%)	2(0.1%)
Colonoscopy	3(0.1%)	5(0.2%)
Heart rate increased	3(0.1%)	3(0.1%)
Vitamin D decreased	3(0.1%)	3(0.1%)
Blood cholesterol decreased	3(0.1%)	2(0.1%)
Blood cholesterol increased	3(0.1%)	2(0.1%)
Blood glucose fluctuation	3(0.1%)	1(0.0%)
Blood sodium decreased	3(0.1%)	1(0.0%)
Low density lipoprotein increased	3(0.1%)	1(0.0%)
Urine output decreased	3(0.1%)	1(0.0%)
N-terminal prohormone brain natriuretic peptide increased	2(0.1%)	6(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Angiocardiogram	2(0.1%)	5(0.2%)
Intraocular pressure increased	2(0.1%)	4(0.2%)
Blood lactate dehydrogenase increased	2(0.1%)	3(0.1%)
Lipase increased	2(0.1%)	3(0.1%)
Ejection fraction decreased	2(0.1%)	2(0.1%)
Low density lipoprotein decreased	2(0.1%)	2(0.1%)
Biopsy kidney	2(0.1%)	1(0.0%)
Blood albumin decreased	2(0.1%)	1(0.0%)
Blood iron decreased	2(0.1%)	1(0.0%)
Blood parathyroid hormone increased	2(0.1%)	1(0.0%)
Blood calcium increased	2(0.1%)	0
Catheterisation cardiac	2(0.1%)	0
Glycosylated haemoglobin abnormal	2(0.1%)	0
Vitamin B12 decreased	2(0.1%)	0
Waist circumference increased	2(0.1%)	0
Electrocardiogram T wave inversion	1(0.0%)	4(0.2%)
Blood pressure diastolic decreased	1(0.0%)	3(0.1%)
Electrocardiogram ST segment depression	1(0.0%)	3(0.1%)
Inflammatory marker increased	1(0.0%)	3(0.1%)
Platelet count decreased	1(0.0%)	3(0.1%)
Transaminases increased	1(0.0%)	3(0.1%)
Amylase increased	1(0.0%)	2(0.1%)
Anticoagulation drug level above therapeutic	1(0.0%)	2(0.1%)
Biopsy skin	1(0.0%)	2(0.1%)
Blood bicarbonate decreased	1(0.0%)	2(0.1%)
Bone density decreased	1(0.0%)	2(0.1%)
Brain natriuretic peptide increased	1(0.0%)	2(0.1%)
Influenza A virus test positive	1(0.0%)	2(0.1%)
Urine albumin/creatinine ratio increased	1(0.0%)	2(0.1%)
Blood calcium decreased	1(0.0%)	1(0.0%)
Blood urine present	1(0.0%)	1(0.0%)
Clostridium test positive	1(0.0%)	1(0.0%)
ECG signs of myocardial ischaemia	1(0.0%)	1(0.0%)
Electrocardiogram T wave amplitude decreased	1(0.0%)	1(0.0%)
Electrocardiogram abnormal	1(0.0%)	1(0.0%)
Mean cell volume increased	1(0.0%)	1(0.0%)
Oxygen consumption increased	1(0.0%)	1(0.0%)
Angiogram peripheral	1(0.0%)	0
Antinuclear antibody positive	1(0.0%)	0
Arteriogram	1(0.0%)	0
Aspiration pleural cavity	1(0.0%)	0
Bacterial test positive	1(0.0%)	0
Biopsy artery	1(0.0%)	0
Biopsy prostate	1(0.0%)	0
Blood albumin abnormal	1(0.0%)	0
Blood chloride decreased	1(0.0%)	0
Blood lactic acid increased	1(0.0%)	0
Blood osmolarity decreased	1(0.0%)	0
Blood pressure systolic increased	1(0.0%)	0
Breath sounds abnormal	1(0.0%)	0
C-reactive protein abnormal	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Cardiac stress test abnormal	1(0.0%)	0
Electrocardiogram P wave abnormal	1(0.0%)	0
Glomerular filtration rate increased	1(0.0%)	0
Haemoglobin increased	1(0.0%)	0
Human chorionic gonadotropin increased	1(0.0%)	0
Intestinal transit time decreased	1(0.0%)	0
Klebsiella test positive	1(0.0%)	0
Legionella test positive	1(0.0%)	0
Liver function test abnormal	1(0.0%)	0
Mean cell haemoglobin concentration decreased	1(0.0%)	0
Myoglobin blood increased	1(0.0%)	0
Nitrite urine present	1(0.0%)	0
Prothrombin time prolonged	1(0.0%)	0
Serum ferritin increased	1(0.0%)	0
Sputum abnormal	1(0.0%)	0
Transaminases abnormal	1(0.0%)	0
Transferrin saturation decreased	1(0.0%)	0
Tumour marker increased	1(0.0%)	0
White blood cell count decreased	1(0.0%)	0
Electrocardiogram QT prolonged	0	3(0.1%)
Electrocardiogram T wave abnormal	0	3(0.1%)
Heart rate decreased	0	3(0.1%)
Polymerase chain reaction positive	0	3(0.1%)
Protein urine present	0	3(0.1%)
Quality of life decreased	0	3(0.1%)
Blood magnesium decreased	0	2(0.1%)
Blood phosphorus increased	0	2(0.1%)
Carcinoembryonic antigen increased	0	2(0.1%)
High density lipoprotein decreased	0	2(0.1%)
Peripheral arteriogram	0	2(0.1%)
QRS axis abnormal	0	2(0.1%)
Ultrasound Doppler abnormal	0	2(0.1%)
Ultrasound kidney abnormal	0	2(0.1%)
Urinary occult blood positive	0	2(0.1%)
Angiogram cerebral	0	1(0.0%)
Anticoagulation drug level increased	0	1(0.0%)
Arthroscopy	0	1(0.0%)
Biopsy breast	0	1(0.0%)
Blood bilirubin increased	0	1(0.0%)
Blood chromogranin A increased	0	1(0.0%)
Brain scan abnormal	0	1(0.0%)
Cardiac index decreased	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)
Carotid bruit	0	1(0.0%)
Computerised tomogram abdomen	0	1(0.0%)
Electrocardiogram QRS complex abnormal	0	1(0.0%)
Electrocardiogram ST segment abnormal	0	1(0.0%)
Electrocardiogram ST-T segment abnormal	0	1(0.0%)
Electrocardiogram repolarisation abnormality	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Face and mouth X-ray abnormal	0	1(0.0%)
Fibrin D dimer increased	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Haematocrit decreased	0	1(0.0%)
Haematology test abnormal	0	1(0.0%)
Heart rate irregular	0	1(0.0%)
Human rhinovirus test positive	0	1(0.0%)
Influenza B virus test positive	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Magnetic resonance imaging brain abnormal	0	1(0.0%)
Myocardial necrosis marker increased	0	1(0.0%)
Platelet count increased	0	1(0.0%)
Red blood cell count decreased	0	1(0.0%)
Red blood cell sedimentation rate increased	0	1(0.0%)
Serum ferritin decreased	0	1(0.0%)
Treponema test positive	0	1(0.0%)
Troponin I increased	0	1(0.0%)
Troponin T increased	0	1(0.0%)
Ultrasound thyroid abnormal	0	1(0.0%)
Urine output increased	0	1(0.0%)
Vascular resistance systemic increased	0	1(0.0%)
Vitamin B12 increased	0	1(0.0%)
White blood cell analysis abnormal	0	1(0.0%)
Nervous System Disorders	526(20.1%)	590(22.6%)
Dizziness	137(5.2%)	149(5.7%)
Headache	79(3.0%)	86(3.3%)
Diabetic neuropathy	42(1.6%)	43(1.6%)
Hypoaesthesia	33(1.3%)	33(1.3%)
Syncope	30(1.1%)	53(2.0%)
Sciatica	24(0.9%)	23(0.9%)
Neuropathy peripheral	17(0.6%)	18(0.7%)
Carpal tunnel syndrome	17(0.6%)	15(0.6%)
Paraesthesia	16(0.6%)	21(0.8%)
Carotid arteriosclerosis	14(0.5%)	15(0.6%)
Tremor	11(0.4%)	10(0.4%)
Facial paralysis	10(0.4%)	11(0.4%)
Transient ischaemic attack	10(0.4%)	6(0.2%)
Dizziness postural	10(0.4%)	5(0.2%)
Cognitive disorder	9(0.3%)	11(0.4%)
Lethargy	9(0.3%)	8(0.3%)
Loss of consciousness	9(0.3%)	3(0.1%)
Presyncope	9(0.3%)	3(0.1%)
Cerebrovascular disorder	8(0.3%)	6(0.2%)
Carotid artery stenosis	7(0.3%)	15(0.6%)
Neuralgia	7(0.3%)	9(0.3%)
Seizure	6(0.2%)	5(0.2%)
Lacunar infarction	6(0.2%)	4(0.2%)
Amnesia	5(0.2%)	10(0.4%)
Polyneuropathy	5(0.2%)	8(0.3%)
Cerebral infarction	5(0.2%)	7(0.3%)
Cerebral ischaemia	5(0.2%)	7(0.3%)
Memory impairment	5(0.2%)	7(0.3%)
Radiculopathy	5(0.2%)	5(0.2%)
Restless legs syndrome	5(0.2%)	3(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Dysarthria	5(0.2%)	2(0.1%)
Somnolence	4(0.2%)	10(0.4%)
Cerebral arteriosclerosis	4(0.2%)	5(0.2%)
Cerebral atrophy	4(0.2%)	5(0.2%)
Cervicobrachial syndrome	4(0.2%)	5(0.2%)
Dysgeusia	4(0.2%)	5(0.2%)
Migraine	4(0.2%)	4(0.2%)
Epilepsy	4(0.2%)	3(0.1%)
Peripheral sensorimotor neuropathy	4(0.2%)	3(0.1%)
Tension headache	4(0.2%)	2(0.1%)
Dementia	3(0.1%)	9(0.3%)
Encephalopathy	3(0.1%)	9(0.3%)
Hemiparesis	3(0.1%)	3(0.1%)
Subarachnoid haemorrhage	3(0.1%)	3(0.1%)
Aphasia	3(0.1%)	2(0.1%)
Parkinson's disease	3(0.1%)	2(0.1%)
Parkinsonism	3(0.1%)	2(0.1%)
Nerve compression	3(0.1%)	1(0.0%)
Poor quality sleep	3(0.1%)	1(0.0%)
Visual field defect	3(0.1%)	0
Cervical radiculopathy	2(0.1%)	3(0.1%)
Carotid artery disease	2(0.1%)	2(0.1%)
Dementia Alzheimer's type	2(0.1%)	2(0.1%)
Hemianaesthesia	2(0.1%)	2(0.1%)
IIIrd nerve paralysis	2(0.1%)	2(0.1%)
Leukoencephalopathy	2(0.1%)	2(0.1%)
Myelopathy	2(0.1%)	2(0.1%)
Post herpetic neuralgia	2(0.1%)	2(0.1%)
Altered state of consciousness	2(0.1%)	1(0.0%)
Burning sensation	2(0.1%)	1(0.0%)
Vocal cord paralysis	2(0.1%)	1(0.0%)
Cerebral haemorrhage	2(0.1%)	0
Hyporeflexia	2(0.1%)	0
Motor dysfunction	2(0.1%)	0
Vascular parkinsonism	2(0.1%)	0
Balance disorder	1(0.0%)	2(0.1%)
Essential tremor	1(0.0%)	2(0.1%)
Facial paresis	1(0.0%)	2(0.1%)
Hydrocephalus	1(0.0%)	2(0.1%)
Intercostal neuralgia	1(0.0%)	2(0.1%)
Intracranial aneurysm	1(0.0%)	2(0.1%)
Lumbar radiculopathy	1(0.0%)	2(0.1%)
Normal pressure hydrocephalus	1(0.0%)	2(0.1%)
Orthostatic intolerance	1(0.0%)	2(0.1%)
Peripheral sensory neuropathy	1(0.0%)	2(0.1%)
Phantom limb syndrome	1(0.0%)	2(0.1%)
Sensory disturbance	1(0.0%)	2(0.1%)
Vertebrobasilar insufficiency	1(0.0%)	2(0.1%)
Ageusia	1(0.0%)	1(0.0%)
Cerebellar infarction	1(0.0%)	1(0.0%)
Cerebral small vessel ischaemic disease	1(0.0%)	1(0.0%)
Cubital tunnel syndrome	1(0.0%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Dizziness exertional	1(0.0%)	1(0.0%)
Focal dyscognitive seizures	1(0.0%)	1(0.0%)
Peroneal nerve palsy	1(0.0%)	1(0.0%)
Senile dementia	1(0.0%)	1(0.0%)
Trigeminal neuralgia	1(0.0%)	1(0.0%)
Amputation stump pain	1(0.0%)	0
Angiopathic neuropathy	1(0.0%)	0
Ataxia	1(0.0%)	0
Bulbar palsy	1(0.0%)	0
Cerebellar stroke	1(0.0%)	0
Cerebral hypoperfusion	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Drop attacks	1(0.0%)	0
Dysmetria	1(0.0%)	0
Frontotemporal dementia	1(0.0%)	0
Hemianopia homonymous	1(0.0%)	0
Hemiparaesthesia	1(0.0%)	0
Hepatic encephalopathy	1(0.0%)	0
Intention tremor	1(0.0%)	0
Migraine without aura	1(0.0%)	0
Mixed dementia	1(0.0%)	0
Monoplegia	1(0.0%)	0
Myoclonus	1(0.0%)	0
Nervous system disorder	1(0.0%)	0
Neuritis	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Neuromuscular blockade	1(0.0%)	0
Parosmia	1(0.0%)	0
Partial seizures	1(0.0%)	0
Peripheral nerve lesion	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Post-traumatic headache	1(0.0%)	0
Resting tremor	1(0.0%)	0
Spinal claudication	1(0.0%)	0
Subdural effusion	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
VIth nerve paralysis	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
White matter lesion	1(0.0%)	0
Neurodegenerative disorder	0	3(0.1%)
Cerebral artery stenosis	0	2(0.1%)
Hemiplegia	0	2(0.1%)
Hypoxic-ischaemic encephalopathy	0	2(0.1%)
Lumbosacral radiculopathy	0	2(0.1%)
Metabolic encephalopathy	0	2(0.1%)
Postural tremor	0	2(0.1%)
Vascular dementia	0	2(0.1%)
Vascular encephalopathy	0	2(0.1%)
Alcohol induced persisting dementia	0	1(0.0%)
Anaesthesia	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Anosmia	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Basal ganglia haemorrhage	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery aneurysm	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Carotid artery thrombosis	0	1(0.0%)
Central nervous system lesion	0	1(0.0%)
Cerebral circulatory failure	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebral microangiopathy	0	1(0.0%)
Cerebrovascular accident	0	1(0.0%)
Cerebrovascular insufficiency	0	1(0.0%)
Cerebrovascular pseudoaneurysm	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Disturbance in attention	0	1(0.0%)
Dysstasia	0	1(0.0%)
Facial nerve disorder	0	1(0.0%)
Facial neuralgia	0	1(0.0%)
Facial spasm	0	1(0.0%)
Gliosis	0	1(0.0%)
Head titubation	0	1(0.0%)
Hemianopia	0	1(0.0%)
Hypersomnia	0	1(0.0%)
Hypogeusia	0	1(0.0%)
Hypotonia	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Ischaemic stroke	0	1(0.0%)
Migraine with aura	0	1(0.0%)
Mononeuropathy	0	1(0.0%)
Multiple sclerosis relapse	0	1(0.0%)
Muscle contractions involuntary	0	1(0.0%)
Myasthenia gravis	0	1(0.0%)
Nystagmus	0	1(0.0%)
Occipital neuralgia	0	1(0.0%)
Optic neuritis	0	1(0.0%)
Paraparesis	0	1(0.0%)
Radicular pain	0	1(0.0%)
Radiculitis brachial	0	1(0.0%)
Sciatic nerve neuropathy	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Tarsal tunnel syndrome	0	1(0.0%)
Taste disorder	0	1(0.0%)
Toxic neuropathy	0	1(0.0%)
Vertebral artery arteriosclerosis	0	1(0.0%)
Vertebral artery stenosis	0	1(0.0%)
Renal And Urinary Disorders	494(18.9%)	524(20.1%)
Acute kidney injury	123(4.7%)	131(5.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Renal impairment	94(3.6%)	95(3.6%)
Chronic kidney disease	45(1.7%)	51(2.0%)
Renal cyst	32(1.2%)	41(1.6%)
Nephrolithiasis	32(1.2%)	37(1.4%)
Diabetic nephropathy	31(1.2%)	18(0.7%)
Urinary retention	26(1.0%)	17(0.7%)
Haematuria	23(0.9%)	35(1.3%)
Renal failure	22(0.8%)	23(0.9%)
Urinary incontinence	20(0.8%)	16(0.6%)
Dysuria	18(0.7%)	21(0.8%)
Nocturia	14(0.5%)	14(0.5%)
Pollakiuria	13(0.5%)	16(0.6%)
Proteinuria	9(0.3%)	15(0.6%)
Polyuria	7(0.3%)	4(0.2%)
Nephrotic syndrome	6(0.2%)	15(0.6%)
Renal colic	5(0.2%)	3(0.1%)
Hydronephrosis	4(0.2%)	10(0.4%)
Nephropathy	4(0.2%)	8(0.3%)
Hypertonic bladder	4(0.2%)	5(0.2%)
Ureterolithiasis	4(0.2%)	5(0.2%)
Urge incontinence	4(0.2%)	5(0.2%)
End stage renal disease	4(0.2%)	4(0.2%)
Micturition urgency	4(0.2%)	4(0.2%)
Azotaemia	4(0.2%)	3(0.1%)
Albuminuria	3(0.1%)	3(0.1%)
Neurogenic bladder	3(0.1%)	2(0.1%)
Urinary tract obstruction	3(0.1%)	2(0.1%)
Oliguria	3(0.1%)	1(0.0%)
Calculus urinary	2(0.1%)	5(0.2%)
Perinephritis	2(0.1%)	4(0.2%)
Renal mass	2(0.1%)	4(0.2%)
Acquired cystic kidney disease	2(0.1%)	2(0.1%)
Pyelocaliectasis	2(0.1%)	2(0.1%)
Urine flow decreased	2(0.1%)	2(0.1%)
Bladder outlet obstruction	2(0.1%)	1(0.0%)
Nephropathy toxic	2(0.1%)	1(0.0%)
Renal artery stenosis	2(0.1%)	1(0.0%)
Renal atrophy	2(0.1%)	1(0.0%)
Urinary tract disorder	2(0.1%)	1(0.0%)
Bladder irritation	2(0.1%)	0
Chromaturia	2(0.1%)	0
Microalbuminuria	2(0.1%)	0
Micturition disorder	2(0.1%)	0
Lower urinary tract symptoms	1(0.0%)	6(0.2%)
Renal injury	1(0.0%)	3(0.1%)
Renal aneurysm	1(0.0%)	2(0.1%)
Renal pain	1(0.0%)	2(0.1%)
Hypertensive nephropathy	1(0.0%)	1(0.0%)
Nephroangiosclerosis	1(0.0%)	1(0.0%)
Nephrosclerosis	1(0.0%)	1(0.0%)
Stress urinary incontinence	1(0.0%)	1(0.0%)
Ureteric obstruction	1(0.0%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Urinary hesitation	1(0.0%)	1(0.0%)
Bladder cyst	1(0.0%)	0
Bladder hypertrophy	1(0.0%)	0
Bladder obstruction	1(0.0%)	0
Bladder pain	1(0.0%)	0
Bladder perforation	1(0.0%)	0
Bladder spasm	1(0.0%)	0
Cystitis haemorrhagic	1(0.0%)	0
Cystitis noninfective	1(0.0%)	0
Focal segmental glomerulosclerosis	1(0.0%)	0
Hydrocalyx	1(0.0%)	0
Hypotonic urinary bladder	1(0.0%)	0
Prerenal failure	1(0.0%)	0
Renal hypertension	1(0.0%)	0
Renal hypertrophy	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Strangury	1(0.0%)	0
Urate nephropathy	1(0.0%)	0
Urethral pain	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Calculus bladder	0	3(0.1%)
Intercapillary glomerulosclerosis	0	3(0.1%)
Renal disorder	0	3(0.1%)
Glomerulonephritis chronic	0	2(0.1%)
Nephrocalcinosis	0	2(0.1%)
Renal artery arteriosclerosis	0	2(0.1%)
Renal haemorrhage	0	2(0.1%)
Sterile pyuria	0	2(0.1%)
Anuria	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Incontinence	0	1(0.0%)
Kidney fibrosis	0	1(0.0%)
Nephroptosis	0	1(0.0%)
Perinephric collection	0	1(0.0%)
Renal haematoma	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Ureteric dilatation	0	1(0.0%)
Urine abnormality	0	1(0.0%)
Urine odour abnormal	0	1(0.0%)
Vesical fistula	0	1(0.0%)
Vascular Disorders	485(18.5%)	492(18.9%)
Hypertension	194(7.4%)	249(9.5%)
Hypotension	113(4.3%)	85(3.3%)
Peripheral arterial occlusive disease	35(1.3%)	38(1.5%)
Hypertensive crisis	28(1.1%)	30(1.1%)
Orthostatic hypotension	18(0.7%)	18(0.7%)
Intermittent claudication	14(0.5%)	16(0.6%)
Peripheral venous disease	11(0.4%)	11(0.4%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Aortic stenosis	10(0.4%)	7(0.3%)
Haematoma	9(0.3%)	5(0.2%)
Aortic arteriosclerosis	8(0.3%)	8(0.3%)
Diabetic vascular disorder	8(0.3%)	8(0.3%)
Varicose vein	8(0.3%)	7(0.3%)
Peripheral artery occlusion	8(0.3%)	2(0.1%)
Peripheral vascular disorder	7(0.3%)	11(0.4%)
Deep vein thrombosis	7(0.3%)	4(0.2%)
Peripheral artery stenosis	6(0.2%)	7(0.3%)
Aortic aneurysm	6(0.2%)	6(0.2%)
Blood pressure inadequately controlled	5(0.2%)	7(0.3%)
Hypertensive urgency	5(0.2%)	5(0.2%)
Peripheral ischaemia	5(0.2%)	3(0.1%)
Extremity necrosis	5(0.2%)	1(0.0%)
Lymphoedema	4(0.2%)	6(0.2%)
Arteriosclerosis	3(0.1%)	5(0.2%)
Thrombophlebitis	3(0.1%)	3(0.1%)
Circulatory collapse	3(0.1%)	2(0.1%)
Brachiocephalic arteriosclerosis	3(0.1%)	1(0.0%)
Lymphostasis	3(0.1%)	1(0.0%)
Labile blood pressure	3(0.1%)	0
Hypertensive emergency	2(0.1%)	5(0.2%)
Thrombophlebitis superficial	2(0.1%)	1(0.0%)
Peripheral artery aneurysm	2(0.1%)	0
Phlebitis superficial	2(0.1%)	0
Raynaud's phenomenon	2(0.1%)	0
Thrombosis	2(0.1%)	0
Phlebitis	1(0.0%)	4(0.2%)
Aortic dilatation	1(0.0%)	3(0.1%)
Blood pressure fluctuation	1(0.0%)	3(0.1%)
Hot flush	1(0.0%)	3(0.1%)
Peripheral coldness	1(0.0%)	2(0.1%)
Arterial occlusive disease	1(0.0%)	1(0.0%)
Arterial stenosis	1(0.0%)	1(0.0%)
Arteriovenous fistula	1(0.0%)	1(0.0%)
Diabetic macroangiopathy	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Ischaemia	1(0.0%)	1(0.0%)
Peripheral artery thrombosis	1(0.0%)	1(0.0%)
Angiodysplasia	1(0.0%)	0
Arteriosclerosis Moenckeberg-type	1(0.0%)	0
Dialysis hypotension	1(0.0%)	0
Diastolic hypotension	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Iliac artery occlusion	1(0.0%)	0
Iliac artery stenosis	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Labile hypertension	1(0.0%)	0
Lymphocele	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Vascular wall hypertrophy	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Vein disorder	1(0.0%)	0
Venous occlusion	1(0.0%)	0
Hypertensive angiopathy	0	3(0.1%)
Aortic disorder	0	2(0.1%)
Arteritis	0	2(0.1%)
Malignant hypertension	0	2(0.1%)
Poor peripheral circulation	0	2(0.1%)
Angiosclerosis	0	1(0.0%)
Aortic thrombosis	0	1(0.0%)
Brachiocephalic artery stenosis	0	1(0.0%)
Embolism venous	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Neovascularisation	0	1(0.0%)
Orthostatic hypertension	0	1(0.0%)
Renovascular hypertension	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Subclavian artery stenosis	0	1(0.0%)
Thromboangiitis obliterans	0	1(0.0%)
Vasculitis	0	1(0.0%)
Vein rupture	0	1(0.0%)
General Disorders And Administration Site Conditions	481(18.4%)	609(23.3%)
Oedema peripheral	175(6.7%)	288(11.0%)
Chest pain	70(2.7%)	76(2.9%)
Fatigue	57(2.2%)	59(2.3%)
Oedema	46(1.8%)	48(1.8%)
Pyrexia	43(1.6%)	37(1.4%)
Asthenia	38(1.5%)	55(2.1%)
Peripheral swelling	30(1.1%)	37(1.4%)
Chest discomfort	16(0.6%)	17(0.7%)
Malaise	15(0.6%)	7(0.3%)
Influenza like illness	12(0.5%)	14(0.5%)
Pain	10(0.4%)	13(0.5%)
Inflammation	7(0.3%)	13(0.5%)
Non-cardiac chest pain	6(0.2%)	4(0.2%)
Face oedema	5(0.2%)	6(0.2%)
Feeling abnormal	4(0.2%)	4(0.2%)
Illness	4(0.2%)	2(0.1%)
Gait disturbance	3(0.1%)	11(0.4%)
Chills	3(0.1%)	5(0.2%)
Discomfort	3(0.1%)	1(0.0%)
Mass	3(0.1%)	1(0.0%)
Impaired healing	3(0.1%)	0
Unevaluable event	3(0.1%)	0
Generalised oedema	2(0.1%)	7(0.3%)
Death	2(0.1%)	4(0.2%)
Oedema due to renal disease	2(0.1%)	3(0.1%)
General physical health deterioration	2(0.1%)	2(0.1%)
Feeling cold	2(0.1%)	1(0.0%)
Swelling face	2(0.1%)	1(0.0%)
Localised oedema	2(0.1%)	0
Medical device site reaction	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Polyp	1(0.0%)	5(0.2%)
Feeling hot	1(0.0%)	2(0.1%)
Xerosis	1(0.0%)	2(0.1%)
Drug intolerance	1(0.0%)	1(0.0%)
Early satiety	1(0.0%)	1(0.0%)
Hypothermia	1(0.0%)	1(0.0%)
Nodule	1(0.0%)	1(0.0%)
Vascular stent stenosis	1(0.0%)	1(0.0%)
Adverse event	1(0.0%)	0
Calcinosis	1(0.0%)	0
Chronic fatigue syndrome	1(0.0%)	0
Crepitations	1(0.0%)	0
Cyst rupture	1(0.0%)	0
Granuloma	1(0.0%)	0
Hernia	1(0.0%)	0
Implant site erosion	1(0.0%)	0
Injection site extravasation	1(0.0%)	0
Injection site nodule	1(0.0%)	0
Medical device site pain	1(0.0%)	0
Multiple organ dysfunction syndrome	1(0.0%)	0
Stent-graft endoleak	1(0.0%)	0
Swelling	1(0.0%)	0
Thirst	1(0.0%)	0
Cyst	0	3(0.1%)
Medical device site ulcer	0	2(0.1%)
Axillary pain	0	1(0.0%)
Catheter site discharge	0	1(0.0%)
Device intolerance	0	1(0.0%)
Drug ineffective	0	1(0.0%)
Facial discomfort	0	1(0.0%)
Facial pain	0	1(0.0%)
Gravitational oedema	0	1(0.0%)
Hernia pain	0	1(0.0%)
Induration	0	1(0.0%)
Injection site erythema	0	1(0.0%)
Injection site pain	0	1(0.0%)
Injection site pruritus	0	1(0.0%)
Injection site swelling	0	1(0.0%)
Medical device site pruritus	0	1(0.0%)
Performance status decreased	0	1(0.0%)
Puncture site pain	0	1(0.0%)
Soft tissue inflammation	0	1(0.0%)
Suprapubic pain	0	1(0.0%)
Temperature intolerance	0	1(0.0%)
Vascular stent thrombosis	0	1(0.0%)
Vessel puncture site bruise	0	1(0.0%)
Vessel puncture site haematoma	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	432(16.5%)	473(18.1%)
Cough	103(3.9%)	116(4.4%)
Dyspnoea	92(3.5%)	95(3.6%)
Chronic obstructive pulmonary disease	43(1.6%)	45(1.7%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Epistaxis	23(0.9%)	19(0.7%)
Oropharyngeal pain	23(0.9%)	12(0.5%)
Dyspnoea exertional	20(0.8%)	26(1.0%)
Sleep apnoea syndrome	18(0.7%)	30(1.1%)
Pleural effusion	18(0.7%)	17(0.7%)
Rhinitis allergic	16(0.6%)	12(0.5%)
Pulmonary mass	16(0.6%)	8(0.3%)
Rhinorrhoea	14(0.5%)	9(0.3%)
Bronchitis chronic	13(0.5%)	10(0.4%)
Asthma	12(0.5%)	19(0.7%)
Respiratory disorder	12(0.5%)	7(0.3%)
Respiratory failure	11(0.4%)	12(0.5%)
Productive cough	9(0.3%)	15(0.6%)
Acute respiratory failure	8(0.3%)	15(0.6%)
Nasal congestion	6(0.2%)	4(0.2%)
Pulmonary embolism	6(0.2%)	4(0.2%)
Catarrh	6(0.2%)	3(0.1%)
Interstitial lung disease	5(0.2%)	6(0.2%)
Emphysema	5(0.2%)	5(0.2%)
Pulmonary hypertension	5(0.2%)	5(0.2%)
Hiccups	5(0.2%)	1(0.0%)
Pulmonary fibrosis	4(0.2%)	2(0.1%)
Atelectasis	3(0.1%)	7(0.3%)
Sinus congestion	3(0.1%)	4(0.2%)
Acute pulmonary oedema	3(0.1%)	3(0.1%)
Hypoxia	3(0.1%)	2(0.1%)
Pleurisy	3(0.1%)	1(0.0%)
Pneumothorax	3(0.1%)	1(0.0%)
Upper respiratory tract inflammation	2(0.1%)	9(0.3%)
Bronchospasm	2(0.1%)	7(0.3%)
Pneumonia aspiration	2(0.1%)	6(0.2%)
Dysphonia	2(0.1%)	4(0.2%)
Pulmonary congestion	2(0.1%)	4(0.2%)
Upper-airway cough syndrome	2(0.1%)	4(0.2%)
Respiratory tract congestion	2(0.1%)	3(0.1%)
Restrictive pulmonary disease	2(0.1%)	3(0.1%)
Bronchiectasis	2(0.1%)	2(0.1%)
Lung opacity	2(0.1%)	1(0.0%)
Nasal septum deviation	2(0.1%)	1(0.0%)
Laryngeal mass	2(0.1%)	0
Vasomotor rhinitis	2(0.1%)	0
Pulmonary oedema	1(0.0%)	11(0.4%)
Pneumonitis	1(0.0%)	5(0.2%)
Pulmonary arterial hypertension	1(0.0%)	3(0.1%)
Rales	1(0.0%)	3(0.1%)
Dyspnoea paroxysmal nocturnal	1(0.0%)	2(0.1%)
Nasal turbinate hypertrophy	1(0.0%)	2(0.1%)
Orthopnoea	1(0.0%)	2(0.1%)
Chronic respiratory failure	1(0.0%)	1(0.0%)
Laryngeal oedema	1(0.0%)	1(0.0%)
Lower respiratory tract inflammation	1(0.0%)	1(0.0%)
Throat irritation	1(0.0%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Tonsillar hypertrophy	1(0.0%)	1(0.0%)
Allergic bronchitis	1(0.0%)	0
Asthmatic crisis	1(0.0%)	0
Dyspnoea at rest	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Hyperventilation	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Nasal crusting	1(0.0%)	0
Nasal disorder	1(0.0%)	0
Nasal pruritus	1(0.0%)	0
Oropharyngeal discomfort	1(0.0%)	0
Pharyngeal disorder	1(0.0%)	0
Pharyngeal erythema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Sinus disorder	1(0.0%)	0
Sneezing	1(0.0%)	0
Sputum discoloured	1(0.0%)	0
Tonsillar inflammation	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Nasal obstruction	0	3(0.1%)
Aspiration	0	2(0.1%)
Haemothorax	0	2(0.1%)
Obstructive airways disorder	0	2(0.1%)
Pulmonary granuloma	0	2(0.1%)
Respiration abnormal	0	2(0.1%)
Respiratory acidosis	0	2(0.1%)
Respiratory distress	0	2(0.1%)
Vocal cord polyp	0	2(0.1%)
Bronchopneumopathy	0	1(0.0%)
Choking	0	1(0.0%)
Cough variant asthma	0	1(0.0%)
Epiglottic oedema	0	1(0.0%)
Haemoptysis	0	1(0.0%)
Hydrothorax	0	1(0.0%)
Hypopnoea	0	1(0.0%)
Idiopathic pulmonary fibrosis	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Laryngospasm	0	1(0.0%)
Nasal dryness	0	1(0.0%)
Nasal polyps	0	1(0.0%)
Nasal varices	0	1(0.0%)
Paranasal sinus discomfort	0	1(0.0%)
Paranasal sinus hypersecretion	0	1(0.0%)
Paranasal sinus inflammation	0	1(0.0%)
Pharyngeal inflammation	0	1(0.0%)
Pharyngeal stenosis	0	1(0.0%)
Pickwickian syndrome	0	1(0.0%)
Pleural thickening	0	1(0.0%)
Pulmonary calcification	0	1(0.0%)
Pulmonary haematoma	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Respiratory tract inflammation	0	1(0.0%)
Sinus polyp	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Upper respiratory tract congestion	0	1(0.0%)
Wheezing	0	1(0.0%)
Injury, Poisoning And Procedural Complications	425(16.2%)	437(16.7%)
Limb injury	70(2.7%)	47(1.8%)
Contusion	49(1.9%)	52(2.0%)
Fall	43(1.6%)	52(2.0%)
Ligament sprain	20(0.8%)	23(0.9%)
Joint injury	19(0.7%)	9(0.3%)
Skin abrasion	18(0.7%)	19(0.7%)
Thermal burn	16(0.6%)	12(0.5%)
Rib fracture	14(0.5%)	16(0.6%)
Radius fracture	14(0.5%)	10(0.4%)
Foot fracture	12(0.5%)	10(0.4%)
Ankle fracture	11(0.4%)	14(0.5%)
Skin laceration	9(0.3%)	15(0.6%)
Post-traumatic pain	9(0.3%)	6(0.2%)
Procedural pain	9(0.3%)	6(0.2%)
Road traffic accident	9(0.3%)	2(0.1%)
Head injury	8(0.3%)	12(0.5%)
Accident	8(0.3%)	4(0.2%)
Femoral neck fracture	8(0.3%)	3(0.1%)
Hand fracture	7(0.3%)	7(0.3%)
Humerus fracture	6(0.2%)	13(0.5%)
Femur fracture	6(0.2%)	11(0.4%)
Muscle strain	6(0.2%)	8(0.3%)
Upper limb fracture	6(0.2%)	7(0.3%)
Subdural haematoma	6(0.2%)	6(0.2%)
Hip fracture	6(0.2%)	5(0.2%)
Skin wound	6(0.2%)	5(0.2%)
Scratch	6(0.2%)	4(0.2%)
Patella fracture	5(0.2%)	4(0.2%)
Wrist fracture	5(0.2%)	3(0.1%)
Fibula fracture	5(0.2%)	2(0.1%)
Soft tissue injury	4(0.2%)	5(0.2%)
Bone contusion	4(0.2%)	4(0.2%)
Tibia fracture	4(0.2%)	4(0.2%)
Muscle rupture	4(0.2%)	3(0.1%)
Ulna fracture	4(0.2%)	2(0.1%)
Joint dislocation	3(0.1%)	8(0.3%)
Tooth fracture	3(0.1%)	6(0.2%)
Arthropod bite	3(0.1%)	5(0.2%)
Accidental overdose	3(0.1%)	4(0.2%)
Chest injury	3(0.1%)	4(0.2%)
Concussion	3(0.1%)	4(0.2%)
Epicondylitis	3(0.1%)	4(0.2%)
Eye injury	3(0.1%)	3(0.1%)
Facial bones fracture	3(0.1%)	3(0.1%)
Back injury	3(0.1%)	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Toxicity to various agents	3(0.1%)	2(0.1%)
Lower limb fracture	3(0.1%)	1(0.0%)
Clavicle fracture	3(0.1%)	0
Meniscus injury	2(0.1%)	10(0.4%)
Injury	2(0.1%)	7(0.3%)
Incisional hernia	2(0.1%)	4(0.2%)
Spinal compression fracture	2(0.1%)	4(0.2%)
Arthropod sting	2(0.1%)	3(0.1%)
Corneal abrasion	2(0.1%)	3(0.1%)
Wound	2(0.1%)	3(0.1%)
Craniocerebral injury	2(0.1%)	2(0.1%)
Face injury	2(0.1%)	2(0.1%)
Cervical vertebral fracture	2(0.1%)	1(0.0%)
Post procedural complication	2(0.1%)	1(0.0%)
Subdural haemorrhage	2(0.1%)	1(0.0%)
Tendon injury	2(0.1%)	1(0.0%)
Tendon rupture	2(0.1%)	1(0.0%)
Wound complication	2(0.1%)	1(0.0%)
Anaemia postoperative	2(0.1%)	0
Heat illness	2(0.1%)	0
Inflammation of wound	2(0.1%)	0
Skeletal injury	2(0.1%)	0
Overdose	1(0.0%)	5(0.2%)
Traumatic fracture	1(0.0%)	5(0.2%)
Animal bite	1(0.0%)	4(0.2%)
Arteriovenous fistula site complication	1(0.0%)	3(0.1%)
Burns second degree	1(0.0%)	3(0.1%)
Heat stroke	1(0.0%)	3(0.1%)
Subcutaneous haematoma	1(0.0%)	3(0.1%)
Lip injury	1(0.0%)	2(0.1%)
Lumbar vertebral fracture	1(0.0%)	2(0.1%)
Muscle injury	1(0.0%)	2(0.1%)
Spinal fracture	1(0.0%)	2(0.1%)
Chillblains	1(0.0%)	1(0.0%)
Dislocation of vertebra	1(0.0%)	1(0.0%)
Exposure to communicable disease	1(0.0%)	1(0.0%)
Foreign body in throat	1(0.0%)	1(0.0%)
Fractured coccyx	1(0.0%)	1(0.0%)
Ligament rupture	1(0.0%)	1(0.0%)
Multiple fractures	1(0.0%)	1(0.0%)
Pelvic fracture	1(0.0%)	1(0.0%)
Scar	1(0.0%)	1(0.0%)
Spinal cord injury cervical	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Thoracic vertebral fracture	1(0.0%)	1(0.0%)
Abdominal wound dehiscence	1(0.0%)	0
Asbestosis	1(0.0%)	0
Avulsion fracture	1(0.0%)	0
Barotrauma	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Cataract operation complication	1(0.0%)	0
Colon injury	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Ear canal injury	1(0.0%)	0
Extradural haematoma	1(0.0%)	0
Foreign body in ear	1(0.0%)	0
Foreign body in eye	1(0.0%)	0
Foreign body in gastrointestinal tract	1(0.0%)	0
Hyphaema	1(0.0%)	0
Incision site complication	1(0.0%)	0
Incision site haematoma	1(0.0%)	0
Incision site inflammation	1(0.0%)	0
Injury corneal	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Ligament injury	1(0.0%)	0
Mallet finger	1(0.0%)	0
Muscle contusion	1(0.0%)	0
Musculoskeletal injury	1(0.0%)	0
Nail injury	1(0.0%)	0
Nerve root injury lumbar	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Peripheral nerve injury	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Post procedural haematoma	1(0.0%)	0
Post procedural haematuria	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radial head dislocation	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Scrotal injury	1(0.0%)	0
Snake bite	1(0.0%)	0
Superficial injury of eye	1(0.0%)	0
Synovial rupture	1(0.0%)	0
Tongue injury	1(0.0%)	0
Traumatic arthritis	1(0.0%)	0
Urinary retention postoperative	1(0.0%)	0
Urostomy complication	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Vascular access steal syndrome	1(0.0%)	0
Wound dehiscence	1(0.0%)	0
Wound haemorrhage	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Incision site pain	0	4(0.2%)
Skin injury	0	4(0.2%)
Traumatic haematoma	0	4(0.2%)
Nasal injury	0	3(0.1%)
Post procedural haemorrhage	0	3(0.1%)
Seroma	0	3(0.1%)
Alcohol poisoning	0	2(0.1%)
Procedural haemorrhage	0	2(0.1%)
Spinal column injury	0	2(0.1%)
Abdominal injury	0	1(0.0%)
Acetabulum fracture	0	1(0.0%)
Animal scratch	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Bite	0	1(0.0%)
Burns third degree	0	1(0.0%)
Cold burn	0	1(0.0%)
Compression fracture	0	1(0.0%)
Dental restoration failure	0	1(0.0%)
Eye contusion	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Fracture	0	1(0.0%)
Fractured sacrum	0	1(0.0%)
Gastroenteritis radiation	0	1(0.0%)
Iliotibial band syndrome	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Incorrect dose administered	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Open globe injury	0	1(0.0%)
Pelvic bone injury	0	1(0.0%)
Pelvic organ injury	0	1(0.0%)
Penis injury	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural hypoparathyroidism	0	1(0.0%)
Post procedural hypothyroidism	0	1(0.0%)
Post procedural inflammation	0	1(0.0%)
Post-traumatic neck syndrome	0	1(0.0%)
Procedural nausea	0	1(0.0%)
Procedural vomiting	0	1(0.0%)
Reactive gastropathy	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Skull fracture	0	1(0.0%)
Stab wound	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Traumatic ulcer	0	1(0.0%)
Vascular pseudoaneurysm	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	422(16.1%)	418(16.0%)
Pruritus	101(3.9%)	69(2.6%)
Skin ulcer	58(2.2%)	60(2.3%)
Eczema	38(1.5%)	37(1.4%)
Rash	31(1.2%)	38(1.5%)
Diabetic foot	27(1.0%)	30(1.1%)
Dry skin	20(0.8%)	14(0.5%)
Dermatitis	17(0.6%)	18(0.7%)
Urticaria	16(0.6%)	13(0.5%)
Hyperkeratosis	11(0.4%)	10(0.4%)
Dermatitis allergic	11(0.4%)	8(0.3%)
Erythema	8(0.3%)	14(0.5%)
Skin lesion	8(0.3%)	11(0.4%)
Dermal cyst	8(0.3%)	9(0.3%)
Stasis dermatitis	8(0.3%)	2(0.1%)
Skin disorder	8(0.3%)	0
Psoriasis	7(0.3%)	6(0.2%)
Ingrowing nail	7(0.3%)	4(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Alopecia	7(0.3%)	3(0.1%)
Decubitus ulcer	6(0.2%)	9(0.3%)
Actinic keratosis	6(0.2%)	8(0.3%)
Eczema asteatotic	6(0.2%)	8(0.3%)
Dermatitis atopic	6(0.2%)	5(0.2%)
Blister	5(0.2%)	14(0.5%)
Dermatitis contact	5(0.2%)	6(0.2%)
Drug eruption	5(0.2%)	6(0.2%)
Angioedema	5(0.2%)	3(0.1%)
Hand dermatitis	5(0.2%)	2(0.1%)
Hyperhidrosis	5(0.2%)	2(0.1%)
Acne	4(0.2%)	5(0.2%)
Neurodermatitis	3(0.1%)	3(0.1%)
Pemphigoid	3(0.1%)	3(0.1%)
Rash pruritic	3(0.1%)	3(0.1%)
Eczema nummular	3(0.1%)	2(0.1%)
Rash macular	3(0.1%)	2(0.1%)
Skin fissures	3(0.1%)	2(0.1%)
Xeroderma	3(0.1%)	2(0.1%)
Onychoclasis	3(0.1%)	1(0.0%)
Rosacea	3(0.1%)	1(0.0%)
Skin exfoliation	3(0.1%)	1(0.0%)
Erythema nodosum	3(0.1%)	0
Seborrhoeic dermatitis	2(0.1%)	7(0.3%)
Dermatitis bullous	2(0.1%)	3(0.1%)
Intertrigo	2(0.1%)	2(0.1%)
Skin hyperpigmentation	2(0.1%)	2(0.1%)
Hidradenitis	2(0.1%)	1(0.0%)
Palmoplantar keratoderma	2(0.1%)	1(0.0%)
Skin mass	2(0.1%)	1(0.0%)
Blood blister	2(0.1%)	0
Nail dystrophy	2(0.1%)	0
Papule	2(0.1%)	0
Skin necrosis	2(0.1%)	0
Prurigo	1(0.0%)	5(0.2%)
Ecchymosis	1(0.0%)	4(0.2%)
Pigmentation disorder	1(0.0%)	3(0.1%)
Dermatosis	1(0.0%)	2(0.1%)
Diabetic ulcer	1(0.0%)	2(0.1%)
Dyshidrotic eczema	1(0.0%)	2(0.1%)
Petechiae	1(0.0%)	2(0.1%)
Rash erythematous	1(0.0%)	2(0.1%)
Rash papular	1(0.0%)	2(0.1%)
Haemorrhage subcutaneous	1(0.0%)	1(0.0%)
Neuropathic ulcer	1(0.0%)	1(0.0%)
Night sweats	1(0.0%)	1(0.0%)
Onycholysis	1(0.0%)	1(0.0%)
Rash maculo-papular	1(0.0%)	1(0.0%)
Skin haemorrhage	1(0.0%)	1(0.0%)
Alopecia scarring	1(0.0%)	0
Androgenetic alopecia	1(0.0%)	0
Angiodermatitis	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Dandruff	1(0.0%)	0
Dermatitis exfoliative	1(0.0%)	0
Dermatitis herpetiformis	1(0.0%)	0
Diffuse alopecia	1(0.0%)	0
Itching scar	1(0.0%)	0
Lichen planus	1(0.0%)	0
Lichen sclerosus	1(0.0%)	0
Lichenoid keratosis	1(0.0%)	0
Myxoid cyst	1(0.0%)	0
Nail bed inflammation	1(0.0%)	0
Nail disorder	1(0.0%)	0
Photosensitivity reaction	1(0.0%)	0
Pruritus allergic	1(0.0%)	0
Reactive perforating collagenosis	1(0.0%)	0
Skin discomfort	1(0.0%)	0
Skin reaction	1(0.0%)	0
Vitiligo	1(0.0%)	0
Asteatosis	0	2(0.1%)
Erythema multiforme	0	2(0.1%)
Purpura	0	2(0.1%)
Skin discolouration	0	2(0.1%)
Skin irritation	0	2(0.1%)
Skin oedema	0	2(0.1%)
Blister rupture	0	1(0.0%)
Cutaneous amyloidosis	0	1(0.0%)
Dermatomyositis	0	1(0.0%)
Diabetic dermopathy	0	1(0.0%)
Fracture blisters	0	1(0.0%)
Hangnail	0	1(0.0%)
Hypertrophic scar	0	1(0.0%)
Hypotrichosis	0	1(0.0%)
Ingrown hair	0	1(0.0%)
Ischaemic skin ulcer	0	1(0.0%)
Lentigo	0	1(0.0%)
Leukoderma	0	1(0.0%)
Leukoplakia	0	1(0.0%)
Lichen planopilaris	0	1(0.0%)
Lipodystrophy acquired	0	1(0.0%)
Lipohypertrophy	0	1(0.0%)
Miliaria	0	1(0.0%)
Pain of skin	0	1(0.0%)
Palmoplantar pustulosis	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Pustular psoriasis	0	1(0.0%)
Skin dystrophy	0	1(0.0%)
Skin erosion	0	1(0.0%)
Skin weeping	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Toxic skin eruption	0	1(0.0%)
Eye Disorders	316(12.1%)	354(13.6%)
Cataract	116(4.4%)	116(4.4%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Diabetic retinopathy	42(1.6%)	65(2.5%)
Vitreous haemorrhage	28(1.1%)	29(1.1%)
Glaucoma	23(0.9%)	21(0.8%)
Dry eye	16(0.6%)	20(0.8%)
Visual impairment	16(0.6%)	13(0.5%)
Macular oedema	12(0.5%)	11(0.4%)
Conjunctival haemorrhage	9(0.3%)	8(0.3%)
Vision blurred	8(0.3%)	11(0.4%)
Diabetic retinal oedema	7(0.3%)	8(0.3%)
Conjunctivitis allergic	7(0.3%)	6(0.2%)
Retinal haemorrhage	5(0.2%)	13(0.5%)
Blepharitis	5(0.2%)	5(0.2%)
Retinopathy hypertensive	5(0.2%)	5(0.2%)
Diplopia	5(0.2%)	3(0.1%)
Eye haemorrhage	5(0.2%)	2(0.1%)
Maculopathy	5(0.2%)	2(0.1%)
Ocular hypertension	5(0.2%)	2(0.1%)
Retinal vein occlusion	5(0.2%)	1(0.0%)
Retinopathy	4(0.2%)	5(0.2%)
Posterior capsule opacification	4(0.2%)	2(0.1%)
Open angle glaucoma	4(0.2%)	1(0.0%)
Keratitis	3(0.1%)	4(0.2%)
Eye pruritus	3(0.1%)	3(0.1%)
Refraction disorder	3(0.1%)	2(0.1%)
Cataract nuclear	3(0.1%)	1(0.0%)
Chalazion	3(0.1%)	1(0.0%)
Age-related macular degeneration	3(0.1%)	0
Meibomian gland dysfunction	3(0.1%)	0
Ocular hyperaemia	3(0.1%)	0
Eye pain	2(0.1%)	6(0.2%)
Retinal detachment	2(0.1%)	6(0.2%)
Blindness unilateral	2(0.1%)	5(0.2%)
Macular fibrosis	2(0.1%)	5(0.2%)
Vitreous floaters	2(0.1%)	4(0.2%)
Vitreous opacities	2(0.1%)	3(0.1%)
Eyelid ptosis	2(0.1%)	2(0.1%)
Tractional retinal detachment	2(0.1%)	2(0.1%)
Non-proliferative retinopathy	2(0.1%)	1(0.0%)
Periorbital swelling	2(0.1%)	1(0.0%)
Polypoidal choroidal vasculopathy	2(0.1%)	0
Visual acuity reduced	2(0.1%)	0
Macular degeneration	1(0.0%)	5(0.2%)
Eyelid oedema	1(0.0%)	4(0.2%)
Dacryostenosis acquired	1(0.0%)	3(0.1%)
Presbyopia	1(0.0%)	3(0.1%)
Cystoid macular oedema	1(0.0%)	2(0.1%)
Ectropion	1(0.0%)	2(0.1%)
Iritis	1(0.0%)	2(0.1%)
Retinal oedema	1(0.0%)	2(0.1%)
Ulcerative keratitis	1(0.0%)	2(0.1%)
Vitreous detachment	1(0.0%)	2(0.1%)
Xerophthalmia	1(0.0%)	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Astigmatism	1(0.0%)	1(0.0%)
Cataract subcapsular	1(0.0%)	1(0.0%)
Entropion	1(0.0%)	1(0.0%)
Eye irritation	1(0.0%)	1(0.0%)
Eyelid cyst	1(0.0%)	1(0.0%)
Keratopathy	1(0.0%)	1(0.0%)
Lacrimation increased	1(0.0%)	1(0.0%)
Lens dislocation	1(0.0%)	1(0.0%)
Optic disc haemorrhage	1(0.0%)	1(0.0%)
Periorbital oedema	1(0.0%)	1(0.0%)
Photophobia	1(0.0%)	1(0.0%)
Retinal degeneration	1(0.0%)	1(0.0%)
Retinal neovascularisation	1(0.0%)	1(0.0%)
Retinopathy proliferative	1(0.0%)	1(0.0%)
Scleral haemorrhage	1(0.0%)	1(0.0%)
Vitreoretinal traction syndrome	1(0.0%)	1(0.0%)
Asthenopia	1(0.0%)	0
Atrophy of globe	1(0.0%)	0
Conjunctival disorder	1(0.0%)	0
Conjunctival oedema	1(0.0%)	0
Corneal epithelium defect	1(0.0%)	0
Corneal erosion	1(0.0%)	0
Dermatochalasis	1(0.0%)	0
Dry age-related macular degeneration	1(0.0%)	0
Erythema of eyelid	1(0.0%)	0
Eye disorder	1(0.0%)	0
Eye inflammation	1(0.0%)	0
Retinal deposits	1(0.0%)	0
Staphyloma	1(0.0%)	0
Sudden visual loss	1(0.0%)	0
Trichiasis	1(0.0%)	0
Eye discharge	0	5(0.2%)
Amaurosis fugax	0	3(0.1%)
Meibomianitis	0	3(0.1%)
Pterygium	0	3(0.1%)
Arteriosclerotic retinopathy	0	2(0.1%)
Blindness	0	2(0.1%)
Iridocyclitis	0	2(0.1%)
Ocular discomfort	0	2(0.1%)
Amblyopia	0	1(0.0%)
Angle closure glaucoma	0	1(0.0%)
Blepharitis allergic	0	1(0.0%)
Borderline glaucoma	0	1(0.0%)
Cataract diabetic	0	1(0.0%)
Chorioretinal atrophy	0	1(0.0%)
Conjunctival hyperaemia	0	1(0.0%)
Corneal disorder	0	1(0.0%)
Corneal oedema	0	1(0.0%)
Endocrine ophthalmopathy	0	1(0.0%)
Extraocular muscle paresis	0	1(0.0%)
Eye allergy	0	1(0.0%)
Eye oedema	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Glaucomatous optic disc atrophy	0	1(0.0%)
Hypermetropia	0	1(0.0%)
Iris disorder	0	1(0.0%)
Keratoconus	0	1(0.0%)
Lenticular opacities	0	1(0.0%)
Macular hole	0	1(0.0%)
Macular rupture	0	1(0.0%)
Metamorphopsia	0	1(0.0%)
Optic disc disorder	0	1(0.0%)
Orbital oedema	0	1(0.0%)
Papilloedema	0	1(0.0%)
Retinal artery embolism	0	1(0.0%)
Retinal artery occlusion	0	1(0.0%)
Retinal tear	0	1(0.0%)
Retinal vascular occlusion	0	1(0.0%)
Rhegmatogenous retinal detachment	0	1(0.0%)
Strabismus	0	1(0.0%)
Uveitis	0	1(0.0%)
Blood And Lymphatic System Disorders	295(11.3%)	283(10.8%)
Anaemia	200(7.6%)	181(6.9%)
Nephrogenic anaemia	30(1.1%)	26(1.0%)
Iron deficiency anaemia	27(1.0%)	28(1.1%)
Thrombocytopenia	13(0.5%)	13(0.5%)
Lymphadenopathy	8(0.3%)	7(0.3%)
Blood loss anaemia	8(0.3%)	3(0.1%)
Thrombocytosis	4(0.2%)	7(0.3%)
Leukocytosis	4(0.2%)	5(0.2%)
Hypochromic anaemia	4(0.2%)	3(0.1%)
Microcytic anaemia	3(0.1%)	4(0.2%)
Normocytic anaemia	3(0.1%)	4(0.2%)
Splenomegaly	2(0.1%)	5(0.2%)
Polycythaemia	2(0.1%)	4(0.2%)
Pancytopenia	2(0.1%)	3(0.1%)
Lymphadenitis	2(0.1%)	1(0.0%)
Anaemia macrocytic	2(0.1%)	0
Normochromic normocytic anaemia	1(0.0%)	4(0.2%)
Lymphadenopathy mediastinal	1(0.0%)	2(0.1%)
Anaemia folate deficiency	1(0.0%)	1(0.0%)
Macrocytosis	1(0.0%)	1(0.0%)
Normochromic anaemia	1(0.0%)	1(0.0%)
Immune thrombocytopenia	1(0.0%)	0
Lymph node pain	1(0.0%)	0
Retroperitoneal lymphadenopathy	1(0.0%)	0
Anaemia megaloblastic	0	1(0.0%)
Anaemia of chronic disease	0	1(0.0%)
Anaemia of malignant disease	0	1(0.0%)
B-lymphocyte abnormalities	0	1(0.0%)
Bone marrow oedema	0	1(0.0%)
Coagulopathy	0	1(0.0%)
Eosinophilia	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Haemoglobinaemia	0	1(0.0%)
Hyperviscosity syndrome	0	1(0.0%)
Increased tendency to bruise	0	1(0.0%)
Neutropenia	0	1(0.0%)
Spleen disorder	0	1(0.0%)
Cardiac Disorders	287(11.0%)	373(14.3%)
Cardiac failure	25(1.0%)	49(1.9%)
Angina pectoris	23(0.9%)	32(1.2%)
Coronary artery disease	23(0.9%)	26(1.0%)
Myocardial ischaemia	21(0.8%)	26(1.0%)
Ventricular extrasystoles	19(0.7%)	19(0.7%)
Cardiac failure congestive	16(0.6%)	30(1.1%)
Atrioventricular block first degree	15(0.6%)	12(0.5%)
Palpitations	14(0.5%)	26(1.0%)
Bradycardia	14(0.5%)	23(0.9%)
Sinus bradycardia	14(0.5%)	14(0.5%)
Bundle branch block left	13(0.5%)	5(0.2%)
Supraventricular extrasystoles	12(0.5%)	9(0.3%)
Atrial fibrillation	11(0.4%)	22(0.8%)
Mitral valve incompetence	11(0.4%)	20(0.8%)
Arteriosclerosis coronary artery	11(0.4%)	8(0.3%)
Tachycardia	10(0.4%)	9(0.3%)
Atrioventricular block second degree	10(0.4%)	5(0.2%)
Cardiac failure chronic	8(0.3%)	25(1.0%)
Tricuspid valve incompetence	8(0.3%)	10(0.4%)
Hypertensive heart disease	8(0.3%)	3(0.1%)
Left ventricular hypertrophy	7(0.3%)	15(0.6%)
Bundle branch block right	7(0.3%)	10(0.4%)
Left ventricular dysfunction	6(0.2%)	4(0.2%)
Atrial flutter	6(0.2%)	3(0.1%)
Diastolic dysfunction	5(0.2%)	10(0.4%)
Aortic valve stenosis	5(0.2%)	6(0.2%)
Arrhythmia	5(0.2%)	6(0.2%)
Angina unstable	4(0.2%)	14(0.5%)
Aortic valve incompetence	4(0.2%)	9(0.3%)
Pericardial effusion	4(0.2%)	7(0.3%)
Coronary artery stenosis	4(0.2%)	5(0.2%)
Sinus tachycardia	4(0.2%)	4(0.2%)
Sinus node dysfunction	4(0.2%)	2(0.1%)
Cardiomegaly	3(0.1%)	7(0.3%)
Ischaemic cardiomyopathy	3(0.1%)	4(0.2%)
Ventricular tachycardia	3(0.1%)	3(0.1%)
Congestive cardiomyopathy	3(0.1%)	2(0.1%)
Ventricular hypokinesia	3(0.1%)	2(0.1%)
Atrioventricular block	2(0.1%)	4(0.2%)
Supraventricular tachycardia	2(0.1%)	3(0.1%)
Left ventricular failure	2(0.1%)	2(0.1%)
Myocardial fibrosis	2(0.1%)	2(0.1%)
Acute left ventricular failure	2(0.1%)	1(0.0%)
Aortic valve sclerosis	2(0.1%)	1(0.0%)
Arrhythmia supraventricular	2(0.1%)	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Sinus arrhythmia	2(0.1%)	1(0.0%)
Cardio-respiratory arrest	2(0.1%)	0
Acute coronary syndrome	1(0.0%)	5(0.2%)
Extrasystoles	1(0.0%)	5(0.2%)
Cardiac failure acute	1(0.0%)	4(0.2%)
Left atrial dilatation	1(0.0%)	4(0.2%)
Aortic valve disease mixed	1(0.0%)	2(0.1%)
Cardiac asthma	1(0.0%)	2(0.1%)
Myocardial infarction	1(0.0%)	2(0.1%)
Wandering pacemaker	1(0.0%)	2(0.1%)
Aortic valve calcification	1(0.0%)	1(0.0%)
Chronic left ventricular failure	1(0.0%)	1(0.0%)
Degenerative aortic valve disease	1(0.0%)	1(0.0%)
Degenerative mitral valve disease	1(0.0%)	1(0.0%)
Mitral valve calcification	1(0.0%)	1(0.0%)
Mitral valve sclerosis	1(0.0%)	1(0.0%)
Mitral valve stenosis	1(0.0%)	1(0.0%)
Pericarditis	1(0.0%)	1(0.0%)
Aortic valve disease	1(0.0%)	0
Atrial enlargement	1(0.0%)	0
Atrial tachycardia	1(0.0%)	0
Bifascicular block	1(0.0%)	0
Cardiac discomfort	1(0.0%)	0
Coronary ostial stenosis	1(0.0%)	0
Myocarditis	1(0.0%)	0
Pericarditis adhesive	1(0.0%)	0
Rhythm idioventricular	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Tachyarrhythmia	1(0.0%)	0
Wellens' syndrome	1(0.0%)	0
Left atrial enlargement	0	5(0.2%)
Atrial thrombosis	0	2(0.1%)
Cardiac arrest	0	2(0.1%)
Cardiac valve disease	0	2(0.1%)
Cardiomyopathy	0	2(0.1%)
Left ventricular dilatation	0	2(0.1%)
Mitral valve disease	0	2(0.1%)
Pulmonary valve incompetence	0	2(0.1%)
Systolic dysfunction	0	2(0.1%)
Acute myocardial infarction	0	1(0.0%)
Atrial conduction time prolongation	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Bundle branch block	0	1(0.0%)
Cardiac amyloidosis	0	1(0.0%)
Cardiac aneurysm	0	1(0.0%)
Cardiac disorder	0	1(0.0%)
Cardiac hypertrophy	0	1(0.0%)
Cardiac valve thickening	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Conduction disorder	0	1(0.0%)
Coronary artery occlusion	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Diabetic cardiomyopathy	0	1(0.0%)
Hypertensive cardiomyopathy	0	1(0.0%)
Left atrial hypertrophy	0	1(0.0%)
Metabolic cardiomyopathy	0	1(0.0%)
Paroxysmal arrhythmia	0	1(0.0%)
Pericardial disease	0	1(0.0%)
Right ventricular dilatation	0	1(0.0%)
Right ventricular failure	0	1(0.0%)
Ventricular arrhythmia	0	1(0.0%)
Ventricular remodelling	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	189(7.2%)	183(7.0%)
Basal cell carcinoma	17(0.6%)	15(0.6%)
Prostate cancer	16(0.6%)	9(0.3%)
Colon adenoma	11(0.4%)	11(0.4%)
Skin papilloma	9(0.3%)	7(0.3%)
Lung neoplasm malignant	9(0.3%)	5(0.2%)
Haemangioma of liver	8(0.3%)	5(0.2%)
Squamous cell carcinoma of skin	7(0.3%)	4(0.2%)
Breast cancer	6(0.2%)	5(0.2%)
Bladder cancer	5(0.2%)	5(0.2%)
Renal neoplasm	5(0.2%)	4(0.2%)
Adenoma benign	5(0.2%)	3(0.1%)
Bladder neoplasm	5(0.2%)	1(0.0%)
Malignant melanoma	4(0.2%)	7(0.3%)
Colon cancer	4(0.2%)	4(0.2%)
Uterine leiomyoma	4(0.2%)	4(0.2%)
Clear cell renal cell carcinoma	4(0.2%)	1(0.0%)
Metastases to lung	4(0.2%)	1(0.0%)
Adrenal adenoma	3(0.1%)	2(0.1%)
Seborrhoeic keratosis	3(0.1%)	1(0.0%)
Metastases to spine	3(0.1%)	0
Oesophageal adenocarcinoma	3(0.1%)	0
Lipoma	2(0.1%)	9(0.3%)
Adenocarcinoma of colon	2(0.1%)	3(0.1%)
Hepatocellular carcinoma	2(0.1%)	3(0.1%)
Pancreatic carcinoma	2(0.1%)	2(0.1%)
Bladder cancer recurrent	2(0.1%)	1(0.0%)
Metastases to bone	2(0.1%)	1(0.0%)
Neoplasm	2(0.1%)	1(0.0%)
Renal cell carcinoma	2(0.1%)	1(0.0%)
Benign lung neoplasm	2(0.1%)	0
Hypergammaglobulinaemia benign monoclonal	2(0.1%)	0
Skin cancer	2(0.1%)	0
Squamous cell carcinoma of the oral cavity	2(0.1%)	0
Metastases to liver	1(0.0%)	5(0.2%)
Prostatic adenoma	1(0.0%)	4(0.2%)
Breast neoplasm	1(0.0%)	3(0.1%)
Metastases to lymph nodes	1(0.0%)	3(0.1%)
Plasma cell myeloma	1(0.0%)	3(0.1%)
Salivary gland neoplasm	1(0.0%)	3(0.1%)
Adenocarcinoma	1(0.0%)	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Anogenital warts	1(0.0%)	2(0.1%)
Renal cancer	1(0.0%)	2(0.1%)
Renal hamartoma	1(0.0%)	2(0.1%)
Squamous cell carcinoma	1(0.0%)	2(0.1%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Hepatic neoplasm	1(0.0%)	1(0.0%)
Infected neoplasm	1(0.0%)	1(0.0%)
Large intestine benign neoplasm	1(0.0%)	1(0.0%)
Lipofibroma	1(0.0%)	1(0.0%)
Metastases to central nervous system	1(0.0%)	1(0.0%)
Monoclonal gammopathy	1(0.0%)	1(0.0%)
Papilloma	1(0.0%)	1(0.0%)
Rectal adenocarcinoma	1(0.0%)	1(0.0%)
Transitional cell carcinoma	1(0.0%)	1(0.0%)
Angiomyofibroblastoma	1(0.0%)	0
Angiomyolipoma	1(0.0%)	0
Benign bone neoplasm	1(0.0%)	0
Benign gastric neoplasm	1(0.0%)	0
Benign neoplasm of thyroid gland	1(0.0%)	0
Benign renal neoplasm	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Brain neoplasm malignant	1(0.0%)	0
Breast cancer metastatic	1(0.0%)	0
Cancer pain	1(0.0%)	0
Cholangiocarcinoma	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Dermatofibrosarcoma protuberans	1(0.0%)	0
Endometrial adenocarcinoma	1(0.0%)	0
Eye naevus	1(0.0%)	0
Fallopian tube leiomyoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Gastrointestinal stromal tumour	1(0.0%)	0
Haemangioma	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Inflammatory carcinoma of the breast	1(0.0%)	0
Intraocular melanoma	1(0.0%)	0
Keratoacanthoma	1(0.0%)	0
Laryngeal squamous cell carcinoma	1(0.0%)	0
Light chain disease	1(0.0%)	0
Lip and/or oral cavity cancer stage 0	1(0.0%)	0
Lip squamous cell carcinoma	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Lymphoma	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0
Malignant pleural effusion	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Muscle neoplasm	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Neuroendocrine tumour	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Oesophageal carcinoma	1(0.0%)	0
Oesophageal neoplasm	1(0.0%)	0
Oral papilloma	1(0.0%)	0
Pancreatic neoplasm	1(0.0%)	0
Polycythaemia vera	1(0.0%)	0
Prostate cancer metastatic	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Acrochordon	0	3(0.1%)
Small cell lung cancer	0	3(0.1%)
Acute myeloid leukaemia	0	2(0.1%)
Adenocarcinoma gastric	0	2(0.1%)
Brain neoplasm	0	2(0.1%)
Gastric cancer	0	2(0.1%)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Melanocytic naevus	0	2(0.1%)
Acoustic neuroma	0	1(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal neoplasm	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign hepatic neoplasm	0	1(0.0%)
Benign pancreatic neoplasm	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Carcinoma in situ of skin	0	1(0.0%)
Chronic lymphocytic leukaemia	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Eyelid tumour	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Ganglioneuroma	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Haemangioma of bone	0	1(0.0%)
Intraductal papillary-mucinous carcinoma of pancreas	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Lung adenocarcinoma	0	1(0.0%)
Lymphocytic leukaemia	0	1(0.0%)
Malignant melanoma in situ	0	1(0.0%)
Meningioma	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Metastases to spleen	0	1(0.0%)
Myelodysplastic syndrome	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Pancreatic carcinoma metastatic	0	1(0.0%)
Pancreatic carcinoma stage IV	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Pleomorphic adenoma	0	1(0.0%)
Rectal adenoma	0	1(0.0%)
Renal adenoma	0	1(0.0%)
Schwannoma	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Soft tissue neoplasm	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Sweat gland tumour	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Vulvovaginal warts	0	1(0.0%)
Waldenstrom's macroglobulinaemia	0	1(0.0%)
Surgical And Medical Procedures	172(6.6%)	181(6.9%)
Cataract operation	36(1.4%)	45(1.7%)
Tooth extraction	17(0.6%)	19(0.7%)
Toe amputation	8(0.3%)	6(0.2%)
Large intestinal polypectomy	7(0.3%)	5(0.2%)
Intraocular lens implant	6(0.2%)	5(0.2%)
Skin neoplasm excision	6(0.2%)	1(0.0%)
Vitrectomy	5(0.2%)	10(0.4%)
Knee arthroplasty	5(0.2%)	8(0.3%)
Arteriovenous fistula operation	5(0.2%)	3(0.1%)
Polypectomy	4(0.2%)	3(0.1%)
Diabetes mellitus management	4(0.2%)	1(0.0%)
Hip arthroplasty	3(0.1%)	7(0.3%)
Cholecystectomy	3(0.1%)	3(0.1%)
Endodontic procedure	3(0.1%)	1(0.0%)
Foot operation	3(0.1%)	0
Haemodialysis	2(0.1%)	2(0.1%)
Carpal tunnel decompression	2(0.1%)	1(0.0%)
Prostatectomy	2(0.1%)	1(0.0%)
Cardiac pacemaker insertion	2(0.1%)	0
Dialysis	2(0.1%)	0
Eye laser surgery	2(0.1%)	0
Eye operation	2(0.1%)	0
Gastric bypass	2(0.1%)	0
Hysterectomy	2(0.1%)	0
Leg amputation	2(0.1%)	0
Parathyroidectomy	2(0.1%)	0
Rehabilitation therapy	2(0.1%)	0
Skin graft	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Dental implantation	1(0.0%)	3(0.1%)
Lens extraction	1(0.0%)	3(0.1%)
Umbilical hernia repair	1(0.0%)	3(0.1%)
Coronary angioplasty	1(0.0%)	2(0.1%)
Debridement	1(0.0%)	2(0.1%)
Dialysis device insertion	1(0.0%)	2(0.1%)
Foot amputation	1(0.0%)	2(0.1%)
Gastrectomy	1(0.0%)	2(0.1%)
Spinal operation	1(0.0%)	2(0.1%)
Blepharoplasty	1(0.0%)	1(0.0%)
Colectomy	1(0.0%)	1(0.0%)
Glaucoma drainage device placement	1(0.0%)	1(0.0%)
Metabolic surgery	1(0.0%)	1(0.0%)
Peripheral artery stent insertion	1(0.0%)	1(0.0%)
Pterygium operation	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Skin lesion removal	1(0.0%)	1(0.0%)
Tenotomy	1(0.0%)	1(0.0%)
Aneurysm repair	1(0.0%)	0
Aortic valve replacement	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Cerumen removal	1(0.0%)	0
Coronary artery bypass	1(0.0%)	0
Dental operation	1(0.0%)	0
Epidural injection	1(0.0%)	0
Femoral hernia repair	1(0.0%)	0
Finger amputation	1(0.0%)	0
Fistula repair	1(0.0%)	0
Implantable defibrillator insertion	1(0.0%)	0
Inguinal hernia repair	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Intra-ocular injection	1(0.0%)	0
Lens capsulotomy	1(0.0%)	0
Mass excision	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Medical device removal	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nail operation	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Nerve block	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Orthopaedic procedure	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Papilloma excision	1(0.0%)	0
Parotidectomy	1(0.0%)	0
Preoperative care	1(0.0%)	0
Radical mastectomy	1(0.0%)	0
Radical prostatectomy	1(0.0%)	0
Removal of foreign body from eye	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Spinal decompression	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Tenolysis	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Tooth repair	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Vasectomy	1(0.0%)	0
Wound treatment	1(0.0%)	0
Tendon sheath incision	0	3(0.1%)
Insertion of ambulatory peritoneal catheter	0	2(0.1%)
Retinopexy	0	2(0.1%)
Sebaceous cyst excision	0	2(0.1%)
Amputation	0	1(0.0%)
Angioplasty	0	1(0.0%)
Antitussive therapy	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Artificial crown procedure	0	1(0.0%)
Astringent therapy	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cardioversion	0	1(0.0%)
Circumcision	0	1(0.0%)
Colon operation	0	1(0.0%)
Colostomy	0	1(0.0%)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Cystostomy	0	1(0.0%)
Dermal filler injection	0	1(0.0%)
Ear tube insertion	0	1(0.0%)
Eye excision	0	1(0.0%)
Eyelid operation	0	1(0.0%)
Facial lesion excision	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Glaucoma surgery	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Hydrocele operation	0	1(0.0%)
Intervertebral disc operation	0	1(0.0%)
Laser therapy	0	1(0.0%)
Limb operation	0	1(0.0%)
Lipoma excision	0	1(0.0%)
Matrixectomy	0	1(0.0%)
Meniscus operation	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Percutaneous coronary intervention	0	1(0.0%)
Peripheral artery bypass	0	1(0.0%)
Pharyngeal polypectomy	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Retinal operation	0	1(0.0%)
Sclerotherapy	0	1(0.0%)
Stent placement	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Transurethral bladder resection	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Urinary cystectomy	0	1(0.0%)
Vascular catheterisation	0	1(0.0%)
Vascular graft	0	1(0.0%)
Wisdom teeth removal	0	1(0.0%)
Psychiatric Disorders	139(5.3%)	183(7.0%)
Insomnia	59(2.3%)	62(2.4%)
Depression	27(1.0%)	43(1.6%)
Anxiety	20(0.8%)	29(1.1%)
Sleep disorder	8(0.3%)	10(0.4%)
Confusional state	4(0.2%)	5(0.2%)
Major depression	4(0.2%)	1(0.0%)
Delirium	3(0.1%)	6(0.2%)
Hallucination	3(0.1%)	4(0.2%)
Mental status changes	3(0.1%)	3(0.1%)
Stress	2(0.1%)	4(0.2%)
Disorientation	2(0.1%)	1(0.0%)
Bipolar disorder	2(0.1%)	0
Personality change due to a general medical condition	2(0.1%)	0
Restlessness	2(0.1%)	0
Depressed mood	1(0.0%)	10(0.4%)
Aggression	1(0.0%)	1(0.0%)
Initial insomnia	1(0.0%)	1(0.0%)
Neurosis	1(0.0%)	1(0.0%)
Abnormal behaviour	1(0.0%)	0
Affective disorder	1(0.0%)	0
Agitation	1(0.0%)	0
Alcohol abuse	1(0.0%)	0
Alcohol withdrawal syndrome	1(0.0%)	0
Drug dependence	1(0.0%)	0
Grief reaction	1(0.0%)	0
Mania	1(0.0%)	0
Nervousness	1(0.0%)	0
Nightmare	1(0.0%)	0
Persistent depressive disorder	1(0.0%)	0
Phonophobia	1(0.0%)	0
Psychotic disorder	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Tension	1(0.0%)	0
Anxiety disorder	0	3(0.1%)
Mixed anxiety and depressive disorder	0	3(0.1%)
Adjustment disorder with depressed mood	0	2(0.1%)
Mood altered	0	2(0.1%)
Panic disorder	0	2(0.1%)
Post-traumatic stress disorder	0	2(0.1%)
Suicidal ideation	0	2(0.1%)
Abulia	0	1(0.0%)
Acute stress disorder	0	1(0.0%)
Adjustment disorder	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Affect lability	0	1(0.0%)
Alcoholism	0	1(0.0%)
Anorgasmia	0	1(0.0%)
Apathy	0	1(0.0%)
Drug abuse	0	1(0.0%)
Dyssomnia	0	1(0.0%)
Enuresis	0	1(0.0%)
Executive dysfunction	0	1(0.0%)
Middle insomnia	0	1(0.0%)
Tobacco abuse	0	1(0.0%)
Reproductive System And Breast Disorders	113(4.3%)	130(5.0%)
Benign prostatic hyperplasia	47(1.8%)	46(1.8%)
Prostatomegaly	8(0.3%)	15(0.6%)
Erectile dysfunction	7(0.3%)	13(0.5%)
Gynaecomastia	6(0.2%)	5(0.2%)
Breast pain	5(0.2%)	3(0.1%)
Pelvic pain	5(0.2%)	2(0.1%)
Prostatitis	4(0.2%)	4(0.2%)
Uterine haemorrhage	3(0.1%)	2(0.1%)
Postmenopausal haemorrhage	3(0.1%)	1(0.0%)
Vaginal haemorrhage	3(0.1%)	1(0.0%)
Breast mass	2(0.1%)	4(0.2%)
Prostatism	2(0.1%)	4(0.2%)
Prostatic calcification	2(0.1%)	3(0.1%)
Cervical dysplasia	2(0.1%)	2(0.1%)
Uterine polyp	2(0.1%)	1(0.0%)
Vulvovaginal pruritus	2(0.1%)	1(0.0%)
Prostatic mass	2(0.1%)	0
Endometrial hyperplasia	1(0.0%)	3(0.1%)
Prostatic disorder	1(0.0%)	3(0.1%)
Fibrocystic breast disease	1(0.0%)	2(0.1%)
Metrorrhagia	1(0.0%)	2(0.1%)
Balanoposthitis	1(0.0%)	1(0.0%)
Breast cyst	1(0.0%)	1(0.0%)
Cystocele	1(0.0%)	1(0.0%)
Pelvic fluid collection	1(0.0%)	1(0.0%)
Uterine prolapse	1(0.0%)	1(0.0%)
Amenorrhoea	1(0.0%)	0
Atrophic vulvovaginitis	1(0.0%)	0
Breast discharge	1(0.0%)	0
Breast disorder	1(0.0%)	0
Cervical polyp	1(0.0%)	0
Ectropion of cervix	1(0.0%)	0
Pelvic haematoma	1(0.0%)	0
Penile pain	1(0.0%)	0
Sexual dysfunction	1(0.0%)	0
Testicular pain	1(0.0%)	0
Vaginal disorder	1(0.0%)	0
Ovarian cyst	0	4(0.2%)
Breast hyperplasia	0	3(0.1%)
Pruritus genital	0	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Adnexa uteri cyst	0	1(0.0%)
Breast calcifications	0	1(0.0%)
Breast dysplasia	0	1(0.0%)
Breast inflammation	0	1(0.0%)
Cervical cyst	0	1(0.0%)
Dysfunctional uterine bleeding	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Epididymal enlargement	0	1(0.0%)
Genital hypoaesthesia	0	1(0.0%)
Genital lesion	0	1(0.0%)
Genital tract inflammation	0	1(0.0%)
Menorrhagia	0	1(0.0%)
Nipple exudate bloody	0	1(0.0%)
Nipple inflammation	0	1(0.0%)
Nipple pain	0	1(0.0%)
Ovarian enlargement	0	1(0.0%)
Pelvic discomfort	0	1(0.0%)
Prostatic cyst	0	1(0.0%)
Scrotal oedema	0	1(0.0%)
Scrotal pain	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine mass	0	1(0.0%)
Ear And Labyrinth Disorders	112(4.3%)	94(3.6%)
Vertigo	51(1.9%)	37(1.4%)
Tinnitus	13(0.5%)	14(0.5%)
Hypoacusis	7(0.3%)	3(0.1%)
Deafness neurosensory	7(0.3%)	1(0.0%)
Ear pain	6(0.2%)	5(0.2%)
Vestibular disorder	6(0.2%)	3(0.1%)
Cerumen impaction	5(0.2%)	5(0.2%)
Deafness	5(0.2%)	4(0.2%)
Vertigo positional	5(0.2%)	4(0.2%)
Sudden hearing loss	4(0.2%)	3(0.1%)
Excessive cerumen production	3(0.1%)	4(0.2%)
Presbyacusis	3(0.1%)	1(0.0%)
Deafness unilateral	1(0.0%)	2(0.1%)
Aural polyp	1(0.0%)	0
Auricular pseudocyst	1(0.0%)	0
Conductive deafness	1(0.0%)	0
Inner ear disorder	1(0.0%)	0
Mixed deafness	1(0.0%)	0
Motion sickness	1(0.0%)	0
Deafness bilateral	0	5(0.2%)
Tympanic membrane perforation	0	2(0.1%)
Ear congestion	0	1(0.0%)
Eustachian tube dysfunction	0	1(0.0%)
Eustachian tube patulous	0	1(0.0%)
Meniere's disease	0	1(0.0%)
Neurosensory hypoacusis	0	1(0.0%)
Tympanic membrane hyperaemia	0	1(0.0%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Hepatobiliary Disorders	111(4.2%)	125(4.8%)
Cholelithiasis	37(1.4%)	33(1.3%)
Hepatic steatosis	28(1.1%)	46(1.8%)
Hepatic function abnormal	10(0.4%)	9(0.3%)
Cholecystitis	9(0.3%)	6(0.2%)
Hepatic cyst	6(0.2%)	4(0.2%)
Hepatic cirrhosis	5(0.2%)	6(0.2%)
Biliary colic	4(0.2%)	2(0.1%)
Hepatomegaly	4(0.2%)	2(0.1%)
Gallbladder polyp	4(0.2%)	1(0.0%)
Cholecystitis acute	3(0.1%)	8(0.3%)
Bile duct stone	3(0.1%)	2(0.1%)
Hepatitis	3(0.1%)	1(0.0%)
Cholangitis	2(0.1%)	4(0.2%)
Cholestasis	2(0.1%)	4(0.2%)
Hepatic lesion	2(0.1%)	2(0.1%)
Biliary obstruction	2(0.1%)	0
Hepatocellular injury	2(0.1%)	0
Nonalcoholic fatty liver disease	2(0.1%)	0
Cholecystitis chronic	1(0.0%)	4(0.2%)
Biliary dilatation	1(0.0%)	2(0.1%)
Drug-induced liver injury	1(0.0%)	2(0.1%)
Non-alcoholic steatohepatitis	1(0.0%)	2(0.1%)
Hepatitis acute	1(0.0%)	1(0.0%)
Biliary dyskinesia	1(0.0%)	0
Chronic hepatitis	1(0.0%)	0
Gallbladder cholesterolosis	1(0.0%)	0
Gallbladder disorder	1(0.0%)	0
Hepatic calcification	1(0.0%)	0
Hepatic fibrosis	1(0.0%)	0
Portal hypertension	1(0.0%)	0
Cholangitis acute	0	2(0.1%)
Hepatitis alcoholic	0	2(0.1%)
Congestive hepatopathy	0	1(0.0%)
Granulomatous liver disease	0	1(0.0%)
Hepatic mass	0	1(0.0%)
Hepatosplenomegaly	0	1(0.0%)
Hydrocholecystis	0	1(0.0%)
Hyperbilirubinaemia	0	1(0.0%)
Hyperplastic cholecystopathy	0	1(0.0%)
Hypertransaminasaemia	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver disorder	0	1(0.0%)
Endocrine Disorders	78(3.0%)	94(3.6%)
Hypothyroidism	26(1.0%)	28(1.1%)
Hyperparathyroidism secondary	18(0.7%)	14(0.5%)
Thyroid mass	9(0.3%)	11(0.4%)
Hyperparathyroidism	6(0.2%)	12(0.5%)
Hyperthyroidism	4(0.2%)	9(0.3%)
Adrenomegaly	3(0.1%)	0
Thyroid disorder	3(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Goitre	2(0.1%)	9(0.3%)
Euthyroid sick syndrome	2(0.1%)	1(0.0%)
Hypogonadism	2(0.1%)	1(0.0%)
Adrenal mass	1(0.0%)	2(0.1%)
Androgen deficiency	1(0.0%)	0
Basedow's disease	1(0.0%)	0
Empty sella syndrome	1(0.0%)	0
Hyperandrogenism	1(0.0%)	0
Hyperpituitarism	1(0.0%)	0
Hypoparathyroidism	1(0.0%)	0
Hypopituitarism	1(0.0%)	0
Thyroid cyst	0	4(0.2%)
Pituitary-dependent Cushing's syndrome	0	2(0.1%)
Adrenal disorder	0	1(0.0%)
Autoimmune thyroiditis	0	1(0.0%)
Hyperplasia adrenal	0	1(0.0%)
Hyperprolactinaemia	0	1(0.0%)
Primary hyperaldosteronism	0	1(0.0%)
Primary hypothyroidism	0	1(0.0%)
Thyroiditis	0	1(0.0%)
Immune System Disorders	22(0.8%)	21(0.8%)
Seasonal allergy	9(0.3%)	11(0.4%)
Hypersensitivity	7(0.3%)	6(0.2%)
Drug hypersensitivity	5(0.2%)	2(0.1%)
Food allergy	1(0.0%)	1(0.0%)
Selective IgM immunodeficiency	1(0.0%)	0
Contrast media allergy	0	1(0.0%)
Congenital, Familial And Genetic Disorders	14(0.5%)	13(0.5%)
Hydrocele	2(0.1%)	2(0.1%)
Congenital cystic kidney disease	2(0.1%)	0
Congenital renal cyst	2(0.1%)	0
Type V hyperlipidaemia	1(0.0%)	2(0.1%)
Hypertrophic cardiomyopathy	1(0.0%)	1(0.0%)
Phimosis	1(0.0%)	1(0.0%)
Arteriovenous malformation	1(0.0%)	0
Factor VIII deficiency	1(0.0%)	0
Keratosis follicular	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Ventricular septal defect	1(0.0%)	0
Adenomatous polyposis coli	0	1(0.0%)
Birth mark	0	1(0.0%)
Congenital poikiloderma	0	1(0.0%)
Dermoid cyst	0	1(0.0%)
Distichiasis	0	1(0.0%)
Hereditary palmoplantar keratoderma	0	1(0.0%)
Left-to-right cardiac shunt	0	1(0.0%)
Product Issues	3(0.1%)	4(0.2%)
Device malfunction	1(0.0%)	1(0.0%)
Device loosening	1(0.0%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Lead dislodgement	1(0.0%)	0
Device dislocation	0	2(0.1%)
Device leakage	0	1(0.0%)
Social Circumstances	1(0.0%)	1(0.0%)
Social stay hospitalisation	1(0.0%)	0
Pregnancy of partner	0	1(0.0%)
Pregnancy, Puerperium And Perinatal Conditions	0	1(0.0%)
Umbilical granuloma	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Any TEAE	837(32.0%)	904(34.6%)
Infections And Infestations	251(9.6%)	260(10.0%)
Pneumonia	65(2.5%)	101(3.9%)
Cellulitis	26(1.0%)	21(0.8%)
Urinary tract infection	18(0.7%)	22(0.8%)
Sepsis	15(0.6%)	16(0.6%)
Osteomyelitis	12(0.5%)	9(0.3%)
Erysipelas	11(0.4%)	11(0.4%)
Bronchitis	9(0.3%)	13(0.5%)
Gastroenteritis	9(0.3%)	13(0.5%)
Influenza	7(0.3%)	3(0.1%)
Localised infection	7(0.3%)	2(0.1%)
Pyelonephritis	6(0.2%)	4(0.2%)
Gangrene	5(0.2%)	5(0.2%)
Pulmonary sepsis	5(0.2%)	1(0.0%)
Pyelonephritis acute	5(0.2%)	0
Urosepsis	4(0.2%)	6(0.2%)
Diabetic foot infection	4(0.2%)	5(0.2%)
Lower respiratory tract infection	4(0.2%)	5(0.2%)
Wound infection	4(0.2%)	2(0.1%)
Septic shock	3(0.1%)	5(0.2%)
Respiratory tract infection	3(0.1%)	4(0.2%)
Abscess limb	3(0.1%)	1(0.0%)
Arthritis bacterial	3(0.1%)	0
Gastroenteritis viral	3(0.1%)	0
Liver abscess	2(0.1%)	5(0.2%)
Appendicitis	2(0.1%)	3(0.1%)
Infected skin ulcer	2(0.1%)	3(0.1%)
Pulmonary tuberculosis	2(0.1%)	2(0.1%)
Abdominal abscess	2(0.1%)	1(0.0%)
Bacteraemia	2(0.1%)	1(0.0%)
Herpes zoster	2(0.1%)	1(0.0%)
Orchitis	2(0.1%)	1(0.0%)
Staphylococcal sepsis	2(0.1%)	1(0.0%)
Tracheobronchitis	2(0.1%)	1(0.0%)
Viral infection	2(0.1%)	1(0.0%)
Appendicitis perforated	2(0.1%)	0
Clostridium difficile infection	2(0.1%)	0
Groin abscess	2(0.1%)	0
Infection	2(0.1%)	0
Otitis media	2(0.1%)	0
Pneumonia streptococcal	2(0.1%)	0
Pyelocystitis	2(0.1%)	0
Diverticulitis	1(0.0%)	5(0.2%)
Epididymitis	1(0.0%)	3(0.1%)
Pneumonia bacterial	1(0.0%)	2(0.1%)
Anal abscess	1(0.0%)	1(0.0%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Soft tissue infection	1(0.0%)	1(0.0%)
Borrelia infection	1(0.0%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Campylobacter gastroenteritis	1(0.0%)	0
Chronic sinusitis	1(0.0%)	0
Dengue fever	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Enteritis infectious	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
Fournier's gangrene	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infected bite	1(0.0%)	0
Infective spondylitis	1(0.0%)	0
Kidney infection	1(0.0%)	0
Labyrinthitis	1(0.0%)	0
Large intestine infection	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oral infection	1(0.0%)	0
Osteomyelitis chronic	1(0.0%)	0
Paronychia	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pharyngitis streptococcal	1(0.0%)	0
Postoperative wound infection	1(0.0%)	0
Prostatic abscess	1(0.0%)	0
Pyelonephritis chronic	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Sinusitis	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Subcutaneous abscess	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Upper respiratory tract infection	0	4(0.2%)
Atypical pneumonia	0	3(0.1%)
Intervertebral discitis	0	3(0.1%)
Acute hepatitis B	0	2(0.1%)
Infective exacerbation of bronchiectasis	0	2(0.1%)
Periodontitis	0	2(0.1%)
Abdominal wall abscess	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Cystitis	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Ear infection	0	1(0.0%)
Endocarditis	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Escherichia urinary tract infection	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Febrile infection	0	1(0.0%)
Gastroenteritis salmonella	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
Hepatitis B	0	1(0.0%)
Infected seroma	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Mastoiditis	0	1(0.0%)
Medical device site joint infection	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Oesophageal candidiasis	0	1(0.0%)
Otitis externa	0	1(0.0%)
Peritonitis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Renal abscess	0	1(0.0%)
Respiratory syncytial virus infection	0	1(0.0%)
Urethritis	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	150(5.7%)	156(6.0%)
Hyperkalaemia	40(1.5%)	12(0.5%)
Hypoglycaemia	20(0.8%)	31(1.2%)
Hyperglycaemia	17(0.6%)	23(0.9%)
Type 2 diabetes mellitus	11(0.4%)	20(0.8%)
Diabetes mellitus inadequate control	11(0.4%)	16(0.6%)
Diabetic metabolic decompensation	11(0.4%)	12(0.5%)
Hyponatraemia	8(0.3%)	1(0.0%)
Diabetes mellitus	7(0.3%)	14(0.5%)
Diabetic ketoacidosis	7(0.3%)	7(0.3%)
Fluid overload	6(0.2%)	7(0.3%)
Dehydration	6(0.2%)	5(0.2%)
Hypokalaemia	3(0.1%)	5(0.2%)
Hypovolaemia	3(0.1%)	2(0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.1%)	4(0.2%)
Metabolic acidosis	2(0.1%)	3(0.1%)
Fluid retention	2(0.1%)	2(0.1%)
Hypercalcaemia	2(0.1%)	0
Hypervolaemia	2(0.1%)	0
Gout	1(0.0%)	7(0.3%)
Hypocalcaemia	1(0.0%)	1(0.0%)
Hypomagnesaemia	1(0.0%)	1(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Diabetic complication	1(0.0%)	0
Hypoglycaemia unawareness	1(0.0%)	0
Malnutrition	1(0.0%)	0
Decreased appetite	0	2(0.1%)
Hypoproteinaemia	0	2(0.1%)
Hyperosmolar state	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Renal And Urinary Disorders	125(4.8%)	140(5.4%)
Acute kidney injury	53(2.0%)	50(1.9%)
Diabetic nephropathy	18(0.7%)	15(0.6%)
Chronic kidney disease	12(0.5%)	22(0.8%)
Renal impairment	7(0.3%)	8(0.3%)
Renal failure	7(0.3%)	7(0.3%)
Nephrolithiasis	6(0.2%)	1(0.0%)
Urinary retention	5(0.2%)	2(0.1%)
End stage renal disease	4(0.2%)	4(0.2%)
Nephrotic syndrome	3(0.1%)	9(0.3%)
Haematuria	3(0.1%)	3(0.1%)
Bladder outlet obstruction	2(0.1%)	1(0.0%)
Hydronephrosis	2(0.1%)	1(0.0%)
Urinary tract obstruction	2(0.1%)	1(0.0%)
Ureterolithiasis	1(0.0%)	3(0.1%)
Nephropathy	1(0.0%)	2(0.1%)
Dysuria	1(0.0%)	1(0.0%)
Renal colic	1(0.0%)	1(0.0%)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Bladder cyst	1(0.0%)	0
Chromaturia	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0
Nocturia	1(0.0%)	0
Renal artery stenosis	1(0.0%)	0
Renal cyst	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Urinary incontinence	1(0.0%)	0
Calculus bladder	0	2(0.1%)
Intercapillary glomerulosclerosis	0	2(0.1%)
Renal haemorrhage	0	2(0.1%)
Azotaemia	0	1(0.0%)
Calculus urinary	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Hypertensive nephropathy	0	1(0.0%)
Nephrosclerosis	0	1(0.0%)
Perinephritis	0	1(0.0%)
Proteinuria	0	1(0.0%)
Renal mass	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Gastrointestinal Disorders	106(4.1%)	89(3.4%)
Gastrointestinal haemorrhage	10(0.4%)	7(0.3%)
Diarrhoea	7(0.3%)	6(0.2%)
Pancreatitis acute	6(0.2%)	8(0.3%)
Abdominal pain	6(0.2%)	5(0.2%)
Lower gastrointestinal haemorrhage	6(0.2%)	1(0.0%)
Rectal haemorrhage	6(0.2%)	1(0.0%)
Large intestine polyp	3(0.1%)	6(0.2%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Constipation	3(0.1%)	3(0.1%)
Duodenal ulcer	3(0.1%)	2(0.1%)
Intestinal obstruction	3(0.1%)	2(0.1%)
Vomiting	3(0.1%)	2(0.1%)
Nausea	3(0.1%)	1(0.0%)
Colitis	3(0.1%)	0
Upper gastrointestinal haemorrhage	2(0.1%)	5(0.2%)
Abdominal pain upper	2(0.1%)	4(0.2%)
Gastritis	2(0.1%)	3(0.1%)
Umbilical hernia	2(0.1%)	2(0.1%)
Haematemesis	2(0.1%)	1(0.0%)
Diverticulum intestinal haemorrhagic	2(0.1%)	0
Gastric ulcer haemorrhage	2(0.1%)	0
Haematochezia	2(0.1%)	0
Haemorrhoidal haemorrhage	2(0.1%)	0
Haemorrhoids	2(0.1%)	0
Ileus	2(0.1%)	0
Inguinal hernia	1(0.0%)	3(0.1%)
Pancreatitis	1(0.0%)	3(0.1%)
Abdominal hernia	1(0.0%)	1(0.0%)
Dental caries	1(0.0%)	1(0.0%)
Diverticulum intestinal	1(0.0%)	1(0.0%)
Duodenal ulcer haemorrhage	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Incarcerated umbilical hernia	1(0.0%)	1(0.0%)
Melaena	1(0.0%)	1(0.0%)
Pancreatitis chronic	1(0.0%)	1(0.0%)
Small intestinal obstruction	1(0.0%)	1(0.0%)
Alcoholic pancreatitis	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0
Diarrhoea haemorrhagic	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Dyspepsia	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric haemorrhage	1(0.0%)	0
Gastritis erosive	1(0.0%)	0
Gastritis haemorrhagic	1(0.0%)	0
Gastroduodenal ulcer	1(0.0%)	0
Gastrointestinal disorder	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Gastrooesophageal reflux disease	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Intra-abdominal fluid collection	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal ulcer haemorrhage	1(0.0%)	0
Oesophagitis	1(0.0%)	0
Pancreatic cyst	1(0.0%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Proctitis	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Small intestinal haemorrhage	1(0.0%)	0
Colitis ischaemic	0	3(0.1%)
Ascites	0	2(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Abdominal strangulated hernia	0	1(0.0%)
Anal fistula	0	1(0.0%)
Change of bowel habit	0	1(0.0%)
Chronic gastritis	0	1(0.0%)
Diverticulum	0	1(0.0%)
Faecaloma	0	1(0.0%)
Gastric mucosal lesion	0	1(0.0%)
Gastrointestinal motility disorder	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Impaired gastric emptying	0	1(0.0%)
Intestinal ischaemia	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Pancreatic duct stenosis	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Rectal polyp	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland calculus	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Subileus	0	1(0.0%)
Varices oesophageal	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	94(3.6%)	85(3.3%)
Prostate cancer	10(0.4%)	5(0.2%)
Lung neoplasm malignant	9(0.3%)	3(0.1%)
Breast cancer	4(0.2%)	5(0.2%)
Colon cancer	4(0.2%)	4(0.2%)
Clear cell renal cell carcinoma	3(0.1%)	1(0.0%)
Colon adenoma	3(0.1%)	0
Oesophageal adenocarcinoma	3(0.1%)	0
Bladder cancer	2(0.1%)	5(0.2%)
Hepatocellular carcinoma	2(0.1%)	3(0.1%)
Renal neoplasm	2(0.1%)	3(0.1%)
Malignant melanoma	2(0.1%)	2(0.1%)
Pancreatic carcinoma	2(0.1%)	2(0.1%)
Bladder neoplasm	2(0.1%)	1(0.0%)
Metastases to lung	2(0.1%)	1(0.0%)
Renal cell carcinoma	2(0.1%)	1(0.0%)
Basal cell carcinoma	2(0.1%)	0
Bladder cancer recurrent	2(0.1%)	0
Metastases to spine	2(0.1%)	0
Squamous cell carcinoma of skin	2(0.1%)	0
Squamous cell carcinoma of the oral cavity	2(0.1%)	0
Adenocarcinoma of colon	1(0.0%)	3(0.1%)
Metastases to lymph nodes	1(0.0%)	3(0.1%)
Renal cancer	1(0.0%)	2(0.1%)
Adenocarcinoma	1(0.0%)	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Breast neoplasm	1(0.0%)	1(0.0%)
Lipoma	1(0.0%)	1(0.0%)
Metastases to bone	1(0.0%)	1(0.0%)
Metastases to central nervous system	1(0.0%)	1(0.0%)
Plasma cell myeloma	1(0.0%)	1(0.0%)
Adenoma benign	1(0.0%)	0
Angiomyofibroblastoma	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Breast cancer metastatic	1(0.0%)	0
Cancer pain	1(0.0%)	0
Cholangiocarcinoma	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Endometrial adenocarcinoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Haemangioma	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Hypergammaglobulinaemia benign monoclonal	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Laryngeal squamous cell carcinoma	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Lymphoma	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0
Neoplasm	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Oesophageal carcinoma	1(0.0%)	0
Prostate cancer metastatic	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Metastases to liver	0	4(0.2%)
Small cell lung cancer	0	3(0.1%)
Acute myeloid leukaemia	0	2(0.1%)
Adenocarcinoma gastric	0	2(0.1%)
Brain neoplasm	0	2(0.1%)
Gastric cancer	0	2(0.1%)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal adenoma	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign pancreatic neoplasm	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Chronic lymphocytic leukaemia	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Lung adenocarcinoma	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Monoclonal gammopathy	0	1(0.0%)
Myelodysplastic syndrome	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Pancreatic carcinoma metastatic	0	1(0.0%)
Pancreatic carcinoma stage IV	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Rectal adenocarcinoma	0	1(0.0%)
Salivary gland neoplasm	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Transitional cell carcinoma	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Injury, Poisoning And Procedural Complications	90(3.4%)	78(3.0%)
Femoral neck fracture	7(0.3%)	3(0.1%)
Femur fracture	6(0.2%)	9(0.3%)
Ankle fracture	6(0.2%)	4(0.2%)
Hip fracture	6(0.2%)	3(0.1%)
Humerus fracture	4(0.2%)	7(0.3%)
Rib fracture	4(0.2%)	4(0.2%)
Subdural haematoma	4(0.2%)	4(0.2%)
Limb injury	4(0.2%)	1(0.0%)
Radius fracture	3(0.1%)	1(0.0%)
Joint injury	3(0.1%)	0
Fall	2(0.1%)	6(0.2%)
Accidental overdose	2(0.1%)	2(0.1%)
Incisional hernia	2(0.1%)	2(0.1%)
Tibia fracture	2(0.1%)	2(0.1%)
Toxicity to various agents	2(0.1%)	2(0.1%)
Road traffic accident	2(0.1%)	1(0.0%)
Cervical vertebral fracture	2(0.1%)	0
Clavicle fracture	2(0.1%)	0
Contusion	2(0.1%)	0
Foot fracture	2(0.1%)	0
Lower limb fracture	2(0.1%)	0
Meniscus injury	1(0.0%)	2(0.1%)
Traumatic fracture	1(0.0%)	2(0.1%)
Ulna fracture	1(0.0%)	2(0.1%)
Fibula fracture	1(0.0%)	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pelvic fracture	1(0.0%)	1(0.0%)
Spinal cord injury cervical	1(0.0%)	1(0.0%)
Spinal fracture	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Subdural haemorrhage	1(0.0%)	1(0.0%)
Tendon injury	1(0.0%)	1(0.0%)
Thermal burn	1(0.0%)	1(0.0%)
Abdominal wound dehiscence	1(0.0%)	0
Back injury	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Craniocerebral injury	1(0.0%)	0
Facial bones fracture	1(0.0%)	0
Incision site haematoma	1(0.0%)	0
Inflammation of wound	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Ligament injury	1(0.0%)	0
Muscle strain	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Patella fracture	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Skin laceration	1(0.0%)	0
Soft tissue injury	1(0.0%)	0
Thoracic vertebral fracture	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Wrist fracture	1(0.0%)	0
Head injury	0	2(0.1%)
Post procedural haemorrhage	0	2(0.1%)
Accident	0	1(0.0%)
Acetabulum fracture	0	1(0.0%)
Alcohol poisoning	0	1(0.0%)
Arteriovenous fistula site complication	0	1(0.0%)
Burns second degree	0	1(0.0%)
Concussion	0	1(0.0%)
Dislocation of vertebra	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Hand fracture	0	1(0.0%)
Heat stroke	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Injury	0	1(0.0%)
Joint dislocation	0	1(0.0%)
Lumbar vertebral fracture	0	1(0.0%)
Muscle rupture	0	1(0.0%)
Overdose	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural inflammation	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Skull fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Upper limb fracture	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Nervous System Disorders	61(2.3%)	85(3.3%)
Syncope	11(0.4%)	21(0.8%)
Dizziness	6(0.2%)	9(0.3%)
Diabetic neuropathy	6(0.2%)	3(0.1%)
Seizure	4(0.2%)	3(0.1%)
Loss of consciousness	4(0.2%)	2(0.1%)
Presyncope	4(0.2%)	2(0.1%)
Cerebrovascular disorder	4(0.2%)	0
Subarachnoid haemorrhage	3(0.1%)	2(0.1%)
Headache	2(0.1%)	3(0.1%)
Facial paralysis	2(0.1%)	1(0.0%)
Cerebral haemorrhage	2(0.1%)	0
Dysarthria	2(0.1%)	0
Cerebral infarction	1(0.0%)	2(0.1%)
Radiculopathy	1(0.0%)	2(0.1%)
IIIrd nerve paralysis	1(0.0%)	1(0.0%)
Lacunar infarction	1(0.0%)	1(0.0%)
Transient ischaemic attack	1(0.0%)	1(0.0%)
Angiopathic neuropathy	1(0.0%)	0
Balance disorder	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Drop attacks	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
Hepatic encephalopathy	1(0.0%)	0
Myelopathy	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Polyneuropathy	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
Vertebrobasilar insufficiency	1(0.0%)	0
Carotid artery stenosis	0	2(0.1%)
Cervicobrachial syndrome	0	2(0.1%)
Epilepsy	0	2(0.1%)
Facial paresis	0	2(0.1%)
Hemiparesis	0	2(0.1%)
Neuralgia	0	2(0.1%)
Alcohol induced persisting dementia	0	1(0.0%)
Altered state of consciousness	0	1(0.0%)
Aphasia	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid arteriosclerosis	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Carpal tunnel syndrome	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebral ischaemia	0	1(0.0%)
Cerebral microangiopathy	0	1(0.0%)
Cerebrovascular accident	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Cerebrovascular insufficiency	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Ischaemic stroke	0	1(0.0%)
Lethargy	0	1(0.0%)
Lumbosacral radiculopathy	0	1(0.0%)
Migraine	0	1(0.0%)
Mononeuropathy	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Neuropathy peripheral	0	1(0.0%)
Post herpetic neuralgia	0	1(0.0%)
Sciatica	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Vascular encephalopathy	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	61(2.3%)	74(2.8%)
Chronic obstructive pulmonary disease	13(0.5%)	11(0.4%)
Dyspnoea	8(0.3%)	7(0.3%)
Acute respiratory failure	6(0.2%)	14(0.5%)
Pulmonary embolism	6(0.2%)	4(0.2%)
Respiratory failure	5(0.2%)	7(0.3%)
Pleural effusion	4(0.2%)	2(0.1%)
Acute pulmonary oedema	3(0.1%)	2(0.1%)
Pneumothorax	3(0.1%)	1(0.0%)
Sleep apnoea syndrome	2(0.1%)	2(0.1%)
Pulmonary mass	2(0.1%)	0
Asthma	1(0.0%)	6(0.2%)
Pneumonia aspiration	1(0.0%)	4(0.2%)
Pulmonary oedema	1(0.0%)	4(0.2%)
Chronic respiratory failure	1(0.0%)	1(0.0%)
Hypoxia	1(0.0%)	1(0.0%)
Interstitial lung disease	1(0.0%)	1(0.0%)
Dyspnoea at rest	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Epistaxis	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Laryngeal mass	1(0.0%)	0
Laryngeal oedema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Pulmonary congestion	1(0.0%)	0
Restrictive pulmonary disease	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Pneumonitis	0	2(0.1%)
Aspiration	0	1(0.0%)
Bronchitis chronic	0	1(0.0%)
Bronchopneumopathy	0	1(0.0%)
Cough	0	1(0.0%)
Dyspnoea exertional	0	1(0.0%)
Emphysema	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Laryngeal stenosis	0	1(0.0%)
Obstructive airways disorder	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)
Pulmonary hypertension	0	1(0.0%)
Respiratory distress	0	1(0.0%)
Vocal cord polyp	0	1(0.0%)
Wheezing	0	1(0.0%)
Surgical And Medical Procedures	59(2.3%)	68(2.6%)
Knee arthroplasty	4(0.2%)	6(0.2%)
Toe amputation	4(0.2%)	4(0.2%)
Cataract operation	3(0.1%)	12(0.5%)
Hip arthroplasty	3(0.1%)	6(0.2%)
Arteriovenous fistula operation	3(0.1%)	3(0.1%)
Diabetes mellitus management	3(0.1%)	0
Prostatectomy	2(0.1%)	1(0.0%)
Hysterectomy	2(0.1%)	0
Vitrectomy	1(0.0%)	4(0.2%)
Cholecystectomy	1(0.0%)	2(0.1%)
Foot amputation	1(0.0%)	2(0.1%)
Gastrectomy	1(0.0%)	2(0.1%)
Colectomy	1(0.0%)	1(0.0%)
Dialysis device insertion	1(0.0%)	1(0.0%)
Haemodialysis	1(0.0%)	1(0.0%)
Metabolic surgery	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Skin neoplasm excision	1(0.0%)	1(0.0%)
Aneurysm repair	1(0.0%)	0
Aortic valve replacement	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Cardiac pacemaker insertion	1(0.0%)	0
Coronary angioplasty	1(0.0%)	0
Coronary artery bypass	1(0.0%)	0
Eye operation	1(0.0%)	0
Foot operation	1(0.0%)	0
Gastric bypass	1(0.0%)	0
Implantable defibrillator insertion	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Intraocular lens implant	1(0.0%)	0
Leg amputation	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nail operation	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Parathyroidectomy	1(0.0%)	0
Radical prostatectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Skin graft	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Tenotomy	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Wound treatment	1(0.0%)	0
Insertion of ambulatory peritoneal catheter	0	2(0.1%)
Spinal operation	0	2(0.1%)
Umbilical hernia repair	0	2(0.1%)
Amputation	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Colon operation	0	1(0.0%)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Hydrocele operation	0	1(0.0%)
Intervertebral disc operation	0	1(0.0%)
Large intestinal polypectomy	0	1(0.0%)
Meniscus operation	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Peripheral artery bypass	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Polypectomy	0	1(0.0%)
Pterygium operation	0	1(0.0%)
Retinopexy	0	1(0.0%)
Transurethral bladder resection	0	1(0.0%)
Transurethral prostatectomy	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Vascular graft	0	1(0.0%)
Vascular Disorders	55(2.1%)	64(2.5%)
Hypertension	14(0.5%)	23(0.9%)
Hypotension	6(0.2%)	4(0.2%)
Hypertensive crisis	4(0.2%)	6(0.2%)
Orthostatic hypotension	4(0.2%)	2(0.1%)
Hypertensive urgency	4(0.2%)	1(0.0%)
Deep vein thrombosis	4(0.2%)	0
Circulatory collapse	2(0.1%)	1(0.0%)
Diabetic vascular disorder	2(0.1%)	1(0.0%)
Peripheral ischaemia	2(0.1%)	1(0.0%)
Hypertensive emergency	1(0.0%)	4(0.2%)
Aortic aneurysm	1(0.0%)	2(0.1%)
Thrombophlebitis	1(0.0%)	2(0.1%)
Aortic stenosis	1(0.0%)	1(0.0%)
Extremity necrosis	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Peripheral artery stenosis	1(0.0%)	1(0.0%)
Peripheral vascular disorder	1(0.0%)	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Arteriovenous fistula	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Peripheral artery aneurysm	1(0.0%)	0
Peripheral artery occlusion	1(0.0%)	0
Peripheral embolism	1(0.0%)	0
Thrombophlebitis superficial	1(0.0%)	0
Venous occlusion	1(0.0%)	0
Peripheral arterial occlusive disease	0	5(0.2%)
Haematoma	0	2(0.1%)
Malignant hypertension	0	2(0.1%)
Blood pressure fluctuation	0	1(0.0%)
Embolism venous	0	1(0.0%)
Lymphoedema	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Peripheral artery thrombosis	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Thromboangiitis obliterans	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	45(1.7%)	55(2.1%)
Osteoarthritis	10(0.4%)	8(0.3%)
Intervertebral disc protrusion	7(0.3%)	12(0.5%)
Gouty arthritis	5(0.2%)	2(0.1%)
Lumbar spinal stenosis	3(0.1%)	6(0.2%)
Back pain	3(0.1%)	4(0.2%)
Arthritis	2(0.1%)	2(0.1%)
Rhabdomyolysis	2(0.1%)	2(0.1%)
Pain in extremity	2(0.1%)	1(0.0%)
Spinal stenosis	2(0.1%)	0
Bursitis	1(0.0%)	2(0.1%)
Foot deformity	1(0.0%)	2(0.1%)
Spinal osteoarthritis	1(0.0%)	2(0.1%)
Polymyalgia rheumatica	1(0.0%)	1(0.0%)
Spondylolisthesis	1(0.0%)	1(0.0%)
Cervical spinal stenosis	1(0.0%)	0
Connective tissue inflammation	1(0.0%)	0
Flank pain	1(0.0%)	0
Haematoma muscle	1(0.0%)	0
Osteitis	1(0.0%)	0
Rotator cuff syndrome	1(0.0%)	0
Spondylitis	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Arthralgia	0	6(0.2%)
Intervertebral disc degeneration	0	2(0.1%)
Back disorder	0	1(0.0%)
Limb mass	0	1(0.0%)
Musculoskeletal chest pain	0	1(0.0%)
Musculoskeletal disorder	0	1(0.0%)
Neck pain	0	1(0.0%)
Neuropathic arthropathy	0	1(0.0%)
Osteoarthropathy	0	1(0.0%)
Osteonecrosis	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Osteonecrosis of jaw	0	1(0.0%)
Rheumatoid arthritis	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Eye Disorders	37(1.4%)	40(1.5%)
Cataract	18(0.7%)	10(0.4%)
Glaucoma	6(0.2%)	1(0.0%)
Vitreous haemorrhage	5(0.2%)	6(0.2%)
Diabetic retinopathy	3(0.1%)	4(0.2%)
Retinal detachment	2(0.1%)	2(0.1%)
Retinal haemorrhage	2(0.1%)	1(0.0%)
Visual impairment	2(0.1%)	1(0.0%)
Lens dislocation	1(0.0%)	1(0.0%)
Tractional retinal detachment	1(0.0%)	1(0.0%)
Cataract subcapsular	1(0.0%)	0
Diabetic retinal oedema	1(0.0%)	0
Eye disorder	1(0.0%)	0
Eye haemorrhage	1(0.0%)	0
Pterygium	0	2(0.1%)
Ulcerative keratitis	0	2(0.1%)
Blindness	0	1(0.0%)
Cataract diabetic	0	1(0.0%)
Ectropion	0	1(0.0%)
Macular fibrosis	0	1(0.0%)
Macular hole	0	1(0.0%)
Macular oedema	0	1(0.0%)
Open angle glaucoma	0	1(0.0%)
Optic disc haemorrhage	0	1(0.0%)
Papilloedema	0	1(0.0%)
Retinal artery occlusion	0	1(0.0%)
Retinopathy	0	1(0.0%)
Rhegmatogenous retinal detachment	0	1(0.0%)
General Disorders And Administration Site Conditions	34(1.3%)	49(1.9%)
Chest pain	11(0.4%)	18(0.7%)
Oedema peripheral	6(0.2%)	6(0.2%)
Pyrexia	4(0.2%)	2(0.1%)
Oedema	4(0.2%)	1(0.0%)
Death	2(0.1%)	4(0.2%)
Malaise	2(0.1%)	0
Fatigue	1(0.0%)	2(0.1%)
Generalised oedema	1(0.0%)	2(0.1%)
Asthenia	1(0.0%)	1(0.0%)
Non-cardiac chest pain	1(0.0%)	1(0.0%)
General physical health deterioration	1(0.0%)	0
Mass	1(0.0%)	0
Multiple organ dysfunction syndrome	1(0.0%)	0
Swelling face	1(0.0%)	0
Chest discomfort	0	2(0.1%)
Gait disturbance	0	2(0.1%)
Oedema due to renal disease	0	2(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Peripheral swelling	0	2(0.1%)
Device intolerance	0	1(0.0%)
Hernia pain	0	1(0.0%)
Hypothermia	0	1(0.0%)
Inflammation	0	1(0.0%)
Soft tissue inflammation	0	1(0.0%)
Vascular stent stenosis	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	30(1.1%)	45(1.7%)
Diabetic foot	13(0.5%)	16(0.6%)
Skin ulcer	8(0.3%)	16(0.6%)
Angioedema	3(0.1%)	1(0.0%)
Pemphigoid	2(0.1%)	0
Dermatitis herpetiformis	1(0.0%)	0
Drug eruption	1(0.0%)	0
Ingrowing nail	1(0.0%)	0
Rash	1(0.0%)	0
Skin disorder	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Stasis dermatitis	1(0.0%)	0
Blister	0	2(0.1%)
Decubitus ulcer	0	1(0.0%)
Dermal cyst	0	1(0.0%)
Dermatitis	0	1(0.0%)
Dermatitis allergic	0	1(0.0%)
Dermatitis bullous	0	1(0.0%)
Ecchymosis	0	1(0.0%)
Eczema	0	1(0.0%)
Hyperkeratosis	0	1(0.0%)
Neuropathic ulcer	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Purpura	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Cardiac Disorders	26(1.0%)	49(1.9%)
Coronary artery disease	8(0.3%)	5(0.2%)
Bradycardia	2(0.1%)	3(0.1%)
Angina pectoris	2(0.1%)	2(0.1%)
Cardio-respiratory arrest	2(0.1%)	0
Sinus node dysfunction	2(0.1%)	0
Cardiac failure	1(0.0%)	10(0.4%)
Acute coronary syndrome	1(0.0%)	2(0.1%)
Atrial fibrillation	1(0.0%)	2(0.1%)
Acute left ventricular failure	1(0.0%)	1(0.0%)
Arrhythmia	1(0.0%)	1(0.0%)
Cardiac failure acute	1(0.0%)	1(0.0%)
Cardiac failure chronic	1(0.0%)	1(0.0%)
Aortic valve calcification	1(0.0%)	0
Aortic valve disease mixed	1(0.0%)	0
Arteriosclerosis coronary artery	1(0.0%)	0
Bifascicular block	1(0.0%)	0
Hypertensive heart disease	1(0.0%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Left ventricular dysfunction	1(0.0%)	0
Left ventricular failure	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Cardiac failure congestive	0	8(0.3%)
Angina unstable	0	5(0.2%)
Myocardial ischaemia	0	4(0.2%)
Aortic valve stenosis	0	2(0.1%)
Atrial thrombosis	0	2(0.1%)
Cardiac arrest	0	2(0.1%)
Atrial flutter	0	1(0.0%)
Atrioventricular block	0	1(0.0%)
Cardiac asthma	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Hepatobiliary Disorders	25(1.0%)	29(1.1%)
Cholelithiasis	9(0.3%)	1(0.0%)
Cholecystitis	4(0.2%)	3(0.1%)
Cholecystitis acute	2(0.1%)	8(0.3%)
Cholangitis	2(0.1%)	4(0.2%)
Bile duct stone	2(0.1%)	0
Biliary obstruction	2(0.1%)	0
Hepatic cirrhosis	1(0.0%)	5(0.2%)
Biliary colic	1(0.0%)	1(0.0%)
Hepatitis acute	1(0.0%)	1(0.0%)
Hepatic function abnormal	1(0.0%)	0
Hepatitis	1(0.0%)	0
Cholangitis acute	0	2(0.1%)
Biliary dilatation	0	1(0.0%)
Cholecystitis chronic	0	1(0.0%)
Cholestasis	0	1(0.0%)
Drug-induced liver injury	0	1(0.0%)
Hepatitis alcoholic	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver disorder	0	1(0.0%)
Blood And Lymphatic System Disorders	23(0.9%)	35(1.3%)
Anaemia	12(0.5%)	18(0.7%)
Iron deficiency anaemia	5(0.2%)	5(0.2%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Microcytic anaemia	1(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	1(0.0%)
Immune thrombocytopenia	1(0.0%)	0
Lymphadenopathy	1(0.0%)	0
Nephrogenic anaemia	0	5(0.2%)
Thrombocytopenia	0	2(0.1%)
Febrile neutropenia	0	1(0.0%)
Lymphadenopathy mediastinal	0	1(0.0%)
Neutropenia	0	1(0.0%)
Normocytic anaemia	0	1(0.0%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Investigations	21(0.8%)	33(1.3%)
Glomerular filtration rate decreased	5(0.2%)	3(0.1%)
Weight decreased	2(0.1%)	3(0.1%)
Blood glucose increased	2(0.1%)	2(0.1%)
Biopsy kidney	2(0.1%)	1(0.0%)
Blood creatinine increased	1(0.0%)	3(0.1%)
Angiocardiogram	1(0.0%)	2(0.1%)
Colonoscopy	1(0.0%)	2(0.1%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Alanine aminotransferase increased	1(0.0%)	0
Arteriogram	1(0.0%)	0
Aspartate aminotransferase increased	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood potassium increased	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0
Cardiac stress test abnormal	1(0.0%)	0
Gamma-glutamyltransferase increased	1(0.0%)	0
Influenza A virus test positive	1(0.0%)	0
Blood creatine phosphokinase increased	0	3(0.1%)
Blood pressure increased	0	2(0.1%)
Hepatic enzyme increased	0	2(0.1%)
Anticoagulation drug level above therapeutic	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)
Computerised tomogram abdomen	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Inflammatory marker increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Liver function test increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Troponin T increased	0	1(0.0%)
Reproductive System And Breast Disorders	10(0.4%)	15(0.6%)
Benign prostatic hyperplasia	4(0.2%)	9(0.3%)
Prostatomegaly	1(0.0%)	1(0.0%)
Balanoposthitis	1(0.0%)	0
Endometrial hyperplasia	1(0.0%)	0
Metrorrhagia	1(0.0%)	0
Uterine polyp	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Ovarian cyst	0	2(0.1%)
Dysfunctional uterine bleeding	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine haemorrhage	0	1(0.0%)
Psychiatric Disorders	10(0.4%)	7(0.3%)
Anxiety	2(0.1%)	0
Depression	1(0.0%)	3(0.1%)
Mental status changes	1(0.0%)	3(0.1%)
Confusional state	1(0.0%)	1(0.0%)
Alcohol abuse	1(0.0%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Bipolar disorder	1(0.0%)	0
Insomnia	1(0.0%)	0
Major depression	1(0.0%)	0
Mania	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Ear And Labyrinth Disorders	8(0.3%)	11(0.4%)
Sudden hearing loss	2(0.1%)	3(0.1%)
Vertigo	2(0.1%)	3(0.1%)
Vestibular disorder	2(0.1%)	1(0.0%)
Deafness neurosensory	1(0.0%)	0
Vertigo positional	1(0.0%)	0
Deafness unilateral	0	1(0.0%)
Ear pain	0	1(0.0%)
Tinnitus	0	1(0.0%)
Tympanic membrane perforation	0	1(0.0%)
Congenital, Familial And Genetic Disorders	2(0.1%)	1(0.0%)
Factor VIII deficiency	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Dermoid cyst	0	1(0.0%)
Immune System Disorders	2(0.1%)	0
Drug hypersensitivity	2(0.1%)	0
Product Issues	1(0.0%)	2(0.1%)
Device malfunction	1(0.0%)	0
Device dislocation	0	2(0.1%)
Social Circumstances	1(0.0%)	0
Social stay hospitalisation	1(0.0%)	0
Endocrine Disorders	0	7(0.3%)
Goitre	0	2(0.1%)
Thyroid mass	0	2(0.1%)
Hyperthyroidism	0	1(0.0%)
Pituitary-dependent Cushing's syndrome	0	1(0.0%)
Thyroiditis	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Any TEAE	466(17.8%)	518(19.8%)
Infections And Infestations	121(4.6%)	139(5.3%)
Pneumonia	30(1.1%)	47(1.8%)
Sepsis	10(0.4%)	14(0.5%)
Cellulitis	10(0.4%)	13(0.5%)
Urinary tract infection	4(0.2%)	10(0.4%)
Osteomyelitis	4(0.2%)	9(0.3%)
Diabetic foot infection	4(0.2%)	4(0.2%)
Septic shock	4(0.2%)	4(0.2%)
Respiratory tract infection	4(0.2%)	2(0.1%)
Pulmonary sepsis	4(0.2%)	1(0.0%)
Bronchitis	3(0.1%)	3(0.1%)
Erysipelas	3(0.1%)	2(0.1%)
Localised infection	3(0.1%)	2(0.1%)
Gastroenteritis	2(0.1%)	5(0.2%)
Pyelonephritis	2(0.1%)	3(0.1%)
Abscess limb	2(0.1%)	1(0.0%)
Staphylococcal sepsis	2(0.1%)	1(0.0%)
Appendicitis	2(0.1%)	0
Appendicitis perforated	2(0.1%)	0
Bacteraemia	2(0.1%)	0
Groin abscess	2(0.1%)	0
Gangrene	1(0.0%)	5(0.2%)
Influenza	1(0.0%)	3(0.1%)
COVID-19	1(0.0%)	2(0.1%)
Lower respiratory tract infection	1(0.0%)	2(0.1%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Epididymitis	1(0.0%)	1(0.0%)
Herpes zoster	1(0.0%)	1(0.0%)
Infected skin ulcer	1(0.0%)	1(0.0%)
Nasopharyngitis	1(0.0%)	1(0.0%)
Otitis media	1(0.0%)	1(0.0%)
Pulmonary tuberculosis	1(0.0%)	1(0.0%)
Soft tissue infection	1(0.0%)	1(0.0%)
Urosepsis	1(0.0%)	1(0.0%)
Wound infection	1(0.0%)	1(0.0%)
Abdominal abscess	1(0.0%)	0
Arthritis bacterial	1(0.0%)	0
Campylobacter gastroenteritis	1(0.0%)	0
Cystitis	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Eye infection	1(0.0%)	0
Fournier's gangrene	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infected bite	1(0.0%)	0
Kidney infection	1(0.0%)	0
Large intestine infection	1(0.0%)	0
Meningitis	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Onychomycosis	1(0.0%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Oral infection	1(0.0%)	0
Orchitis	1(0.0%)	0
Paronychia	1(0.0%)	0
Periodontitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pneumonia bacterial	1(0.0%)	0
Pseudomonas infection	1(0.0%)	0
Pyelonephritis acute	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Skin infection	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Viral upper respiratory tract infection	1(0.0%)	0
Atypical pneumonia	0	3(0.1%)
Liver abscess	0	3(0.1%)
Upper respiratory tract infection	0	3(0.1%)
Anal abscess	0	2(0.1%)
Intervertebral discitis	0	2(0.1%)
Mastoiditis	0	2(0.1%)
Oral candidiasis	0	2(0.1%)
Otitis externa	0	2(0.1%)
Bacterial sepsis	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Diverticulitis	0	1(0.0%)
Ear infection	0	1(0.0%)
Endocarditis	0	1(0.0%)
Escherichia urinary tract infection	0	1(0.0%)
Gastroenteritis salmonella	0	1(0.0%)
Infected seroma	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Medical device site joint infection	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Ophthalmic herpes zoster	0	1(0.0%)
Peritonsillitis	0	1(0.0%)
Pharyngitis	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Tooth infection	0	1(0.0%)
Viral infection	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	84(3.2%)	80(3.1%)
Hyperkalaemia	31(1.2%)	9(0.3%)
Hypoglycaemia	19(0.7%)	23(0.9%)
Hyperglycaemia	6(0.2%)	6(0.2%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Dehydration	4(0.2%)	4(0.2%)
Diabetic ketoacidosis	4(0.2%)	4(0.2%)
Diabetes mellitus	4(0.2%)	3(0.1%)
Fluid overload	3(0.1%)	6(0.2%)
Hyponatraemia	3(0.1%)	0
Diabetes mellitus inadequate control	2(0.1%)	4(0.2%)
Type 2 diabetes mellitus	2(0.1%)	3(0.1%)
Hyperlipidaemia	2(0.1%)	1(0.0%)
Hypercalcaemia	2(0.1%)	0
Gout	1(0.0%)	3(0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	1(0.0%)	3(0.1%)
Hypocalcaemia	1(0.0%)	2(0.1%)
Hypokalaemia	1(0.0%)	2(0.1%)
Metabolic acidosis	1(0.0%)	2(0.1%)
Fluid retention	1(0.0%)	1(0.0%)
Hypertriglyceridaemia	1(0.0%)	1(0.0%)
Hypomagnesaemia	1(0.0%)	1(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Hypercholesterolaemia	1(0.0%)	0
Vitamin D deficiency	0	4(0.2%)
Hypoproteinaemia	0	3(0.1%)
Decreased appetite	0	2(0.1%)
Diabetic metabolic decompensation	0	1(0.0%)
Hyperphosphataemia	0	1(0.0%)
Hypovolaemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)
Renal And Urinary Disorders	62(2.4%)	76(2.9%)
Acute kidney injury	27(1.0%)	35(1.3%)
Renal failure	7(0.3%)	5(0.2%)
Chronic kidney disease	5(0.2%)	10(0.4%)
Renal impairment	4(0.2%)	6(0.2%)
Diabetic nephropathy	3(0.1%)	3(0.1%)
End stage renal disease	3(0.1%)	3(0.1%)
Nephropathy	2(0.1%)	3(0.1%)
Nephrolithiasis	2(0.1%)	1(0.0%)
Nephrotic syndrome	1(0.0%)	3(0.1%)
Hydronephrosis	1(0.0%)	2(0.1%)
Urinary retention	1(0.0%)	2(0.1%)
Bladder outlet obstruction	1(0.0%)	1(0.0%)
Bladder perforation	1(0.0%)	0
Dysuria	1(0.0%)	0
Micturition disorder	1(0.0%)	0
Renal artery stenosis	1(0.0%)	0
Renal mass	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Urinary tract obstruction	1(0.0%)	0
Azotaemia	0	1(0.0%)
Calculus urinary	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pollakiuria	0	1(0.0%)
Polyuria	0	1(0.0%)
Renal haemorrhage	0	1(0.0%)
Urinary bladder polyp	0	1(0.0%)
Urinary incontinence	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	46(1.8%)	57(2.2%)
Lung neoplasm malignant	6(0.2%)	3(0.1%)
Prostate cancer	5(0.2%)	4(0.2%)
Oesophageal adenocarcinoma	3(0.1%)	0
Colon cancer	2(0.1%)	2(0.1%)
Hepatocellular carcinoma	2(0.1%)	2(0.1%)
Metastases to lung	2(0.1%)	0
Metastases to spine	2(0.1%)	0
Squamous cell carcinoma of the oral cavity	2(0.1%)	0
Breast cancer	1(0.0%)	3(0.1%)
Renal neoplasm	1(0.0%)	3(0.1%)
Adenocarcinoma of colon	1(0.0%)	2(0.1%)
Bladder cancer	1(0.0%)	2(0.1%)
Malignant melanoma	1(0.0%)	2(0.1%)
Pancreatic carcinoma	1(0.0%)	2(0.1%)
Bladder transitional cell carcinoma	1(0.0%)	1(0.0%)
Metastases to bone	1(0.0%)	1(0.0%)
Renal cell carcinoma	1(0.0%)	1(0.0%)
Breast neoplasm	1(0.0%)	0
Colon adenoma	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Endometrial adenocarcinoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0
Metastases to central nervous system	1(0.0%)	0
Metastases to lymph nodes	1(0.0%)	0
Oesophageal carcinoma	1(0.0%)	0
Pancreatic neoplasm	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Metastases to liver	0	3(0.1%)
Brain neoplasm	0	2(0.1%)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Small cell lung cancer	0	2(0.1%)
Acute myeloid leukaemia	0	1(0.0%)
Adenocarcinoma gastric	0	1(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal adenoma	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
B-cell lymphoma stage IV	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Clear cell renal cell carcinoma	0	1(0.0%)
Colorectal cancer	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Gastric cancer	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Lung adenocarcinoma	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Pancreatic carcinoma stage IV	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Plasma cell myeloma	0	1(0.0%)
Rectal adenocarcinoma	0	1(0.0%)
Renal cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Squamous cell carcinoma	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Transitional cell carcinoma	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Injury, Poisoning And Procedural Complications	45(1.7%)	41(1.6%)
Femoral neck fracture	7(0.3%)	0
Femur fracture	5(0.2%)	5(0.2%)
Hip fracture	5(0.2%)	2(0.1%)
Ankle fracture	3(0.1%)	2(0.1%)
Fall	2(0.1%)	3(0.1%)
Road traffic accident	2(0.1%)	1(0.0%)
Cervical vertebral fracture	2(0.1%)	0
Joint injury	2(0.1%)	0
Humerus fracture	1(0.0%)	2(0.1%)
Radius fracture	1(0.0%)	2(0.1%)
Skin laceration	1(0.0%)	1(0.0%)
Subdural haemorrhage	1(0.0%)	1(0.0%)
Thoracic vertebral fracture	1(0.0%)	1(0.0%)
Ulna fracture	1(0.0%)	1(0.0%)
Accidental overdose	1(0.0%)	0
Back injury	1(0.0%)	0
Clavicle fracture	1(0.0%)	0
Craniocerebral injury	1(0.0%)	0
Fibula fracture	1(0.0%)	0
Hand fracture	1(0.0%)	0
Limb injury	1(0.0%)	0
Lumbar vertebral fracture	1(0.0%)	0
Patella fracture	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Post procedural haematoma	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Spinal cord injury cervical	1(0.0%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Spinal fracture	1(0.0%)	0
Sternal fracture	1(0.0%)	0
Toxicity to various agents	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Rib fracture	0	4(0.2%)
Contusion	0	2(0.1%)
Post procedural haemorrhage	0	2(0.1%)
Subdural haematoma	0	2(0.1%)
Acetabulum fracture	0	1(0.0%)
Alcohol poisoning	0	1(0.0%)
Burns third degree	0	1(0.0%)
Cold burn	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Head injury	0	1(0.0%)
Heat stroke	0	1(0.0%)
Injury	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Ligament sprain	0	1(0.0%)
Nasal injury	0	1(0.0%)
Pelvic fracture	0	1(0.0%)
Post-traumatic pain	0	1(0.0%)
Procedural pain	0	1(0.0%)
Skull fracture	0	1(0.0%)
Spinal compression fracture	0	1(0.0%)
Tibia fracture	0	1(0.0%)
Tooth fracture	0	1(0.0%)
Traumatic fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	44(1.7%)	51(2.0%)
Chronic obstructive pulmonary disease	10(0.4%)	7(0.3%)
Respiratory failure	8(0.3%)	6(0.2%)
Acute respiratory failure	6(0.2%)	12(0.5%)
Pulmonary embolism	5(0.2%)	4(0.2%)
Dyspnoea	4(0.2%)	6(0.2%)
Sleep apnoea syndrome	2(0.1%)	3(0.1%)
Acute pulmonary oedema	2(0.1%)	2(0.1%)
Pneumothorax	2(0.1%)	0
Pulmonary mass	2(0.1%)	0
Pleural effusion	1(0.0%)	4(0.2%)
Pulmonary oedema	1(0.0%)	3(0.1%)
Hypoxia	1(0.0%)	1(0.0%)
Bronchitis chronic	1(0.0%)	0
Chronic respiratory failure	1(0.0%)	0
Laryngeal oedema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Pulmonary fibrosis	1(0.0%)	0
Pulmonary hypertension	1(0.0%)	0
Haemothorax	0	2(0.1%)
Pneumonia aspiration	0	2(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pneumonitis	0	2(0.1%)
Asthma	0	1(0.0%)
Cough	0	1(0.0%)
Dyspnoea exertional	0	1(0.0%)
Emphysema	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Obstructive airways disorder	0	1(0.0%)
Productive cough	0	1(0.0%)
Rales	0	1(0.0%)
Respiratory acidosis	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Wheezing	0	1(0.0%)
Gastrointestinal Disorders	41(1.6%)	45(1.7%)
Pancreatitis acute	5(0.2%)	4(0.2%)
Diarrhoea	4(0.2%)	2(0.1%)
Vomiting	4(0.2%)	1(0.0%)
Abdominal pain	3(0.1%)	4(0.2%)
Gastrointestinal haemorrhage	2(0.1%)	4(0.2%)
Lower gastrointestinal haemorrhage	2(0.1%)	1(0.0%)
Rectal haemorrhage	2(0.1%)	0
Upper gastrointestinal haemorrhage	1(0.0%)	5(0.2%)
Haematochezia	1(0.0%)	1(0.0%)
Intestinal obstruction	1(0.0%)	1(0.0%)
Nausea	1(0.0%)	1(0.0%)
Small intestinal obstruction	1(0.0%)	1(0.0%)
Alcoholic pancreatitis	1(0.0%)	0
Chronic gastritis	1(0.0%)	0
Diverticulum intestinal haemorrhagic	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Faecaloma	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric ulcer haemorrhage	1(0.0%)	0
Gastritis haemorrhagic	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Haematemesis	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids	1(0.0%)	0
Ileus	1(0.0%)	0
Incarcerated umbilical hernia	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Constipation	0	3(0.1%)
Ascites	0	2(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Gastritis	0	2(0.1%)
Varices oesophageal	0	2(0.1%)
Abdominal discomfort	0	1(0.0%)
Abdominal pain upper	0	1(0.0%)
Anal fistula	0	1(0.0%)
Colitis	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Colitis ischaemic	0	1(0.0%)
Dental caries	0	1(0.0%)
Duodenal ulcer	0	1(0.0%)
Duodenal ulcer haemorrhage	0	1(0.0%)
Dysphagia	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Inguinal hernia	0	1(0.0%)
Intestinal ischaemia	0	1(0.0%)
Large intestine polyp	0	1(0.0%)
Melaena	0	1(0.0%)
Pancreatitis	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Subileus	0	1(0.0%)
Nervous System Disorders	38(1.5%)	40(1.5%)
Syncope	5(0.2%)	8(0.3%)
Loss of consciousness	4(0.2%)	0
Seizure	3(0.1%)	3(0.1%)
Dizziness	2(0.1%)	3(0.1%)
Facial paralysis	2(0.1%)	1(0.0%)
Sciatica	2(0.1%)	1(0.0%)
Headache	2(0.1%)	0
Carpal tunnel syndrome	1(0.0%)	2(0.1%)
Diabetic neuropathy	1(0.0%)	1(0.0%)
Encephalopathy	1(0.0%)	1(0.0%)
Presyncope	1(0.0%)	1(0.0%)
Subarachnoid haemorrhage	1(0.0%)	1(0.0%)
Transient ischaemic attack	1(0.0%)	1(0.0%)
Carotid arteriosclerosis	1(0.0%)	0
Cerebral haemorrhage	1(0.0%)	0
Cerebrovascular disorder	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
Hepatic encephalopathy	1(0.0%)	0
IIIrd nerve paralysis	1(0.0%)	0
Myelopathy	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Parkinson's disease	1(0.0%)	0
Partial seizures	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
Epilepsy	0	2(0.1%)
Migraine	0	2(0.1%)
Altered state of consciousness	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Carotid artery stenosis	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Cerebral disorder	0	1(0.0%)
Cognitive disorder	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Metabolic encephalopathy	0	1(0.0%)
Neuralgia	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Vascular encephalopathy	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	36(1.4%)	42(1.6%)
Back pain	5(0.2%)	8(0.3%)
Osteoarthritis	4(0.2%)	4(0.2%)
Pain in extremity	3(0.1%)	4(0.2%)
Intervertebral disc protrusion	3(0.1%)	3(0.1%)
Rhabdomyolysis	3(0.1%)	2(0.1%)
Gouty arthritis	3(0.1%)	1(0.0%)
Arthralgia	2(0.1%)	5(0.2%)
Spinal osteoarthritis	2(0.1%)	2(0.1%)
Myalgia	1(0.0%)	1(0.0%)
Arthritis	1(0.0%)	0
Cervical spinal stenosis	1(0.0%)	0
Kyphosis	1(0.0%)	0
Musculoskeletal chest pain	1(0.0%)	0
Musculoskeletal pain	1(0.0%)	0
Osteitis	1(0.0%)	0
Polymyalgia rheumatica	1(0.0%)	0
Rheumatoid arthritis	1(0.0%)	0
Spondylitis	1(0.0%)	0
Tendonitis	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Torticollis	1(0.0%)	0
Trigger finger	1(0.0%)	0
Muscle spasms	0	3(0.1%)
Rotator cuff syndrome	0	3(0.1%)
Lumbar spinal stenosis	0	2(0.1%)
Back disorder	0	1(0.0%)
Bursitis	0	1(0.0%)
Foot deformity	0	1(0.0%)
Intervertebral disc degeneration	0	1(0.0%)
Limb discomfort	0	1(0.0%)
Osteolysis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Osteopenia	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Spondylolisthesis	0	1(0.0%)
Vascular Disorders	33(1.3%)	43(1.6%)
Hypotension	7(0.3%)	2(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Hypertension	4(0.2%)	21(0.8%)
Orthostatic hypotension	4(0.2%)	0
Aortic stenosis	3(0.1%)	1(0.0%)
Hypertensive crisis	2(0.1%)	2(0.1%)
Hypertensive urgency	2(0.1%)	2(0.1%)
Peripheral ischaemia	2(0.1%)	1(0.0%)
Deep vein thrombosis	2(0.1%)	0
Hypertensive emergency	1(0.0%)	3(0.1%)
Circulatory collapse	1(0.0%)	1(0.0%)
Extremity necrosis	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Peripheral arterial occlusive disease	1(0.0%)	1(0.0%)
Peripheral artery stenosis	1(0.0%)	1(0.0%)
Brachiocephalic arteriosclerosis	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Peripheral artery aneurysm	1(0.0%)	0
Haematoma	0	2(0.1%)
Aortic aneurysm	0	1(0.0%)
Blood pressure inadequately controlled	0	1(0.0%)
Intermittent claudication	0	1(0.0%)
Lymphoedema	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Cardiac Disorders	30(1.1%)	42(1.6%)
Coronary artery disease	8(0.3%)	2(0.1%)
Bradycardia	4(0.2%)	1(0.0%)
Cardiac failure congestive	2(0.1%)	6(0.2%)
Cardio-respiratory arrest	2(0.1%)	0
Cardiac failure	1(0.0%)	12(0.5%)
Angina unstable	1(0.0%)	4(0.2%)
Cardiac failure chronic	1(0.0%)	3(0.1%)
Ischaemic cardiomyopathy	1(0.0%)	1(0.0%)
Acute left ventricular failure	1(0.0%)	0
Aortic valve calcification	1(0.0%)	0
Aortic valve disease mixed	1(0.0%)	0
Arrhythmia	1(0.0%)	0
Arrhythmia supraventricular	1(0.0%)	0
Atrial enlargement	1(0.0%)	0
Cardiac failure acute	1(0.0%)	0
Congestive cardiomyopathy	1(0.0%)	0
Coronary artery stenosis	1(0.0%)	0
Left ventricular dysfunction	1(0.0%)	0
Myocarditis	1(0.0%)	0
Sinus node dysfunction	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Ventricular hypokinesia	1(0.0%)	0
Atrial fibrillation	0	3(0.1%)
Acute coronary syndrome	0	2(0.1%)
Left atrial dilatation	0	2(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Aortic valve stenosis	0	1(0.0%)
Atrial flutter	0	1(0.0%)
Atrial thrombosis	0	1(0.0%)
Atrioventricular block second degree	0	1(0.0%)
Cardiac arrest	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Diastolic dysfunction	0	1(0.0%)
Left ventricular hypertrophy	0	1(0.0%)
Mitral valve incompetence	0	1(0.0%)
Palpitations	0	1(0.0%)
Wandering pacemaker	0	1(0.0%)
Investigations	27(1.0%)	20(0.8%)
Glomerular filtration rate decreased	12(0.5%)	8(0.3%)
Blood potassium increased	2(0.1%)	0
Gamma-glutamyltransferase increased	2(0.1%)	0
Blood creatinine increased	1(0.0%)	1(0.0%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Anticoagulation drug level above therapeutic	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood calcium decreased	1(0.0%)	0
Blood pressure increased	1(0.0%)	0
Blood triglycerides increased	1(0.0%)	0
Catheterisation cardiac	1(0.0%)	0
Glycosylated haemoglobin increased	1(0.0%)	0
Influenza A virus test positive	1(0.0%)	0
Low density lipoprotein decreased	1(0.0%)	0
Oxygen consumption increased	1(0.0%)	0
Angiocardiogram	0	1(0.0%)
Biopsy kidney	0	1(0.0%)
Blood creatine phosphokinase increased	0	1(0.0%)
Colonoscopy	0	1(0.0%)
Haematology test abnormal	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Liver function test increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Weight decreased	0	1(0.0%)
Blood And Lymphatic System Disorders	19(0.7%)	24(0.9%)
Anaemia	10(0.4%)	16(0.6%)
Iron deficiency anaemia	4(0.2%)	3(0.1%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Thrombocytopenia	1(0.0%)	2(0.1%)
Immune thrombocytopenia	1(0.0%)	0
Pancytopenia	1(0.0%)	0
Febrile neutropenia	0	1(0.0%)
Lymphadenopathy mediastinal	0	1(0.0%)
Microcytic anaemia	0	1(0.0%)
Nephrogenic anaemia	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Normocytic anaemia	0	1(0.0%)
General Disorders And Administration Site Conditions	18(0.7%)	30(1.1%)
Chest pain	3(0.1%)	9(0.3%)
Oedema peripheral	3(0.1%)	5(0.2%)
Death	2(0.1%)	4(0.2%)
Pyrexia	2(0.1%)	0
Fatigue	1(0.0%)	2(0.1%)
General physical health deterioration	1(0.0%)	1(0.0%)
Feeling abnormal	1(0.0%)	0
Malaise	1(0.0%)	0
Multiple organ dysfunction syndrome	1(0.0%)	0
Oedema	1(0.0%)	0
Pain	1(0.0%)	0
Swelling face	1(0.0%)	0
Asthenia	0	3(0.1%)
Gait disturbance	0	2(0.1%)
Generalised oedema	0	2(0.1%)
Peripheral swelling	0	2(0.1%)
Chest discomfort	0	1(0.0%)
Discomfort	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	17(0.6%)	24(0.9%)
Diabetic foot	8(0.3%)	10(0.4%)
Angioedema	2(0.1%)	0
Pemphigoid	2(0.1%)	0
Skin ulcer	1(0.0%)	6(0.2%)
Pruritus	1(0.0%)	1(0.0%)
Skin lesion	1(0.0%)	1(0.0%)
Drug eruption	1(0.0%)	0
Ingrowing nail	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Decubitus ulcer	0	2(0.1%)
Blister	0	1(0.0%)
Dermatitis	0	1(0.0%)
Dermatitis bullous	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Surgical And Medical Procedures	16(0.6%)	17(0.7%)
Toe amputation	3(0.1%)	4(0.2%)
Hip arthroplasty	2(0.1%)	1(0.0%)
Leg amputation	2(0.1%)	0
Cataract operation	1(0.0%)	1(0.0%)
Foot amputation	1(0.0%)	1(0.0%)
Coronary angioplasty	1(0.0%)	0
Hysterectomy	1(0.0%)	0
Prostatectomy	1(0.0%)	0
Radical prostatectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Gastrectomy	0	2(0.1%)
Haemodialysis	0	2(0.1%)
Amputation	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Insertion of ambulatory peritoneal catheter	0	1(0.0%)
Spinal operation	0	1(0.0%)
Umbilical hernia repair	0	1(0.0%)
Vitrectomy	0	1(0.0%)
Eye Disorders	12(0.5%)	13(0.5%)
Cataract	3(0.1%)	6(0.2%)
Vitreous haemorrhage	2(0.1%)	1(0.0%)
Glaucoma	2(0.1%)	0
Retinal vein occlusion	2(0.1%)	0
Retinal detachment	1(0.0%)	2(0.1%)
Diabetic retinopathy	1(0.0%)	1(0.0%)
Macular fibrosis	1(0.0%)	1(0.0%)
Eye disorder	1(0.0%)	0
Retinal haemorrhage	1(0.0%)	0
Tractional retinal detachment	1(0.0%)	0
Visual impairment	1(0.0%)	0
Blindness	0	2(0.1%)
Blindness unilateral	0	2(0.1%)
Macular oedema	0	1(0.0%)
Retinopathy	0	1(0.0%)
Rhegmatogenous retinal detachment	0	1(0.0%)
Hepatobiliary Disorders	11(0.4%)	14(0.5%)
Cholangitis	2(0.1%)	3(0.1%)
Cholecystitis	2(0.1%)	2(0.1%)
Cholecystitis acute	1(0.0%)	3(0.1%)
Hepatic cirrhosis	1(0.0%)	2(0.1%)
Cholelithiasis	1(0.0%)	1(0.0%)
Bile duct stone	1(0.0%)	0
Hepatic steatosis	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatomegaly	1(0.0%)	0
Cholangitis acute	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver disorder	0	1(0.0%)
Reproductive System And Breast Disorders	7(0.3%)	4(0.2%)
Prostatomegaly	2(0.1%)	0
Benign prostatic hyperplasia	1(0.0%)	2(0.1%)
Endometrial hyperplasia	1(0.0%)	1(0.0%)
Uterine haemorrhage	1(0.0%)	1(0.0%)
Uterine prolapse	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Dysfunctional uterine bleeding	0	1(0.0%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Testicular mass	0	1(0.0%)
Uterine mass	0	1(0.0%)
Psychiatric Disorders	3(0.1%)	8(0.3%)
Anxiety	1(0.0%)	1(0.0%)
Confusional state	1(0.0%)	1(0.0%)
Alcohol withdrawal syndrome	1(0.0%)	0
Depression	0	2(0.1%)
Insomnia	0	2(0.1%)
Mental status changes	0	2(0.1%)
Ear And Labyrinth Disorders	2(0.1%)	4(0.2%)
Vertigo	1(0.0%)	1(0.0%)
Vertigo positional	1(0.0%)	0
Sudden hearing loss	0	2(0.1%)
Deafness	0	1(0.0%)
Congenital, Familial And Genetic Disorders	1(0.0%)	1(0.0%)
Truncus arteriosus persistent	1(0.0%)	0
Type V hyperlipidaemia	0	1(0.0%)
Immune System Disorders	1(0.0%)	0
Drug hypersensitivity	1(0.0%)	0
Product Issues	0	2(0.1%)
Device dislocation	0	1(0.0%)
Device leakage	0	1(0.0%)
Endocrine Disorders	0	1(0.0%)
Thyroiditis	0	1(0.0%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Any TEAE	197(7.5%)	157(6.0%)
Metabolism And Nutrition Disorders	50(1.9%)	20(0.8%)
Hyperkalaemia	49(1.9%)	17(0.7%)
Hyponatraemia	1(0.0%)	0
Fluid retention	0	1(0.0%)
Hypoglycaemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Renal And Urinary Disorders	26(1.0%)	33(1.3%)
Renal impairment	8(0.3%)	8(0.3%)
Acute kidney injury	5(0.2%)	7(0.3%)
Renal failure	3(0.1%)	4(0.2%)
Chronic kidney disease	2(0.1%)	8(0.3%)
Proteinuria	2(0.1%)	1(0.0%)
Diabetic nephropathy	1(0.0%)	1(0.0%)
End stage renal disease	1(0.0%)	1(0.0%)
Nephropathy	1(0.0%)	1(0.0%)
Nephrolithiasis	1(0.0%)	0
Nephrotic syndrome	1(0.0%)	0
Urinary retention	1(0.0%)	0
Perinephritis	0	1(0.0%)
Renal mass	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Investigations	23(0.9%)	19(0.7%)
Blood potassium increased	11(0.4%)	6(0.2%)
Glomerular filtration rate decreased	6(0.2%)	7(0.3%)
Blood creatinine increased	5(0.2%)	5(0.2%)
Blood pressure increased	1(0.0%)	0
Blood urea increased	1(0.0%)	0
Weight decreased	1(0.0%)	0
Amylase increased	0	1(0.0%)
Lipase increased	0	1(0.0%)
Protein urine present	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	22(0.8%)	24(0.9%)
Lung neoplasm malignant	4(0.2%)	1(0.0%)
Colon cancer	1(0.0%)	1(0.0%)
Renal neoplasm	1(0.0%)	1(0.0%)
Transitional cell carcinoma	1(0.0%)	1(0.0%)
Benign salivary gland neoplasm	1(0.0%)	0
Breast cancer	1(0.0%)	0
Cholangiocarcinoma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Lung cancer metastatic	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Metastases to lung	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Oesophageal adenocarcinoma	1(0.0%)	0

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pancreatic neoplasm	1(0.0%)	0
Prostate cancer metastatic	1(0.0%)	0
Rectal adenocarcinoma	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Brain neoplasm	0	2(0.1%)
Hepatocellular carcinoma	0	2(0.1%)
Metastases to lymph nodes	0	2(0.1%)
Small cell lung cancer	0	2(0.1%)
Acoustic neuroma	0	1(0.0%)
Acute myeloid leukaemia	0	1(0.0%)
Adenocarcinoma gastric	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal adenoma	0	1(0.0%)
Bladder cancer	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Lung adenocarcinoma	0	1(0.0%)
Malignant neoplasm of unknown primary site	0	1(0.0%)
Metastases to liver	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Pancreatic carcinoma metastatic	0	1(0.0%)
Renal cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Gastrointestinal Disorders	14(0.5%)	15(0.6%)
Diarrhoea	4(0.2%)	8(0.3%)
Nausea	2(0.1%)	4(0.2%)
Vomiting	2(0.1%)	2(0.1%)
Constipation	1(0.0%)	2(0.1%)
Gastric haemorrhage	1(0.0%)	0
Gastrointestinal haemorrhage	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Pancreatic cyst	1(0.0%)	0
Pancreatitis acute	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Abdominal pain upper	0	2(0.1%)
Abdominal discomfort	0	1(0.0%)
Anal fistula	0	1(0.0%)
Ascites	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	12(0.5%)	6(0.2%)
Pruritus	5(0.2%)	1(0.0%)
Rash	3(0.1%)	1(0.0%)
Eczema	1(0.0%)	2(0.1%)
Decubitus ulcer	1(0.0%)	0
Dermatitis allergic	1(0.0%)	0
Diabetic foot	1(0.0%)	0
Rash papular	1(0.0%)	0
Blister	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Infections And Infestations	11(0.4%)	8(0.3%)
Sepsis	2(0.1%)	2(0.1%)
Localised infection	1(0.0%)	1(0.0%)
Acarodermatitis	1(0.0%)	0
Influenza	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pulmonary sepsis	1(0.0%)	0
Pulmonary tuberculosis	1(0.0%)	0
Soft tissue infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Urinary tract infection	1(0.0%)	0
Pneumonia	0	3(0.1%)
Cellulitis	0	1(0.0%)
Osteomyelitis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Nervous System Disorders	8(0.3%)	9(0.3%)
Headache	3(0.1%)	0
Dizziness	2(0.1%)	2(0.1%)
Dementia with Lewy bodies	1(0.0%)	0
Memory impairment	1(0.0%)	0
Seizure	1(0.0%)	0
Dementia	0	2(0.1%)
Carotid artery stenosis	0	1(0.0%)
Epilepsy	0	1(0.0%)
Somnolence	0	1(0.0%)
Transient ischaemic attack	0	1(0.0%)
Trigeminal neuralgia	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	8(0.3%)	3(0.1%)
Arthralgia	2(0.1%)	0
Myalgia	1(0.0%)	1(0.0%)
Connective tissue inflammation	1(0.0%)	0
Flank pain	1(0.0%)	0
Musculoskeletal pain	1(0.0%)	0
Polymyalgia rheumatica	1(0.0%)	0
Rhabdomyolysis	1(0.0%)	0
Pain in extremity	0	1(0.0%)
Rotator cuff syndrome	0	1(0.0%)
General Disorders And Administration Site Conditions	5(0.2%)	6(0.2%)
Malaise	2(0.1%)	0
Asthenia	1(0.0%)	0
Fatigue	1(0.0%)	0
Oedema	1(0.0%)	0
Oedema peripheral	0	2(0.1%)
Peripheral swelling	0	2(0.1%)
Chills	0	1(0.0%)
Generalised oedema	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	4(0.2%)	6(0.2%)
Respiratory failure	2(0.1%)	0

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Pleural effusion	1(0.0%)	0
Pulmonary mass	1(0.0%)	0
Dyspnoea	0	3(0.1%)
Acute respiratory failure	0	1(0.0%)
Dyspnoea exertional	0	1(0.0%)
Interstitial lung disease	0	1(0.0%)
Vascular Disorders	4(0.2%)	3(0.1%)
Hypertensive crisis	1(0.0%)	1(0.0%)
Hypertensive urgency	1(0.0%)	0
Hypotension	1(0.0%)	0
Peripheral ischaemia	1(0.0%)	0
Hypertension	0	2(0.1%)
Surgical And Medical Procedures	4(0.2%)	0
Dialysis	1(0.0%)	0
Leg amputation	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Cardiac Disorders	3(0.1%)	6(0.2%)
Cardiac failure	1(0.0%)	3(0.1%)
Ischaemic cardiomyopathy	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Atrial fibrillation	0	1(0.0%)
Bradycardia	0	1(0.0%)
Palpitations	0	1(0.0%)
Blood And Lymphatic System Disorders	3(0.1%)	3(0.1%)
Anaemia	2(0.1%)	1(0.0%)
Pancytopenia	1(0.0%)	0
Blood loss anaemia	0	1(0.0%)
Iron deficiency anaemia	0	1(0.0%)
Injury, Poisoning And Procedural Complications	2(0.1%)	2(0.1%)
Road traffic accident	1(0.0%)	1(0.0%)
Hip fracture	1(0.0%)	0
Concussion	0	1(0.0%)
Femur fracture	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Radius fracture	0	1(0.0%)
Rib fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Hepatobiliary Disorders	2(0.1%)	1(0.0%)
Hepatic cirrhosis	1(0.0%)	0
Nonalcoholic fatty liver disease	1(0.0%)	0
Liver disorder	0	1(0.0%)
Immune System Disorders	2(0.1%)	0
Drug hypersensitivity	1(0.0%)	0
Hypersensitivity	1(0.0%)	0

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=2617)	Placebo (N=2610)
Psychiatric Disorders	1(0.0%)	4(0.2%)
Alcohol abuse	1(0.0%)	0
Anorgasmia	0	1(0.0%)
Confusional state	0	1(0.0%)
Depression	0	1(0.0%)
Suicidal ideation	0	1(0.0%)
Ear And Labyrinth Disorders	0	1(0.0%)
Vertigo	0	1(0.0%)

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

Table A2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=2617)	Placebo (N=2610)	Total (N= 5227
Treatment duration (months)			
n	2617	2610	5227
Mean	26.5	26.9	26.7
SD	12.32	12.05	12.19
Median	26.1	26.5	26.3
Q1-Q3	19.4 - 35.8	19.8 - 35.7	19.6 - 35.7
Range	0.03 - 51.48	0.07 - 51.52	0.03 - 51.52

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

Table A2.1.1: Effect Measures of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		2287 (87.4%)	2300 (88.1%)	4587 (87.8%)
Number of subjects without events		330 (12.6%)	310 (11.9%)	640 (12.2%)
Odds Ratio [a]				
OR, 95% CI	0.934 [0.792, 1.102]			
p-value	0.4193			
Relative Risk [b]				
RR, 95% CI	0.992 [0.972, 1.012]			
p-value	0.4192			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.025, 0.010]			
p-value	0.4192			

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

Table A2.1.2: Effect Measures of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		2263 (86.5%)	2281 (87.4%)	4544 (86.9%)
Number of subjects without events		354 (13.5%)	329 (12.6%)	683 (13.1%)
Odds Ratio [a]				
OR, 95% CI	0.922 [0.785, 1.083]			
p-value	0.3230			
Relative Risk [b]				
RR, 95% CI	0.989 [0.969, 1.010]			
p-value	0.3230			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.027, 0.009]			
p-value	0.3229			

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

Table A2.1.3: Effect Measures of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		837 (32.0%)	904 (34.6%)	1741 (33.3%)
Number of subjects without events		1780 (68.0%)	1706 (65.4%)	3486 (66.7%)
Odds Ratio [a]				
OR, 95% CI	0.887 [0.791, 0.996]			
p-value	0.0419			
Relative Risk [b]				
RR, 95% CI	0.923 [0.855, 0.997]			
p-value	0.0420			
Risk Difference [c]				
RD, 95% CI	-0.027 [-0.052, -0.001]			
p-value	0.0418			

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

Table A2.1.4: Effect Measures of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		814 (31.1%)	881 (33.8%)	1695 (32.4%)
Number of subjects without events		1803 (68.9%)	1729 (66.2%)	3532 (67.6%)
Odds Ratio [a]				
OR, 95% CI	0.886 [0.789, 0.995]			
p-value	0.0407			
Relative Risk [b]				
RR, 95% CI	0.921 [0.852, 0.997]			
p-value	0.0408			
Risk Difference [c]				
RD, 95% CI	-0.027 [-0.052, -0.001]			
p-value	0.0406			

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

Table A2.1.5: Effect Measures of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		466 (17.8%)	518 (19.8%)	984 (18.8%)
Number of subjects without events		2151 (82.2%)	2092 (80.2%)	4243 (81.2%)
Odds Ratio [a]				
OR, 95% CI	0.875 [0.762, 1.005]			
p-value	0.0593			
Relative Risk [b]				
RR, 95% CI	0.897 [0.802, 1.004]			
p-value	0.0594			
Risk Difference [c]				
RD, 95% CI	-0.020 [-0.042, 0.001]			
p-value	0.0592			

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

Table A2.1.6: Effect Measures of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		444 (17.0%)	497 (19.0%)	941 (18.0%)
Number of subjects without events		2173 (83.0%)	2113 (81.0%)	4286 (82.0%)
Odds Ratio [a]				
OR, 95% CI	0.869 [0.754, 1.001]			
p-value	0.0509			
Relative Risk [b]				
RR, 95% CI	0.891 [0.793, 1.000]			
p-value	0.0510			
Risk Difference [c]				
RD, 95% CI	-0.021 [-0.042, 0.000]			
p-value	0.0507			

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

Table A2.1.7: Effect Measures of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		197 (7.5%)	157 (6.0%)	354 (6.8%)
Number of subjects without events		2420 (92.5%)	2453 (94.0%)	4873 (93.2%)
Odds Ratio [a]				
OR, 95% CI	1.272 [1.024, 1.580]			
p-value	0.0299			
Relative Risk [b]				
RR, 95% CI	1.251 [1.022, 1.532]			
p-value	0.0300			
Risk Difference [c]				
RD, 95% CI	0.015 [0.002, 0.029]			
p-value	0.0295			

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

Table A2.1.8: Effect Measures of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		295 (11.3%)	283 (10.8%)	578 (11.1%)
Number of subjects without events		2322 (88.7%)	2327 (89.2%)	4649 (88.9%)
Odds Ratio [a]				
OR, 95% CI	1.045 [0.879, 1.242]			
p-value	0.6205			
Relative Risk [b]				
RR, 95% CI	1.040 [0.891, 1.212]			
p-value	0.6206			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.013, 0.021]			
p-value	0.6205			

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

Table A2.1.9: Effect Measures of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		200 (7.6%)	181 (6.9%)	381 (7.3%)
Number of subjects without events		2417 (92.4%)	2429 (93.1%)	4846 (92.7%)
Odds Ratio [a]				
OR, 95% CI	1.110 [0.901, 1.368]			
p-value	0.3254			
Relative Risk [b]				
RR, 95% CI	1.102 [0.908, 1.337]			
p-value	0.3255			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.007, 0.021]			
p-value	0.3251			

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

Table A2.1.10: Effect Measures of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	28 (1.1%)	55 (1.1%)
Number of subjects without events		2590 (99.0%)	2582 (98.9%)	5172 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.961 [0.565, 1.636]			
p-value	0.8843			
Relative Risk [b]				
RR, 95% CI	0.962 [0.568, 1.627]			
p-value	0.8843			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.005]			
p-value	0.8843			

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

Table A2.1.11: Effect Measures of Proportion of Subjects with TEAEs - Nephrogenic anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	26 (1.0%)	56 (1.1%)
Number of subjects without events		2587 (98.9%)	2584 (99.0%)	5171 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.153 [0.680, 1.954]			
p-value	0.5983			
Relative Risk [b]				
RR, 95% CI	1.151 [0.683, 1.940]			
p-value	0.5983			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.007]			
p-value	0.5979			

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

Table A2.1.12: Effect Measures of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		287 (11.0%)	373 (14.3%)	660 (12.6%)
Number of subjects without events		2330 (89.0%)	2237 (85.7%)	4567 (87.4%)
Odds Ratio [a]				
OR, 95% CI	0.739 [0.627, 0.871]			
p-value	0.0003			
Relative Risk [b]				
RR, 95% CI	0.767 [0.664, 0.886]			
p-value	0.0003			
Risk Difference [c]				
RD, 95% CI	-0.033 [-0.051, -0.015]			
p-value	0.0003			

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

Table A2.1.13: Effect Measures of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	32 (1.2%)	55 (1.1%)
Number of subjects without events		2594 (99.1%)	2578 (98.8%)	5172 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.714 [0.417, 1.224]			
p-value	0.2208			
Relative Risk [b]				
RR, 95% CI	0.717 [0.421, 1.222]			
p-value	0.2209			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.002]			
p-value	0.2187			

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

Table A2.1.14: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		25 (1.0%)	49 (1.9%)	74 (1.4%)
Number of subjects without events		2592 (99.0%)	2561 (98.1%)	5153 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.504 [0.310, 0.819]			
p-value	0.0056			
Relative Risk [b]				
RR, 95% CI	0.509 [0.315, 0.821]			
p-value	0.0057			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.016, -0.003]			
p-value	0.0048			

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

Table A2.1.15: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		8 (0.3%)	25 (1.0%)	33 (0.6%)
Number of subjects without events		2609 (99.7%)	2585 (99.0%)	5194 (99.4%)
Odds Ratio [a]				
OR, 95% CI	0.317 [0.143, 0.704]			
p-value	0.0048			
Relative Risk [b]				
RR, 95% CI	0.319 [0.144, 0.706]			
p-value	0.0048			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.011, -0.002]			
p-value	0.0029			

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

Table A2.1.16: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure congestive (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		16 (0.6%)	30 (1.1%)	46 (0.9%)
Number of subjects without events		2601 (99.4%)	2580 (98.9%)	5181 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.529 [0.288, 0.973]			
p-value	0.0405			
Relative Risk [b]				
RR, 95% CI	0.532 [0.291, 0.973]			
p-value	0.0406			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.000]			
p-value	0.0373			

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

Table A2.1.17: Effect Measures of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	26 (1.0%)	49 (0.9%)
Number of subjects without events		2594 (99.1%)	2584 (99.0%)	5178 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.881 [0.502, 1.548]			
p-value	0.6601			
Relative Risk [b]				
RR, 95% CI	0.882 [0.505, 1.542]			
p-value	0.6601			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.004]			
p-value	0.6599			

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

Table A2.1.18: Effect Measures of Proportion of Subjects with TEAEs - Myocardial ischaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		21 (0.8%)	26 (1.0%)	47 (0.9%)
Number of subjects without events		2596 (99.2%)	2584 (99.0%)	5180 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.804 [0.451, 1.432]			
p-value	0.4590			
Relative Risk [b]				
RR, 95% CI	0.806 [0.454, 1.428]			
p-value	0.4591			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.003]			
p-value	0.4582			

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

Table A2.1.19: Effect Measures of Proportion of Subjects with TEAEs - Palpitations (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		14 (0.5%)	26 (1.0%)	40 (0.8%)
Number of subjects without events		2603 (99.5%)	2584 (99.0%)	5187 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.535 [0.278, 1.026]			
p-value	0.0597			
Relative Risk [b]				
RR, 95% CI	0.537 [0.281, 1.026]			
p-value	0.0598			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.009, 0.000]			
p-value	0.0557			

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

Table A2.1.20: Effect Measures of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		112 (4.3%)	94 (3.6%)	206 (3.9%)
Number of subjects without events		2505 (95.7%)	2516 (96.4%)	5021 (96.1%)
Odds Ratio [a]				
OR, 95% CI	1.197 [0.905, 1.583]			
p-value	0.2082			
Relative Risk [b]				
RR, 95% CI	1.188 [0.908, 1.555]			
p-value	0.2083			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.004, 0.017]			
p-value	0.2076			

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

Table A2.1.21: Effect Measures of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		51 (1.9%)	37 (1.4%)	88 (1.7%)
Number of subjects without events		2566 (98.1%)	2573 (98.6%)	5139 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.382 [0.902, 2.118]			
p-value	0.1372			
Relative Risk [b]				
RR, 95% CI	1.375 [0.903, 2.092]			
p-value	0.1373			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.002, 0.012]			
p-value	0.1354			

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

Table A2.1.22: Effect Measures of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		78 (3.0%)	94 (3.6%)	172 (3.3%)
Number of subjects without events		2539 (97.0%)	2516 (96.4%)	5055 (96.7%)
Odds Ratio [a]				
OR, 95% CI	0.822 [0.606, 1.116]			
p-value	0.2089			
Relative Risk [b]				
RR, 95% CI	0.828 [0.616, 1.112]			
p-value	0.2090			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.016, 0.003]			
p-value	0.2082			

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

Table A2.1.23: Effect Measures of Proportion of Subjects with TEAEs - Hypothyroidism (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		26 (1.0%)	28 (1.1%)	54 (1.0%)
Number of subjects without events		2591 (99.0%)	2582 (98.9%)	5173 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.925 [0.541, 1.582]			
p-value	0.7769			
Relative Risk [b]				
RR, 95% CI	0.926 [0.545, 1.575]			
p-value	0.7769			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.005]			
p-value	0.7768			

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

Table A2.1.24: Effect Measures of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		316 (12.1%)	354 (13.6%)	670 (12.8%)
Number of subjects without events		2301 (87.9%)	2256 (86.4%)	4557 (87.2%)
Odds Ratio [a]				
OR, 95% CI	0.875 [0.744, 1.030]			
p-value	0.1077			
Relative Risk [b]				
RR, 95% CI	0.890 [0.773, 1.026]			
p-value	0.1078			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.033, 0.003]			
p-value	0.1075			

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

Table A2.1.25: Effect Measures of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		116 (4.4%)	116 (4.4%)	232 (4.4%)
Number of subjects without events		2501 (95.6%)	2494 (95.6%)	4995 (95.6%)
Odds Ratio [a]				
OR, 95% CI	0.997 [0.766, 1.298]			
p-value	0.9834			
Relative Risk [b]				
RR, 95% CI	0.997 [0.775, 1.283]			
p-value	0.9834			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.011, 0.011]			
p-value	0.9834			

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

Table A2.1.26: Effect Measures of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		42 (1.6%)	65 (2.5%)	107 (2.0%)
Number of subjects without events		2575 (98.4%)	2545 (97.5%)	5120 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.639 [0.432, 0.945]			
p-value	0.0249			
Relative Risk [b]				
RR, 95% CI	0.644 [0.439, 0.946]			
p-value	0.0250			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.017, -0.001]			
p-value	0.0238			

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

Table A2.1.27: Effect Measures of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	29 (1.1%)	57 (1.1%)
Number of subjects without events		2589 (98.9%)	2581 (98.9%)	5170 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.963 [0.571, 1.622]			
p-value	0.8860			
Relative Risk [b]				
RR, 95% CI	0.963 [0.575, 1.614]			
p-value	0.8860			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.005]			
p-value	0.8860			

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

Table A2.1.28: Effect Measures of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		693 (26.5%)	728 (27.9%)	1421 (27.2%)
Number of subjects without events		1924 (73.5%)	1882 (72.1%)	3806 (72.8%)
Odds Ratio [a]				
OR, 95% CI	0.931 [0.824, 1.052]			
p-value	0.2513			
Relative Risk [b]				
RR, 95% CI	0.949 [0.869, 1.038]			
p-value	0.2514			
Risk Difference [c]				
RD, 95% CI	-0.014 [-0.038, 0.010]			
p-value	0.2512			

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

Table A2.1.29: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		41 (1.6%)	44 (1.7%)	85 (1.6%)
Number of subjects without events		2576 (98.4%)	2566 (98.3%)	5142 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.928 [0.604, 1.425]			
p-value	0.7335			
Relative Risk [b]				
RR, 95% CI	0.929 [0.609, 1.417]			
p-value	0.7335			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.7335			

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

Table A2.1.30: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		47 (1.8%)	49 (1.9%)	96 (1.8%)
Number of subjects without events		2570 (98.2%)	2561 (98.1%)	5131 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.956 [0.638, 1.431]			
p-value	0.8265			
Relative Risk [b]				
RR, 95% CI	0.957 [0.644, 1.422]			
p-value	0.8265			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.8264			

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

Table A2.1.31: Effect Measures of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		124 (4.7%)	156 (6.0%)	280 (5.4%)
Number of subjects without events		2493 (95.3%)	2454 (94.0%)	4947 (94.6%)
Odds Ratio [a]				
OR, 95% CI	0.782 [0.614, 0.997]			
p-value	0.0472			
Relative Risk [b]				
RR, 95% CI	0.793 [0.630, 0.997]			
p-value	0.0473			
Risk Difference [c]				
RD, 95% CI	-0.012 [-0.025, 0.000]			
p-value	0.0467			

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

Table A2.1.32: Effect Measures of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		170 (6.5%)	181 (6.9%)	351 (6.7%)
Number of subjects without events		2447 (93.5%)	2429 (93.1%)	4876 (93.3%)
Odds Ratio [a]				
OR, 95% CI	0.932 [0.751, 1.158]			
p-value	0.5262			
Relative Risk [b]				
RR, 95% CI	0.937 [0.765, 1.147]			
p-value	0.5262			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.018, 0.009]			
p-value	0.5262			

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

Table A2.1.33: Effect Measures of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	35 (1.3%)	65 (1.2%)
Number of subjects without events		2587 (98.9%)	2575 (98.7%)	5162 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.853 [0.522, 1.394]			
p-value	0.5259			
Relative Risk [b]				
RR, 95% CI	0.855 [0.527, 1.388]			
p-value	0.5259			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.5255			

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

Table A2.1.34: Effect Measures of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		40 (1.5%)	34 (1.3%)	74 (1.4%)
Number of subjects without events		2577 (98.5%)	2576 (98.7%)	5153 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.176 [0.742, 1.864]			
p-value	0.4901			
Relative Risk [b]				
RR, 95% CI	1.173 [0.745, 1.847]			
p-value	0.4901			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.009]			
p-value	0.4896			

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

Table A2.1.35: Effect Measures of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		35 (1.3%)	56 (2.1%)	91 (1.7%)
Number of subjects without events		2582 (98.7%)	2554 (97.9%)	5136 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.618 [0.404, 0.946]			
p-value	0.0269			
Relative Risk [b]				
RR, 95% CI	0.623 [0.410, 0.948]			
p-value	0.0270			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.015, -0.001]			
p-value	0.0255			

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

Table A2.1.36: Effect Measures of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	29 (1.1%)	59 (1.1%)
Number of subjects without events		2587 (98.9%)	2581 (98.9%)	5168 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.032 [0.618, 1.724]			
p-value	0.9040			
Relative Risk [b]				
RR, 95% CI	1.032 [0.621, 1.714]			
p-value	0.9040			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.005, 0.006]			
p-value	0.9040			

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

Table A2.1.37: Effect Measures of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	43 (1.6%)	70 (1.3%)
Number of subjects without events		2590 (99.0%)	2567 (98.4%)	5157 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.622 [0.383, 1.010]			
p-value	0.0550			
Relative Risk [b]				
RR, 95% CI	0.626 [0.388, 1.010]			
p-value	0.0551			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.012, 0.000]			
p-value	0.0528			

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

Table A2.1.38: Effect Measures of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		83 (3.2%)	82 (3.1%)	165 (3.2%)
Number of subjects without events		2534 (96.8%)	2528 (96.9%)	5062 (96.8%)
Odds Ratio [a]				
OR, 95% CI	1.010 [0.741, 1.377]			
p-value	0.9509			
Relative Risk [b]				
RR, 95% CI	1.009 [0.748, 1.363]			
p-value	0.9509			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.009, 0.010]			
p-value	0.9509			

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

Table A2.1.39: Effect Measures of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		72 (2.8%)	59 (2.3%)	131 (2.5%)
Number of subjects without events		2545 (97.2%)	2551 (97.7%)	5096 (97.5%)
Odds Ratio [a]				
OR, 95% CI	1.223 [0.863, 1.733]			
p-value	0.2572			
Relative Risk [b]				
RR, 95% CI	1.217 [0.866, 1.710]			
p-value	0.2573			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.004, 0.013]			
p-value	0.2563			

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

Table A2.1.40: Effect Measures of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		481 (18.4%)	609 (23.3%)	1090 (20.9%)
Number of subjects without events		2136 (81.6%)	2001 (76.7%)	4137 (79.1%)
Odds Ratio [a]				
OR, 95% CI	0.740 [0.647, 0.846]			
p-value	0.0000			
Relative Risk [b]				
RR, 95% CI	0.788 [0.708, 0.876]			
p-value	0.0000			
Risk Difference [c]				
RD, 95% CI	-0.050 [-0.072, -0.028]			
p-value	0.0000			

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

Table A2.1.41: Effect Measures of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		38 (1.5%)	55 (2.1%)	93 (1.8%)
Number of subjects without events		2579 (98.5%)	2555 (97.9%)	5134 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.684 [0.451, 1.039]			
p-value	0.0748			
Relative Risk [b]				
RR, 95% CI	0.689 [0.457, 1.038]			
p-value	0.0749			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.014, 0.001]			
p-value	0.0732			

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

Table A2.1.42: Effect Measures of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		70 (2.7%)	76 (2.9%)	146 (2.8%)
Number of subjects without events		2547 (97.3%)	2534 (97.1%)	5081 (97.2%)
Odds Ratio [a]				
OR, 95% CI	0.916 [0.659, 1.274]			
p-value	0.6031			
Relative Risk [b]				
RR, 95% CI	0.919 [0.667, 1.265]			
p-value	0.6031			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.007]			
p-value	0.6030			

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

Table A2.1.43: Effect Measures of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		57 (2.2%)	59 (2.3%)	116 (2.2%)
Number of subjects without events		2560 (97.8%)	2551 (97.7%)	5111 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.963 [0.666, 1.391]			
p-value	0.8396			
Relative Risk [b]				
RR, 95% CI	0.964 [0.672, 1.381]			
p-value	0.8396			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.007]			
p-value	0.8396			

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

Table A2.1.44: Effect Measures of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		46 (1.8%)	48 (1.8%)	94 (1.8%)
Number of subjects without events		2571 (98.2%)	2562 (98.2%)	5133 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.955 [0.635, 1.436]			
p-value	0.8249			
Relative Risk [b]				
RR, 95% CI	0.956 [0.640, 1.427]			
p-value	0.8249			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.8249			

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

Table A2.1.45: Effect Measures of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		175 (6.7%)	288 (11.0%)	463 (8.9%)
Number of subjects without events		2442 (93.3%)	2322 (89.0%)	4764 (91.1%)
Odds Ratio [a]				
OR, 95% CI	0.578 [0.475, 0.703]			
p-value	0.0000			
Relative Risk [b]				
RR, 95% CI	0.606 [0.506, 0.725]			
p-value	0.0000			
Risk Difference [c]				
RD, 95% CI	-0.043 [-0.059, -0.028]			
p-value	0.0000			

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

Table A2.1.46: Effect Measures of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	37 (1.4%)	67 (1.3%)
Number of subjects without events		2587 (98.9%)	2573 (98.6%)	5160 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.806 [0.497, 1.309]			
p-value	0.3842			
Relative Risk [b]				
RR, 95% CI	0.809 [0.501, 1.305]			
p-value	0.3843			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.003]			
p-value	0.3834			

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

Table A2.1.47: Effect Measures of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		43 (1.6%)	37 (1.4%)	80 (1.5%)
Number of subjects without events		2574 (98.4%)	2573 (98.6%)	5147 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.162 [0.746, 1.809]			
p-value	0.5071			
Relative Risk [b]				
RR, 95% CI	1.159 [0.749, 1.793]			
p-value	0.5071			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.009]			
p-value	0.5067			

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

Table A2.1.48: Effect Measures of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		111 (4.2%)	125 (4.8%)	236 (4.5%)
Number of subjects without events		2506 (95.8%)	2485 (95.2%)	4991 (95.5%)
Odds Ratio [a]				
OR, 95% CI	0.881 [0.678, 1.144]			
p-value	0.3405			
Relative Risk [b]				
RR, 95% CI	0.886 [0.690, 1.137]			
p-value	0.3406			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.017, 0.006]			
p-value	0.3402			

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

Table A2.1.49: Effect Measures of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		37 (1.4%)	33 (1.3%)	70 (1.3%)
Number of subjects without events		2580 (98.6%)	2577 (98.7%)	5157 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.120 [0.698, 1.796]			
p-value	0.6385			
Relative Risk [b]				
RR, 95% CI	1.118 [0.702, 1.782]			
p-value	0.6385			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.005, 0.008]			
p-value	0.6383			

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

Table A2.1.50: Effect Measures of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	46 (1.8%)	74 (1.4%)
Number of subjects without events		2589 (98.9%)	2564 (98.2%)	5153 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.603 [0.376, 0.967]			
p-value	0.0360			
Relative Risk [b]				
RR, 95% CI	0.607 [0.381, 0.968]			
p-value	0.0361			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.013, -0.001]			
p-value	0.0341			

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

Table A2.1.51: Effect Measures of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		1139 (43.5%)	1165 (44.6%)	2304 (44.1%)
Number of subjects without events		1478 (56.5%)	1445 (55.4%)	2923 (55.9%)
Odds Ratio [a]				
OR, 95% CI	0.956 [0.857, 1.066]			
p-value	0.4178			
Relative Risk [b]				
RR, 95% CI	0.975 [0.917, 1.036]			
p-value	0.4178			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.038, 0.016]			
p-value	0.4177			

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

Table A2.1.52: Effect Measures of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		129 (4.9%)	143 (5.5%)	272 (5.2%)
Number of subjects without events		2488 (95.1%)	2467 (94.5%)	4955 (94.8%)
Odds Ratio [a]				
OR, 95% CI	0.894 [0.701, 1.142]			
p-value	0.3712			
Relative Risk [b]				
RR, 95% CI	0.900 [0.714, 1.134]			
p-value	0.3713			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.018, 0.007]			
p-value	0.3710			

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

Table A2.1.53: Effect Measures of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		71 (2.7%)	55 (2.1%)	126 (2.4%)
Number of subjects without events		2546 (97.3%)	2555 (97.9%)	5101 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.295 [0.907, 1.850]			
p-value	0.1545			
Relative Risk [b]				
RR, 95% CI	1.287 [0.909, 1.823]			
p-value	0.1546			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.002, 0.014]			
p-value	0.1532			

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

Table A2.1.54: Effect Measures of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		37 (1.4%)	37 (1.4%)	74 (1.4%)
Number of subjects without events		2580 (98.6%)	2573 (98.6%)	5153 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.997 [0.630, 1.578]			
p-value	0.9907			
Relative Risk [b]				
RR, 95% CI	0.997 [0.634, 1.568]			
p-value	0.9907			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9907			

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

Table A2.1.55: Effect Measures of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		44 (1.7%)	50 (1.9%)	94 (1.8%)
Number of subjects without events		2573 (98.3%)	2560 (98.1%)	5133 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.876 [0.582, 1.318]			
p-value	0.5240			
Relative Risk [b]				
RR, 95% CI	0.878 [0.587, 1.311]			
p-value	0.5240			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.010, 0.005]			
p-value	0.5238			

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

Table A2.1.56: Effect Measures of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		31 (1.2%)	29 (1.1%)	60 (1.1%)
Number of subjects without events		2586 (98.8%)	2581 (98.9%)	5167 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.067 [0.641, 1.775]			
p-value	0.8032			
Relative Risk [b]				
RR, 95% CI	1.066 [0.644, 1.764]			
p-value	0.8032			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.005, 0.007]			
p-value	0.8032			

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

Table A2.1.57: Effect Measures of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		104 (4.0%)	98 (3.8%)	202 (3.9%)
Number of subjects without events		2513 (96.0%)	2512 (96.2%)	5025 (96.1%)
Odds Ratio [a]				
OR, 95% CI	1.061 [0.801, 1.406]			
p-value	0.6810			
Relative Risk [b]				
RR, 95% CI	1.058 [0.808, 1.387]			
p-value	0.6810			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.008, 0.013]			
p-value	0.6809			

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

Table A2.1.58: Effect Measures of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		227 (8.7%)	232 (8.9%)	459 (8.8%)
Number of subjects without events		2390 (91.3%)	2378 (91.1%)	4768 (91.2%)
Odds Ratio [a]				
OR, 95% CI	0.974 [0.804, 1.179]			
p-value	0.7838			
Relative Risk [b]				
RR, 95% CI	0.976 [0.819, 1.162]			
p-value	0.7838			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.017, 0.013]			
p-value	0.7838			

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

Table A2.1.59: Effect Measures of Proportion of Subjects with TEAEs - Periodontitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		15 (0.6%)	25 (1.0%)	40 (0.8%)
Number of subjects without events		2602 (99.4%)	2585 (99.0%)	5187 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.596 [0.314, 1.133]			
p-value	0.1145			
Relative Risk [b]				
RR, 95% CI	0.598 [0.316, 1.132]			
p-value	0.1146			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.009, 0.001]			
p-value	0.1106			

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

Table A2.1.60: Effect Measures of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		32 (1.2%)	31 (1.2%)	63 (1.2%)
Number of subjects without events		2585 (98.8%)	2579 (98.8%)	5164 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.030 [0.627, 1.693]			
p-value	0.9076			
Relative Risk [b]				
RR, 95% CI	1.029 [0.630, 1.682]			
p-value	0.9076			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9076			

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

Table A2.1.61: Effect Measures of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		118 (4.5%)	175 (6.7%)	293 (5.6%)
Number of subjects without events		2499 (95.5%)	2435 (93.3%)	4934 (94.4%)
Odds Ratio [a]				
OR, 95% CI	0.657 [0.517, 0.835]			
p-value	0.0006			
Relative Risk [b]				
RR, 95% CI	0.672 [0.536, 0.844]			
p-value	0.0006			
Risk Difference [c]				
RD, 95% CI	-0.022 [-0.034, -0.009]			
p-value	0.0006			

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

Table A2.1.62: Effect Measures of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		43 (1.6%)	37 (1.4%)	80 (1.5%)
Number of subjects without events		2574 (98.4%)	2573 (98.6%)	5147 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.162 [0.746, 1.809]			
p-value	0.5071			
Relative Risk [b]				
RR, 95% CI	1.159 [0.749, 1.793]			
p-value	0.5071			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.004, 0.009]			
p-value	0.5067			

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

Table A2.1.63: Effect Measures of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	28 (1.1%)	56 (1.1%)
Number of subjects without events		2589 (98.9%)	2582 (98.9%)	5171 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.997 [0.589, 1.689]			
p-value	0.9920			
Relative Risk [b]				
RR, 95% CI	0.997 [0.592, 1.679]			
p-value	0.9920			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9920			

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

Table A2.1.64: Effect Measures of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		170 (6.5%)	171 (6.6%)	341 (6.5%)
Number of subjects without events		2447 (93.5%)	2439 (93.4%)	4886 (93.5%)
Odds Ratio [a]				
OR, 95% CI	0.991 [0.796, 1.234]			
p-value	0.9350			
Relative Risk [b]				
RR, 95% CI	0.991 [0.808, 1.217]			
p-value	0.9350			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.014, 0.013]			
p-value	0.9350			

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

Table A2.1.65: Effect Measures of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		165 (6.3%)	177 (6.8%)	342 (6.5%)
Number of subjects without events		2452 (93.7%)	2433 (93.2%)	4885 (93.5%)
Odds Ratio [a]				
OR, 95% CI	0.925 [0.743, 1.152]			
p-value	0.4860			
Relative Risk [b]				
RR, 95% CI	0.930 [0.757, 1.141]			
p-value	0.4860			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.018, 0.009]			
p-value	0.4859			

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

Table A2.1.66: Effect Measures of Proportion of Subjects with TEAEs - Viral infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		16 (0.6%)	25 (1.0%)	41 (0.8%)
Number of subjects without events		2601 (99.4%)	2585 (99.0%)	5186 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.636 [0.339, 1.194]			
p-value	0.1591			
Relative Risk [b]				
RR, 95% CI	0.638 [0.342, 1.193]			
p-value	0.1593			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.008, 0.001]			
p-value	0.1557			

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

Table A2.1.67: Effect Measures of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		425 (16.2%)	437 (16.7%)	862 (16.5%)
Number of subjects without events		2192 (83.8%)	2173 (83.3%)	4365 (83.5%)
Odds Ratio [a]				
OR, 95% CI	0.964 [0.833, 1.116]			
p-value	0.6239			
Relative Risk [b]				
RR, 95% CI	0.970 [0.859, 1.096]			
p-value	0.6240			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.025, 0.015]			
p-value	0.6239			

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

Table A2.1.68: Effect Measures of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		49 (1.9%)	52 (2.0%)	101 (1.9%)
Number of subjects without events		2568 (98.1%)	2558 (98.0%)	5126 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.939 [0.633, 1.392]			
p-value	0.7528			
Relative Risk [b]				
RR, 95% CI	0.940 [0.639, 1.383]			
p-value	0.7528			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.006]			
p-value	0.7527			

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

Table A2.1.69: Effect Measures of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		43 (1.6%)	52 (2.0%)	95 (1.8%)
Number of subjects without events		2574 (98.4%)	2558 (98.0%)	5132 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.822 [0.547, 1.235]			
p-value	0.3454			
Relative Risk [b]				
RR, 95% CI	0.825 [0.553, 1.231]			
p-value	0.3454			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.004]			
p-value	0.3446			

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

Table A2.1.70: Effect Measures of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		70 (2.7%)	47 (1.8%)	117 (2.2%)
Number of subjects without events		2547 (97.3%)	2563 (98.2%)	5110 (97.8%)
Odds Ratio [a]				
OR, 95% CI	1.499 [1.031, 2.178]			
p-value	0.0338			
Relative Risk [b]				
RR, 95% CI	1.485 [1.031, 2.141]			
p-value	0.0339			
Risk Difference [c]				
RD, 95% CI	0.009 [0.001, 0.017]			
p-value	0.0326			

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

Table A2.1.71: Effect Measures of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		598 (22.9%)	630 (24.1%)	1228 (23.5%)
Number of subjects without events		2019 (77.1%)	1980 (75.9%)	3999 (76.5%)
Odds Ratio [a]				
OR, 95% CI	0.931 [0.819, 1.058]			
p-value	0.2724			
Relative Risk [b]				
RR, 95% CI	0.947 [0.858, 1.044]			
p-value	0.2725			
Risk Difference [c]				
RD, 95% CI	-0.013 [-0.036, 0.010]			
p-value	0.2723			

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

Table A2.1.72: Effect Measures of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		56 (2.1%)	94 (3.6%)	150 (2.9%)
Number of subjects without events		2561 (97.9%)	2516 (96.4%)	5077 (97.1%)
Odds Ratio [a]				
OR, 95% CI	0.585 [0.419, 0.819]			
p-value	0.0017			
Relative Risk [b]				
RR, 95% CI	0.594 [0.429, 0.823]			
p-value	0.0018			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.024, -0.006]			
p-value	0.0015			

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

Table A2.1.73: Effect Measures of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		100 (3.8%)	82 (3.1%)	182 (3.5%)
Number of subjects without events		2517 (96.2%)	2528 (96.9%)	5045 (96.5%)
Odds Ratio [a]				
OR, 95% CI	1.225 [0.910, 1.649]			
p-value	0.1810			
Relative Risk [b]				
RR, 95% CI	1.216 [0.913, 1.620]			
p-value	0.1811			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.003, 0.017]			
p-value	0.1802			

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

Table A2.1.74: Effect Measures of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		72 (2.8%)	37 (1.4%)	109 (2.1%)
Number of subjects without events		2545 (97.2%)	2573 (98.6%)	5118 (97.9%)
Odds Ratio [a]				
OR, 95% CI	1.967 [1.318, 2.936]			
p-value	0.0009			
Relative Risk [b]				
RR, 95% CI	1.941 [1.310, 2.874]			
p-value	0.0009			
Risk Difference [c]				
RD, 95% CI	0.013 [0.006, 0.021]			
p-value	0.0007			

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

Table A2.1.75: Effect Measures of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		51 (1.9%)	66 (2.5%)	117 (2.2%)
Number of subjects without events		2566 (98.1%)	2544 (97.5%)	5110 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.766 [0.529, 1.109]			
p-value	0.1576			
Relative Risk [b]				
RR, 95% CI	0.771 [0.537, 1.106]			
p-value	0.1577			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.014, 0.002]			
p-value	0.1564			

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

Table A2.1.76: Effect Measures of Proportion of Subjects with TEAEs - Blood urea increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		25 (1.0%)	11 (0.4%)	36 (0.7%)
Number of subjects without events		2592 (99.0%)	2599 (99.6%)	5191 (99.3%)
Odds Ratio [a]				
OR, 95% CI	2.279 [1.119, 4.641]			
p-value	0.0232			
Relative Risk [b]				
RR, 95% CI	2.267 [1.118, 4.597]			
p-value	0.0233			
Risk Difference [c]				
RD, 95% CI	0.005 [0.001, 0.010]			
p-value	0.0195			

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

Table A2.1.77: Effect Measures of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		46 (1.8%)	55 (2.1%)	101 (1.9%)
Number of subjects without events		2571 (98.2%)	2555 (97.9%)	5126 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.831 [0.560, 1.234]			
p-value	0.3593			
Relative Risk [b]				
RR, 95% CI	0.834 [0.566, 1.229]			
p-value	0.3594			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.004]			
p-value	0.3587			

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

Table A2.1.78: Effect Measures of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	19 (0.7%)	49 (0.9%)
Number of subjects without events		2587 (98.9%)	2591 (99.3%)	5178 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.581 [0.888, 2.817]			
p-value	0.1197			
Relative Risk [b]				
RR, 95% CI	1.575 [0.889, 2.790]			
p-value	0.1198			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.001, 0.009]			
p-value	0.1164			

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

Table A2.1.79: Effect Measures of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		167 (6.4%)	126 (4.8%)	293 (5.6%)
Number of subjects without events		2450 (93.6%)	2484 (95.2%)	4934 (94.4%)
Odds Ratio [a]				
OR, 95% CI	1.344 [1.059, 1.705]			
p-value	0.0149			
Relative Risk [b]				
RR, 95% CI	1.322 [1.056, 1.655]			
p-value	0.0150			
Risk Difference [c]				
RD, 95% CI	0.016 [0.003, 0.028]			
p-value	0.0145			

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

Table A2.1.80: Effect Measures of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		35 (1.3%)	25 (1.0%)	60 (1.1%)
Number of subjects without events		2582 (98.7%)	2585 (99.0%)	5167 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.402 [0.837, 2.348]			
p-value	0.1998			
Relative Risk [b]				
RR, 95% CI	1.396 [0.838, 2.326]			
p-value	0.1999			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.002, 0.010]			
p-value	0.1976			

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

Table A2.1.81: Effect Measures of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		19 (0.7%)	30 (1.1%)	49 (0.9%)
Number of subjects without events		2598 (99.3%)	2580 (98.9%)	5178 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.629 [0.353, 1.120]			
p-value	0.1154			
Relative Risk [b]				
RR, 95% CI	0.632 [0.356, 1.119]			
p-value	0.1155			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.009, 0.001]			
p-value	0.1122			

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

Table A2.1.82: Effect Measures of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		971 (37.1%)	894 (34.3%)	1865 (35.7%)
Number of subjects without events		1646 (62.9%)	1716 (65.7%)	3362 (64.3%)
Odds Ratio [a]				
OR, 95% CI	1.132 [1.011, 1.268]			
p-value	0.0315			
Relative Risk [b]				
RR, 95% CI	1.083 [1.007, 1.165]			
p-value	0.0316			
Risk Difference [c]				
RD, 95% CI	0.029 [0.003, 0.054]			
p-value	0.0314			

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

Table A2.1.83: Effect Measures of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	30 (1.1%)	58 (1.1%)
Number of subjects without events		2589 (98.9%)	2580 (98.9%)	5169 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.930 [0.554, 1.561]			
p-value	0.7839			
Relative Risk [b]				
RR, 95% CI	0.931 [0.558, 1.553]			
p-value	0.7839			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.005]			
p-value	0.7838			

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

Table A2.1.84: Effect Measures of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		35 (1.3%)	28 (1.1%)	63 (1.2%)
Number of subjects without events		2582 (98.7%)	2582 (98.9%)	5164 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.250 [0.758, 2.061]			
p-value	0.3817			
Relative Risk [b]				
RR, 95% CI	1.247 [0.761, 2.043]			
p-value	0.3817			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.003, 0.009]			
p-value	0.3806			

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

Table A2.1.85: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		45 (1.7%)	72 (2.8%)	117 (2.2%)
Number of subjects without events		2572 (98.3%)	2538 (97.2%)	5110 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.617 [0.423, 0.899]			
p-value	0.0119			
Relative Risk [b]				
RR, 95% CI	0.623 [0.431, 0.901]			
p-value	0.0119			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.018, -0.002]			
p-value	0.0111			

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

Table A2.1.86: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		54 (2.1%)	68 (2.6%)	122 (2.3%)
Number of subjects without events		2563 (97.9%)	2542 (97.4%)	5105 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.788 [0.549, 1.131]			
p-value	0.1954			
Relative Risk [b]				
RR, 95% CI	0.792 [0.556, 1.127]			
p-value	0.1955			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.014, 0.003]			
p-value	0.1944			

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

Table A2.1.87: Effect Measures of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	28 (1.1%)	51 (1.0%)
Number of subjects without events		2594 (99.1%)	2582 (98.9%)	5176 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.818 [0.470, 1.423]			
p-value	0.4765			
Relative Risk [b]				
RR, 95% CI	0.819 [0.473, 1.418]			
p-value	0.4765			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.003]			
p-value	0.4758			

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

Table A2.1.88: Effect Measures of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		61 (2.3%)	74 (2.8%)	135 (2.6%)
Number of subjects without events		2556 (97.7%)	2536 (97.2%)	5092 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.818 [0.580, 1.153]			
p-value	0.2511			
Relative Risk [b]				
RR, 95% CI	0.822 [0.588, 1.149]			
p-value	0.2512			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.014, 0.004]			
p-value	0.2504			

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

Table A2.1.89: Effect Measures of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		68 (2.6%)	73 (2.8%)	141 (2.7%)
Number of subjects without events		2549 (97.4%)	2537 (97.2%)	5086 (97.3%)
Odds Ratio [a]				
OR, 95% CI	0.927 [0.663, 1.296]			
p-value	0.6578			
Relative Risk [b]				
RR, 95% CI	0.929 [0.671, 1.287]			
p-value	0.6578			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.007]			
p-value	0.6578			

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

Table A2.1.90: Effect Measures of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		428 (16.4%)	208 (8.0%)	636 (12.2%)
Number of subjects without events		2189 (83.6%)	2402 (92.0%)	4591 (87.8%)
Odds Ratio [a]				
OR, 95% CI	2.258 [1.894, 2.691]			
p-value	0.0000			
Relative Risk [b]				
RR, 95% CI	2.052 [1.755, 2.400]			
p-value	0.0000			
Risk Difference [c]				
RD, 95% CI	0.084 [0.066, 0.101]			
p-value	0.0000			

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

Table A2.1.91: Effect Measures of Proportion of Subjects with TEAEs - Hyperlipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	27 (1.0%)	50 (1.0%)
Number of subjects without events		2594 (99.1%)	2583 (99.0%)	5177 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.848 [0.485, 1.483]			
p-value	0.5637			
Relative Risk [b]				
RR, 95% CI	0.850 [0.488, 1.478]			
p-value	0.5638			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.004]			
p-value	0.5633			

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

Table A2.1.92: Effect Measures of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		25 (1.0%)	20 (0.8%)	45 (0.9%)
Number of subjects without events		2592 (99.0%)	2590 (99.2%)	5182 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.249 [0.692, 2.254]			
p-value	0.4605			
Relative Risk [b]				
RR, 95% CI	1.247 [0.694, 2.239]			
p-value	0.4605			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.003, 0.007]			
p-value	0.4595			

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

Table A2.1.93: Effect Measures of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		111 (4.2%)	108 (4.1%)	219 (4.2%)
Number of subjects without events		2506 (95.8%)	2502 (95.9%)	5008 (95.8%)
Odds Ratio [a]				
OR, 95% CI	1.026 [0.783, 1.345]			
p-value	0.8518			
Relative Risk [b]				
RR, 95% CI	1.025 [0.791, 1.328]			
p-value	0.8518			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.010, 0.012]			
p-value	0.8518			

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

Table A2.1.94: Effect Measures of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		143 (5.5%)	177 (6.8%)	320 (6.1%)
Number of subjects without events		2474 (94.5%)	2433 (93.2%)	4907 (93.9%)
Odds Ratio [a]				
OR, 95% CI	0.795 [0.633, 0.997]			
p-value	0.0474			
Relative Risk [b]				
RR, 95% CI	0.806 [0.651, 0.998]			
p-value	0.0475			
Risk Difference [c]				
RD, 95% CI	-0.013 [-0.026, 0.000]			
p-value	0.0469			

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

Table A2.1.95: Effect Measures of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		26 (1.0%)	58 (2.2%)	84 (1.6%)
Number of subjects without events		2591 (99.0%)	2552 (97.8%)	5143 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.442 [0.277, 0.703]			
p-value	0.0006			
Relative Risk [b]				
RR, 95% CI	0.447 [0.282, 0.708]			
p-value	0.0006			
Risk Difference [c]				
RD, 95% CI	-0.012 [-0.019, -0.005]			
p-value	0.0004			

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

Table A2.1.96: Effect Measures of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		36 (1.4%)	18 (0.7%)	54 (1.0%)
Number of subjects without events		2581 (98.6%)	2592 (99.3%)	5173 (99.0%)
Odds Ratio [a]				
OR, 95% CI	2.009 [1.138, 3.546]			
p-value	0.0162			
Relative Risk [b]				
RR, 95% CI	1.995 [1.136, 3.503]			
p-value	0.0163			
Risk Difference [c]				
RD, 95% CI	0.007 [0.001, 0.012]			
p-value	0.0141			

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

Table A2.1.97: Effect Measures of Proportion of Subjects with TEAEs - Metabolic acidosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		32 (1.2%)	26 (1.0%)	58 (1.1%)
Number of subjects without events		2585 (98.8%)	2584 (99.0%)	5169 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.230 [0.731, 2.070]			
p-value	0.4350			
Relative Risk [b]				
RR, 95% CI	1.227 [0.734, 2.054]			
p-value	0.4351			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.003, 0.008]			
p-value	0.4341			

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

Table A2.1.98: Effect Measures of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		31 (1.2%)	36 (1.4%)	67 (1.3%)
Number of subjects without events		2586 (98.8%)	2574 (98.6%)	5160 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.857 [0.529, 1.390]			
p-value	0.5318			
Relative Risk [b]				
RR, 95% CI	0.859 [0.533, 1.384]			
p-value	0.5318			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.5314			

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

Table A2.1.99: Effect Measures of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		48 (1.8%)	56 (2.1%)	104 (2.0%)
Number of subjects without events		2569 (98.2%)	2554 (97.9%)	5123 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.852 [0.577, 1.258]			
p-value	0.4206			
Relative Risk [b]				
RR, 95% CI	0.855 [0.584, 1.252]			
p-value	0.4206			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.004]			
p-value	0.4202			

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

Table A2.1.100: Effect Measures of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		720 (27.5%)	739 (28.3%)	1459 (27.9%)
Number of subjects without events		1897 (72.5%)	1871 (71.7%)	3768 (72.1%)
Odds Ratio [a]				
OR, 95% CI	0.961 [0.852, 1.084]			
p-value	0.5182			
Relative Risk [b]				
RR, 95% CI	0.972 [0.891, 1.060]			
p-value	0.5182			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.032, 0.016]			
p-value	0.5182			

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

Table A2.1.101: Effect Measures of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		184 (7.0%)	186 (7.1%)	370 (7.1%)
Number of subjects without events		2433 (93.0%)	2424 (92.9%)	4857 (92.9%)
Odds Ratio [a]				
OR, 95% CI	0.986 [0.798, 1.218]			
p-value	0.8929			
Relative Risk [b]				
RR, 95% CI	0.987 [0.811, 1.201]			
p-value	0.8929			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.015, 0.013]			
p-value	0.8929			

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

Table A2.1.102: Effect Measures of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	19 (0.7%)	46 (0.9%)
Number of subjects without events		2590 (99.0%)	2591 (99.3%)	5181 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.422 [0.788, 2.563]			
p-value	0.2421			
Relative Risk [b]				
RR, 95% CI	1.417 [0.790, 2.542]			
p-value	0.2422			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.002, 0.008]			
p-value	0.2396			

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

Table A2.1.103: Effect Measures of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		160 (6.1%)	163 (6.2%)	323 (6.2%)
Number of subjects without events		2457 (93.9%)	2447 (93.8%)	4904 (93.8%)
Odds Ratio [a]				
OR, 95% CI	0.978 [0.780, 1.225]			
p-value	0.8437			
Relative Risk [b]				
RR, 95% CI	0.979 [0.793, 1.209]			
p-value	0.8437			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.014, 0.012]			
p-value	0.8437			

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

Table A2.1.104: Effect Measures of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		17 (0.6%)	35 (1.3%)	52 (1.0%)
Number of subjects without events		2600 (99.4%)	2575 (98.7%)	5175 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.481 [0.269, 0.861]			
p-value	0.0137			
Relative Risk [b]				
RR, 95% CI	0.484 [0.272, 0.862]			
p-value	0.0138			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.012, -0.002]			
p-value	0.0118			

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

Table A2.1.105: Effect Measures of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		100 (3.8%)	90 (3.4%)	190 (3.6%)
Number of subjects without events		2517 (96.2%)	2520 (96.6%)	5037 (96.4%)
Odds Ratio [a]				
OR, 95% CI	1.112 [0.832, 1.487]			
p-value	0.4716			
Relative Risk [b]				
RR, 95% CI	1.108 [0.838, 1.466]			
p-value	0.4716			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.006, 0.014]			
p-value	0.4713			

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

Table A2.1.106: Effect Measures of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		49 (1.9%)	39 (1.5%)	88 (1.7%)
Number of subjects without events		2568 (98.1%)	2571 (98.5%)	5139 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.258 [0.823, 1.922]			
p-value	0.2891			
Relative Risk [b]				
RR, 95% CI	1.253 [0.826, 1.902]			
p-value	0.2891			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.003, 0.011]			
p-value	0.2879			

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

Table A2.1.107: Effect Measures of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		25 (1.0%)	32 (1.2%)	57 (1.1%)
Number of subjects without events		2592 (99.0%)	2578 (98.8%)	5170 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.777 [0.459, 1.315]			
p-value	0.3472			
Relative Risk [b]				
RR, 95% CI	0.779 [0.463, 1.311]			
p-value	0.3473			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.008, 0.003]			
p-value	0.3460			

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

Table A2.1.108: Effect Measures of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		67 (2.6%)	75 (2.9%)	142 (2.7%)
Number of subjects without events		2550 (97.4%)	2535 (97.1%)	5085 (97.3%)
Odds Ratio [a]				
OR, 95% CI	0.888 [0.636, 1.240]			
p-value	0.4861			
Relative Risk [b]				
RR, 95% CI	0.891 [0.644, 1.233]			
p-value	0.4862			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.006]			
p-value	0.4859			

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

Table A2.1.109: Effect Measures of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		100 (3.8%)	101 (3.9%)	201 (3.8%)
Number of subjects without events		2517 (96.2%)	2509 (96.1%)	5026 (96.2%)
Odds Ratio [a]				
OR, 95% CI	0.987 [0.744, 1.308]			
p-value	0.9273			
Relative Risk [b]				
RR, 95% CI	0.987 [0.753, 1.295]			
p-value	0.9273			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.011, 0.010]			
p-value	0.9273			

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

Table A2.1.110: Effect Measures of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	42 (1.6%)	70 (1.3%)
Number of subjects without events		2589 (98.9%)	2568 (98.4%)	5157 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.661 [0.409, 1.070]			
p-value	0.0921			
Relative Risk [b]				
RR, 95% CI	0.665 [0.413, 1.069]			
p-value	0.0922			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.012, 0.001]			
p-value	0.0899			

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

Table A2.1.111: Effect Measures of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		189 (7.2%)	183 (7.0%)	372 (7.1%)
Number of subjects without events		2428 (92.8%)	2427 (93.0%)	4855 (92.9%)
Odds Ratio [a]				
OR, 95% CI	1.032 [0.836, 1.275]			
p-value	0.7673			
Relative Risk [b]				
RR, 95% CI	1.030 [0.847, 1.253]			
p-value	0.7673			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.012, 0.016]			
p-value	0.7672			

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

Table A2.1.112: Effect Measures of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		526 (20.1%)	590 (22.6%)	1116 (21.4%)
Number of subjects without events		2091 (79.9%)	2020 (77.4%)	4111 (78.6%)
Odds Ratio [a]				
OR, 95% CI	0.861 [0.754, 0.983]			
p-value	0.0271			
Relative Risk [b]				
RR, 95% CI	0.889 [0.801, 0.987]			
p-value	0.0272			
Risk Difference [c]				
RD, 95% CI	-0.025 [-0.047, -0.003]			
p-value	0.0270			

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

Table A2.1.113: Effect Measures of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		42 (1.6%)	43 (1.6%)	85 (1.6%)
Number of subjects without events		2575 (98.4%)	2567 (98.4%)	5142 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.974 [0.634, 1.495]			
p-value	0.9031			
Relative Risk [b]				
RR, 95% CI	0.974 [0.639, 1.485]			
p-value	0.9031			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.006]			
p-value	0.9031			

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

Table A2.1.114: Effect Measures of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		137 (5.2%)	149 (5.7%)	286 (5.5%)
Number of subjects without events		2480 (94.8%)	2461 (94.3%)	4941 (94.5%)
Odds Ratio [a]				
OR, 95% CI	0.912 [0.719, 1.158]			
p-value	0.4515			
Relative Risk [b]				
RR, 95% CI	0.917 [0.732, 1.149]			
p-value	0.4515			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.017, 0.008]			
p-value	0.4514			

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

Table A2.1.115: Effect Measures of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		79 (3.0%)	86 (3.3%)	165 (3.2%)
Number of subjects without events		2538 (97.0%)	2524 (96.7%)	5062 (96.8%)
Odds Ratio [a]				
OR, 95% CI	0.914 [0.670, 1.246]			
p-value	0.5680			
Relative Risk [b]				
RR, 95% CI	0.916 [0.678, 1.237]			
p-value	0.5680			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.007]			
p-value	0.5678			

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

Table A2.1.116: Effect Measures of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		33 (1.3%)	33 (1.3%)	66 (1.3%)
Number of subjects without events		2584 (98.7%)	2577 (98.7%)	5161 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.997 [0.614, 1.621]			
p-value	0.9913			
Relative Risk [b]				
RR, 95% CI	0.997 [0.617, 1.611]			
p-value	0.9913			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.006]			
p-value	0.9913			

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

Table A2.1.117: Effect Measures of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	53 (2.0%)	83 (1.6%)
Number of subjects without events		2587 (98.9%)	2557 (98.0%)	5144 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.559 [0.356, 0.878]			
p-value	0.0116			
Relative Risk [b]				
RR, 95% CI	0.565 [0.362, 0.881]			
p-value	0.0117			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.016, -0.002]			
p-value	0.0105			

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

Table A2.1.118: Effect Measures of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		139 (5.3%)	183 (7.0%)	322 (6.2%)
Number of subjects without events		2478 (94.7%)	2427 (93.0%)	4905 (93.8%)
Odds Ratio [a]				
OR, 95% CI	0.744 [0.593, 0.934]			
p-value	0.0108			
Relative Risk [b]				
RR, 95% CI	0.758 [0.612, 0.938]			
p-value	0.0109			
Risk Difference [c]				
RD, 95% CI	-0.017 [-0.030, -0.004]			
p-value	0.0106			

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

Table A2.1.119: Effect Measures of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		20 (0.8%)	29 (1.1%)	49 (0.9%)
Number of subjects without events		2597 (99.2%)	2581 (98.9%)	5178 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.685 [0.387, 1.215]			
p-value	0.1958			
Relative Risk [b]				
RR, 95% CI	0.688 [0.390, 1.213]			
p-value	0.1959			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.002]			
p-value	0.1932			

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

Table A2.1.120: Effect Measures of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	43 (1.6%)	70 (1.3%)
Number of subjects without events		2590 (99.0%)	2567 (98.4%)	5157 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.622 [0.383, 1.010]			
p-value	0.0550			
Relative Risk [b]				
RR, 95% CI	0.626 [0.388, 1.010]			
p-value	0.0551			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.012, 0.000]			
p-value	0.0528			

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

Table A2.1.121: Effect Measures of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		59 (2.3%)	62 (2.4%)	121 (2.3%)
Number of subjects without events		2558 (97.7%)	2548 (97.6%)	5106 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.948 [0.661, 1.360]			
p-value	0.7712			
Relative Risk [b]				
RR, 95% CI	0.949 [0.667, 1.350]			
p-value	0.7712			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.007]			
p-value	0.7712			

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

Table A2.1.122: Effect Measures of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		494 (18.9%)	524 (20.1%)	1018 (19.5%)
Number of subjects without events		2123 (81.1%)	2086 (79.9%)	4209 (80.5%)
Odds Ratio [a]				
OR, 95% CI	0.926 [0.808, 1.062]			
p-value	0.2734			
Relative Risk [b]				
RR, 95% CI	0.940 [0.842, 1.050]			
p-value	0.2735			
Risk Difference [c]				
RD, 95% CI	-0.012 [-0.033, 0.009]			
p-value	0.2733			

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

Table A2.1.123: Effect Measures of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		123 (4.7%)	131 (5.0%)	254 (4.9%)
Number of subjects without events		2494 (95.3%)	2479 (95.0%)	4973 (95.1%)
Odds Ratio [a]				
OR, 95% CI	0.933 [0.725, 1.201]			
p-value	0.5917			
Relative Risk [b]				
RR, 95% CI	0.936 [0.737, 1.190]			
p-value	0.5917			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.015, 0.008]			
p-value	0.5916			

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

Table A2.1.124: Effect Measures of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		45 (1.7%)	51 (2.0%)	96 (1.8%)
Number of subjects without events		2572 (98.3%)	2559 (98.0%)	5131 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.878 [0.586, 1.316]			
p-value	0.5281			
Relative Risk [b]				
RR, 95% CI	0.880 [0.592, 1.309]			
p-value	0.5281			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.010, 0.005]			
p-value	0.5279			

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

Table A2.1.125: Effect Measures of Proportion of Subjects with TEAEs - Diabetic nephropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		31 (1.2%)	18 (0.7%)	49 (0.9%)
Number of subjects without events		2586 (98.8%)	2592 (99.3%)	5178 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.726 [0.963, 3.093]			
p-value	0.0666			
Relative Risk [b]				
RR, 95% CI	1.718 [0.963, 3.062]			
p-value	0.0667			
Risk Difference [c]				
RD, 95% CI	0.005 [0.000, 0.010]			
p-value	0.0632			

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

Table A2.1.126: Effect Measures of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	35 (1.3%)	58 (1.1%)
Number of subjects without events		2594 (99.1%)	2575 (98.7%)	5169 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.652 [0.384, 1.107]			
p-value	0.1134			
Relative Risk [b]				
RR, 95% CI	0.655 [0.388, 1.106]			
p-value	0.1135			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.001]			
p-value	0.1108			

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

Table A2.1.127: Effect Measures of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		32 (1.2%)	37 (1.4%)	69 (1.3%)
Number of subjects without events		2585 (98.8%)	2573 (98.6%)	5158 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.861 [0.535, 1.386]			
p-value	0.5375			
Relative Risk [b]				
RR, 95% CI	0.863 [0.539, 1.380]			
p-value	0.5375			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.004]			
p-value	0.5372			

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

Table A2.1.128: Effect Measures of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		32 (1.2%)	41 (1.6%)	73 (1.4%)
Number of subjects without events		2585 (98.8%)	2569 (98.4%)	5154 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.776 [0.487, 1.236]			
p-value	0.2848			
Relative Risk [b]				
RR, 95% CI	0.778 [0.492, 1.232]			
p-value	0.2849			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.003]			
p-value	0.2836			

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

Table A2.1.129: Effect Measures of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		94 (3.6%)	95 (3.6%)	189 (3.6%)
Number of subjects without events		2523 (96.4%)	2515 (96.4%)	5038 (96.4%)
Odds Ratio [a]				
OR, 95% CI	0.986 [0.738, 1.319]			
p-value	0.9260			
Relative Risk [b]				
RR, 95% CI	0.987 [0.746, 1.306]			
p-value	0.9260			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.011, 0.010]			
p-value	0.9260			

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

Table A2.1.130: Effect Measures of Proportion of Subjects with TEAEs - Urinary retention (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		26 (1.0%)	17 (0.7%)	43 (0.8%)
Number of subjects without events		2591 (99.0%)	2593 (99.3%)	5184 (99.2%)
Odds Ratio [a]				
OR, 95% CI	1.531 [0.829, 2.828]			
p-value	0.1740			
Relative Risk [b]				
RR, 95% CI	1.525 [0.830, 2.804]			
p-value	0.1742			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.001, 0.008]			
p-value	0.1707			

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

Table A2.1.131: Effect Measures of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		113 (4.3%)	130 (5.0%)	243 (4.6%)
Number of subjects without events		2504 (95.7%)	2480 (95.0%)	4984 (95.4%)
Odds Ratio [a]				
OR, 95% CI	0.861 [0.665, 1.114]			
p-value	0.2554			
Relative Risk [b]				
RR, 95% CI	0.867 [0.678, 1.109]			
p-value	0.2555			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.018, 0.005]			
p-value	0.2550			

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

Table A2.1.132: Effect Measures of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		47 (1.8%)	46 (1.8%)	93 (1.8%)
Number of subjects without events		2570 (98.2%)	2564 (98.2%)	5134 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.019 [0.676, 1.536]			
p-value	0.9270			
Relative Risk [b]				
RR, 95% CI	1.019 [0.681, 1.525]			
p-value	0.9270			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.007, 0.008]			
p-value	0.9270			

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

Table A2.1.133: Effect Measures of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		432 (16.5%)	473 (18.1%)	905 (17.3%)
Number of subjects without events		2185 (83.5%)	2137 (81.9%)	4322 (82.7%)
Odds Ratio [a]				
OR, 95% CI	0.893 [0.774, 1.031]			
p-value	0.1229			
Relative Risk [b]				
RR, 95% CI	0.911 [0.809, 1.026]			
p-value	0.1230			
Risk Difference [c]				
RD, 95% CI	-0.016 [-0.037, 0.004]			
p-value	0.1227			

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

Table A2.1.134: Effect Measures of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		43 (1.6%)	45 (1.7%)	88 (1.7%)
Number of subjects without events		2574 (98.4%)	2565 (98.3%)	5139 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.952 [0.625, 1.451]			
p-value	0.8199			
Relative Risk [b]				
RR, 95% CI	0.953 [0.630, 1.442]			
p-value	0.8199			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.006]			
p-value	0.8199			

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

Table A2.1.135: Effect Measures of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		103 (3.9%)	116 (4.4%)	219 (4.2%)
Number of subjects without events		2514 (96.1%)	2494 (95.6%)	5008 (95.8%)
Odds Ratio [a]				
OR, 95% CI	0.881 [0.672, 1.155]			
p-value	0.3591			
Relative Risk [b]				
RR, 95% CI	0.886 [0.683, 1.148]			
p-value	0.3591			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.016, 0.006]			
p-value	0.3588			

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

Table A2.1.136: Effect Measures of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		92 (3.5%)	95 (3.6%)	187 (3.6%)
Number of subjects without events		2525 (96.5%)	2515 (96.4%)	5040 (96.4%)
Odds Ratio [a]				
OR, 95% CI	0.965 [0.720, 1.292]			
p-value	0.8087			
Relative Risk [b]				
RR, 95% CI	0.966 [0.729, 1.280]			
p-value	0.8087			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.011, 0.009]			
p-value	0.8087			

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

Table A2.1.137: Effect Measures of Proportion of Subjects with TEAEs - Dyspnoea exertional (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		20 (0.8%)	26 (1.0%)	46 (0.9%)
Number of subjects without events		2597 (99.2%)	2584 (99.0%)	5181 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.765 [0.426, 1.375]			
p-value	0.3707			
Relative Risk [b]				
RR, 95% CI	0.767 [0.429, 1.371]			
p-value	0.3708			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.003]			
p-value	0.3694			

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

Table A2.1.138: Effect Measures of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		18 (0.7%)	30 (1.1%)	48 (0.9%)
Number of subjects without events		2599 (99.3%)	2580 (98.9%)	5179 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.596 [0.331, 1.071]			
p-value	0.0835			
Relative Risk [b]				
RR, 95% CI	0.598 [0.334, 1.071]			
p-value	0.0837			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.001]			
p-value	0.0802			

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

Table A2.1.139: Effect Measures of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		422 (16.1%)	418 (16.0%)	840 (16.1%)
Number of subjects without events		2195 (83.9%)	2192 (84.0%)	4387 (83.9%)
Odds Ratio [a]				
OR, 95% CI	1.008 [0.870, 1.169]			
p-value	0.9138			
Relative Risk [b]				
RR, 95% CI	1.007 [0.890, 1.140]			
p-value	0.9138			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.019, 0.021]			
p-value	0.9138			

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

Table A2.1.140: Effect Measures of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	30 (1.1%)	57 (1.1%)
Number of subjects without events		2590 (99.0%)	2580 (98.9%)	5170 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.897 [0.532, 1.512]			
p-value	0.6822			
Relative Risk [b]				
RR, 95% CI	0.898 [0.535, 1.505]			
p-value	0.6822			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.007, 0.004]			
p-value	0.6820			

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

Table A2.1.141: Effect Measures of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		38 (1.5%)	37 (1.4%)	75 (1.4%)
Number of subjects without events		2579 (98.5%)	2573 (98.6%)	5152 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.025 [0.649, 1.617]			
p-value	0.9167			
Relative Risk [b]				
RR, 95% CI	1.024 [0.653, 1.605]			
p-value	0.9167			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.006, 0.007]			
p-value	0.9167			

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

Table A2.1.142: Effect Measures of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		101 (3.9%)	69 (2.6%)	170 (3.3%)
Number of subjects without events		2516 (96.1%)	2541 (97.4%)	5057 (96.7%)
Odds Ratio [a]				
OR, 95% CI	1.478 [1.083, 2.018]			
p-value	0.0138			
Relative Risk [b]				
RR, 95% CI	1.460 [1.080, 1.973]			
p-value	0.0138			
Risk Difference [c]				
RD, 95% CI	0.012 [0.003, 0.022]			
p-value	0.0132			

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

Table A2.1.143: Effect Measures of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		31 (1.2%)	38 (1.5%)	69 (1.3%)
Number of subjects without events		2586 (98.8%)	2572 (98.5%)	5158 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.811 [0.503, 1.308]			
p-value	0.3909			
Relative Risk [b]				
RR, 95% CI	0.814 [0.508, 1.303]			
p-value	0.3909			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.003]			
p-value	0.3901			

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

Table A2.1.144: Effect Measures of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		58 (2.2%)	60 (2.3%)	118 (2.3%)
Number of subjects without events		2559 (97.8%)	2550 (97.7%)	5109 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.963 [0.669, 1.388]			
p-value	0.8408			
Relative Risk [b]				
RR, 95% CI	0.964 [0.675, 1.377]			
p-value	0.8408			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.007]			
p-value	0.8407			

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

Table A2.1.145: Effect Measures of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		172 (6.6%)	181 (6.9%)	353 (6.8%)
Number of subjects without events		2445 (93.4%)	2429 (93.1%)	4874 (93.2%)
Odds Ratio [a]				
OR, 95% CI	0.944 [0.761, 1.172]			
p-value	0.6016			
Relative Risk [b]				
RR, 95% CI	0.948 [0.775, 1.159]			
p-value	0.6016			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.017, 0.010]			
p-value	0.6016			

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

Table A2.1.146: Effect Measures of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		36 (1.4%)	45 (1.7%)	81 (1.5%)
Number of subjects without events		2581 (98.6%)	2565 (98.3%)	5146 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.795 [0.511, 1.237]			
p-value	0.3087			
Relative Risk [b]				
RR, 95% CI	0.798 [0.516, 1.233]			
p-value	0.3088			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.003]			
p-value	0.3078			

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

Table A2.1.147: Effect Measures of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		485 (18.5%)	492 (18.9%)	977 (18.7%)
Number of subjects without events		2132 (81.5%)	2118 (81.1%)	4250 (81.3%)
Odds Ratio [a]				
OR, 95% CI	0.979 [0.852, 1.125]			
p-value	0.7682			
Relative Risk [b]				
RR, 95% CI	0.983 [0.878, 1.101]			
p-value	0.7682			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.024, 0.018]			
p-value	0.7682			

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

Table A2.1.148: Effect Measures of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		194 (7.4%)	249 (9.5%)	443 (8.5%)
Number of subjects without events		2423 (92.6%)	2361 (90.5%)	4784 (91.5%)
Odds Ratio [a]				
OR, 95% CI	0.759 [0.624, 0.924]			
p-value	0.0059			
Relative Risk [b]				
RR, 95% CI	0.777 [0.649, 0.930]			
p-value	0.0059			
Risk Difference [c]				
RD, 95% CI	-0.021 [-0.036, -0.006]			
p-value	0.0057			

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

Table A2.1.149: Effect Measures of Proportion of Subjects with TEAEs - Hypertensive crisis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		28 (1.1%)	30 (1.1%)	58 (1.1%)
Number of subjects without events		2589 (98.9%)	2580 (98.9%)	5169 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.930 [0.554, 1.561]			
p-value	0.7839			
Relative Risk [b]				
RR, 95% CI	0.931 [0.558, 1.553]			
p-value	0.7839			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.006, 0.005]			
p-value	0.7838			

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

Table A2.1.150: Effect Measures of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		113 (4.3%)	85 (3.3%)	198 (3.8%)
Number of subjects without events		2504 (95.7%)	2525 (96.7%)	5029 (96.2%)
Odds Ratio [a]				
OR, 95% CI	1.341 [1.006, 1.786]			
p-value	0.0452			
Relative Risk [b]				
RR, 95% CI	1.326 [1.006, 1.748]			
p-value	0.0453			
Risk Difference [c]				
RD, 95% CI	0.011 [0.000, 0.021]			
p-value	0.0444			

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

Table A2.1.151: Effect Measures of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		35 (1.3%)	38 (1.5%)	73 (1.4%)
Number of subjects without events		2582 (98.7%)	2572 (98.5%)	5154 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.917 [0.578, 1.457]			
p-value	0.7151			
Relative Risk [b]				
RR, 95% CI	0.919 [0.582, 1.449]			
p-value	0.7151			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.005]			
p-value	0.7150			

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

Table A2.1.152: Effect Measures of Proportion of Subjects with TESAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		23 (0.9%)	35 (1.3%)	58 (1.1%)
Number of subjects without events		2594 (99.1%)	2575 (98.7%)	5169 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.652 [0.384, 1.107]			
p-value	0.1134			
Relative Risk [b]				
RR, 95% CI	0.655 [0.388, 1.106]			
p-value	0.1135			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.001]			
p-value	0.1108			

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

Table A2.1.153: Effect Measures of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		26 (1.0%)	49 (1.9%)	75 (1.4%)
Number of subjects without events		2591 (99.0%)	2561 (98.1%)	5152 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.524 [0.325, 0.846]			
p-value	0.0082			
Relative Risk [b]				
RR, 95% CI	0.529 [0.330, 0.849]			
p-value	0.0083			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.015, -0.002]			
p-value	0.0072			

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

Table A2.1.154: Effect Measures of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		37 (1.4%)	40 (1.5%)	77 (1.5%)
Number of subjects without events		2580 (98.6%)	2570 (98.5%)	5150 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.921 [0.587, 1.446]			
p-value	0.7217			
Relative Risk [b]				
RR, 95% CI	0.923 [0.592, 1.438]			
p-value	0.7217			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.005]			
p-value	0.7217			

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

Table A2.1.155: Effect Measures of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		106 (4.1%)	89 (3.4%)	195 (3.7%)
Number of subjects without events		2511 (95.9%)	2521 (96.6%)	5032 (96.3%)
Odds Ratio [a]				
OR, 95% CI	1.196 [0.897, 1.593]			
p-value	0.2224			
Relative Risk [b]				
RR, 95% CI	1.188 [0.901, 1.566]			
p-value	0.2225			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.004, 0.017]			
p-value	0.2217			

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

Table A2.1.156: Effect Measures of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		34 (1.3%)	49 (1.9%)	83 (1.6%)
Number of subjects without events		2583 (98.7%)	2561 (98.1%)	5144 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.688 [0.443, 1.069]			
p-value	0.0964			
Relative Risk [b]				
RR, 95% CI	0.692 [0.448, 1.068]			
p-value	0.0965			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.013, 0.001]			
p-value	0.0945			

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

Table A2.1.157: Effect Measures of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		25 (1.0%)	29 (1.1%)	54 (1.0%)
Number of subjects without events		2592 (99.0%)	2581 (98.9%)	5173 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.858 [0.501, 1.470]			
p-value	0.5778			
Relative Risk [b]				
RR, 95% CI	0.860 [0.505, 1.464]			
p-value	0.5779			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.007, 0.004]			
p-value	0.5775			

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

Table A2.1.158: Effect Measures of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		251 (9.6%)	260 (10.0%)	511 (9.8%)
Number of subjects without events		2366 (90.4%)	2350 (90.0%)	4716 (90.2%)
Odds Ratio [a]				
OR, 95% CI	0.959 [0.799, 1.151]			
p-value	0.6520			
Relative Risk [b]				
RR, 95% CI	0.963 [0.817, 1.135]			
p-value	0.6520			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.020, 0.012]			
p-value	0.6520			

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

Table A2.1.159: Effect Measures of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		26 (1.0%)	21 (0.8%)	47 (0.9%)
Number of subjects without events		2591 (99.0%)	2589 (99.2%)	5180 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.237 [0.694, 2.204]			
p-value	0.4702			
Relative Risk [b]				
RR, 95% CI	1.235 [0.697, 2.189]			
p-value	0.4703			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.003, 0.007]			
p-value	0.4693			

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

Table A2.1.160: Effect Measures of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		65 (2.5%)	101 (3.9%)	166 (3.2%)
Number of subjects without events		2552 (97.5%)	2509 (96.1%)	5061 (96.8%)
Odds Ratio [a]				
OR, 95% CI	0.633 [0.461, 0.868]			
p-value	0.0046			
Relative Risk [b]				
RR, 95% CI	0.642 [0.472, 0.872]			
p-value	0.0046			
Risk Difference [c]				
RD, 95% CI	-0.014 [-0.023, -0.004]			
p-value	0.0043			

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

Table A2.1.161: Effect Measures of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		90 (3.4%)	78 (3.0%)	168 (3.2%)
Number of subjects without events		2527 (96.6%)	2532 (97.0%)	5059 (96.8%)
Odds Ratio [a]				
OR, 95% CI	1.156 [0.850, 1.573]			
p-value	0.3562			
Relative Risk [b]				
RR, 95% CI	1.151 [0.854, 1.551]			
p-value	0.3562			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.005, 0.014]			
p-value	0.3557			

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

Table A2.1.162: Effect Measures of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		21 (0.8%)	33 (1.3%)	54 (1.0%)
Number of subjects without events		2596 (99.2%)	2577 (98.7%)	5173 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.632 [0.365, 1.095]			
p-value	0.1015			
Relative Risk [b]				
RR, 95% CI	0.635 [0.368, 1.094]			
p-value	0.1017			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.001]			
p-value	0.0987			

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

Table A2.1.163: Effect Measures of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		150 (5.7%)	156 (6.0%)	306 (5.9%)
Number of subjects without events		2467 (94.3%)	2454 (94.0%)	4921 (94.1%)
Odds Ratio [a]				
OR, 95% CI	0.956 [0.759, 1.205]			
p-value	0.7057			
Relative Risk [b]				
RR, 95% CI	0.959 [0.772, 1.192]			
p-value	0.7057			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.015, 0.010]			
p-value	0.7057			

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

Table A2.1.164: Effect Measures of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		40 (1.5%)	12 (0.5%)	52 (1.0%)
Number of subjects without events		2577 (98.5%)	2598 (99.5%)	5175 (99.0%)
Odds Ratio [a]				
OR, 95% CI	3.360 [1.759, 6.420]			
p-value	0.0002			
Relative Risk [b]				
RR, 95% CI	3.324 [1.748, 6.322]			
p-value	0.0002			
Risk Difference [c]				
RD, 95% CI	0.011 [0.005, 0.016]			
p-value	0.0001			

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

Table A2.1.165: Effect Measures of Proportion of Subjects with TESAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		20 (0.8%)	31 (1.2%)	51 (1.0%)
Number of subjects without events		2597 (99.2%)	2579 (98.8%)	5176 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.641 [0.364, 1.127]			
p-value	0.1223			
Relative Risk [b]				
RR, 95% CI	0.643 [0.368, 1.126]			
p-value	0.1224			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.010, 0.001]			
p-value	0.1194			

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

Table A2.1.166: Effect Measures of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		45 (1.7%)	55 (2.1%)	100 (1.9%)
Number of subjects without events		2572 (98.3%)	2555 (97.9%)	5127 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.813 [0.546, 1.210]			
p-value	0.3070			
Relative Risk [b]				
RR, 95% CI	0.816 [0.552, 1.205]			
p-value	0.3071			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.011, 0.004]			
p-value	0.3062			

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

Table A2.1.167: Effect Measures of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		94 (3.6%)	85 (3.3%)	179 (3.4%)
Number of subjects without events		2523 (96.4%)	2525 (96.7%)	5048 (96.6%)
Odds Ratio [a]				
OR, 95% CI	1.107 [0.821, 1.492]			
p-value	0.5054			
Relative Risk [b]				
RR, 95% CI	1.103 [0.827, 1.471]			
p-value	0.5054			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.007, 0.013]			
p-value	0.5052			

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

Table A2.1.168: Effect Measures of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		61 (2.3%)	85 (3.3%)	146 (2.8%)
Number of subjects without events		2556 (97.7%)	2525 (96.7%)	5081 (97.2%)
Odds Ratio [a]				
OR, 95% CI	0.709 [0.508, 0.990]			
p-value	0.0432			
Relative Risk [b]				
RR, 95% CI	0.716 [0.517, 0.990]			
p-value	0.0433			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.018, 0.000]			
p-value	0.0422			

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

Table A2.1.169: Effect Measures of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		125 (4.8%)	140 (5.4%)	265 (5.1%)
Number of subjects without events		2492 (95.2%)	2470 (94.6%)	4962 (94.9%)
Odds Ratio [a]				
OR, 95% CI	0.885 [0.691, 1.134]			
p-value	0.3333			
Relative Risk [b]				
RR, 95% CI	0.890 [0.704, 1.126]			
p-value	0.3333			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.018, 0.006]			
p-value	0.3330			

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

Table A2.1.170: Effect Measures of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		53 (2.0%)	50 (1.9%)	103 (2.0%)
Number of subjects without events		2564 (98.0%)	2560 (98.1%)	5124 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.058 [0.716, 1.564]			
p-value	0.7758			
Relative Risk [b]				
RR, 95% CI	1.057 [0.721, 1.550]			
p-value	0.7758			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.7758			

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

Table A2.1.171: Effect Measures of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		61 (2.3%)	74 (2.8%)	135 (2.6%)
Number of subjects without events		2556 (97.7%)	2536 (97.2%)	5092 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.818 [0.580, 1.153]			
p-value	0.2511			
Relative Risk [b]				
RR, 95% CI	0.822 [0.588, 1.149]			
p-value	0.2512			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.014, 0.004]			
p-value	0.2504			

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

Table A2.1.172: Effect Measures of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	45 (1.7%)	75 (1.4%)
Number of subjects without events		2587 (98.9%)	2565 (98.3%)	5152 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.661 [0.415, 1.053]			
p-value	0.0811			
Relative Risk [b]				
RR, 95% CI	0.665 [0.420, 1.052]			
p-value	0.0812			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.012, 0.001]			
p-value	0.0790			

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

Table A2.1.173: Effect Measures of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		59 (2.3%)	68 (2.6%)	127 (2.4%)
Number of subjects without events		2558 (97.7%)	2542 (97.4%)	5100 (97.6%)
Odds Ratio [a]				
OR, 95% CI	0.862 [0.606, 1.227]			
p-value	0.4105			
Relative Risk [b]				
RR, 95% CI	0.865 [0.613, 1.221]			
p-value	0.4105			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.012, 0.005]			
p-value	0.4101			

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

Table A2.1.174: Effect Measures of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		55 (2.1%)	64 (2.5%)	119 (2.3%)
Number of subjects without events		2562 (97.9%)	2546 (97.5%)	5108 (97.7%)
Odds Ratio [a]				
OR, 95% CI	0.854 [0.593, 1.230]			
p-value	0.3961			
Relative Risk [b]				
RR, 95% CI	0.857 [0.600, 1.224]			
p-value	0.3962			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.012, 0.005]			
p-value	0.3957			

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

Table A2.1.175: Effect Measures of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	42 (1.6%)	72 (1.4%)
Number of subjects without events		2587 (98.9%)	2568 (98.4%)	5155 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.709 [0.442, 1.136]			
p-value	0.1531			
Relative Risk [b]				
RR, 95% CI	0.712 [0.447, 1.135]			
p-value	0.1532			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.011, 0.002]			
p-value	0.1512			

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

Table A2.1.176: Effect Measures of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		41 (1.6%)	45 (1.7%)	86 (1.6%)
Number of subjects without events		2576 (98.4%)	2565 (98.3%)	5141 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.907 [0.592, 1.390]			
p-value	0.6547			
Relative Risk [b]				
RR, 95% CI	0.909 [0.597, 1.383]			
p-value	0.6547			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.008, 0.005]			
p-value	0.6546			

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

Table A2.1.177: Effect Measures of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		18 (0.7%)	30 (1.1%)	48 (0.9%)
Number of subjects without events		2599 (99.3%)	2580 (98.9%)	5179 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.596 [0.331, 1.071]			
p-value	0.0835			
Relative Risk [b]				
RR, 95% CI	0.598 [0.334, 1.071]			
p-value	0.0837			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.010, 0.001]			
p-value	0.0802			

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

Table A2.1.178: Effect Measures of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		121 (4.6%)	139 (5.3%)	260 (5.0%)
Number of subjects without events		2496 (95.4%)	2471 (94.7%)	4967 (95.0%)
Odds Ratio [a]				
OR, 95% CI	0.862 [0.671, 1.107]			
p-value	0.2435			
Relative Risk [b]				
RR, 95% CI	0.868 [0.685, 1.101]			
p-value	0.2435			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.019, 0.005]			
p-value	0.2431			

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

Table A2.1.179: Effect Measures of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		30 (1.1%)	47 (1.8%)	77 (1.5%)
Number of subjects without events		2587 (98.9%)	2563 (98.2%)	5150 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.632 [0.399, 1.003]			
p-value	0.0515			
Relative Risk [b]				
RR, 95% CI	0.637 [0.404, 1.003]			
p-value	0.0516			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.013, 0.000]			
p-value	0.0496			

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

Table A2.1.180: Effect Measures of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		45 (1.7%)	41 (1.6%)	86 (1.6%)
Number of subjects without events		2572 (98.3%)	2569 (98.4%)	5141 (98.4%)
Odds Ratio [a]				
OR, 95% CI	1.096 [0.716, 1.680]			
p-value	0.6728			
Relative Risk [b]				
RR, 95% CI	1.095 [0.719, 1.665]			
p-value	0.6728			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.005, 0.008]			
p-value	0.6727			

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

Table A2.1.181: Effect Measures of Proportion of Subjects with Severe TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	20 (0.8%)	47 (0.9%)
Number of subjects without events		2590 (99.0%)	2590 (99.2%)	5180 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.350 [0.755, 2.413]			
p-value	0.3112			
Relative Risk [b]				
RR, 95% CI	1.346 [0.757, 2.394]			
p-value	0.3112			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.002, 0.008]			
p-value	0.3093			

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

Table A2.1.182: Effect Measures of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		84 (3.2%)	80 (3.1%)	164 (3.1%)
Number of subjects without events		2533 (96.8%)	2530 (96.9%)	5063 (96.9%)
Odds Ratio [a]				
OR, 95% CI	1.049 [0.768, 1.431]			
p-value	0.7642			
Relative Risk [b]				
RR, 95% CI	1.047 [0.775, 1.415]			
p-value	0.7642			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.008, 0.011]			
p-value	0.7642			

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

Table A2.1.183: Effect Measures of Proportion of Subjects with Severe TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		31 (1.2%)	9 (0.3%)	40 (0.8%)
Number of subjects without events		2586 (98.8%)	2601 (99.7%)	5187 (99.2%)
Odds Ratio [a]				
OR, 95% CI	3.464 [1.646, 7.291]			
p-value	0.0011			
Relative Risk [b]				
RR, 95% CI	3.435 [1.639, 7.201]			
p-value	0.0011			
Risk Difference [c]				
RD, 95% CI	0.008 [0.004, 0.013]			
p-value	0.0005			

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

Table A2.1.184: Effect Measures of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		36 (1.4%)	42 (1.6%)	78 (1.5%)
Number of subjects without events		2581 (98.6%)	2568 (98.4%)	5149 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.853 [0.545, 1.335]			
p-value	0.4866			
Relative Risk [b]				
RR, 95% CI	0.855 [0.550, 1.330]			
p-value	0.4866			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.004]			
p-value	0.4862			

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

Table A2.1.185: Effect Measures of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		46 (1.8%)	57 (2.2%)	103 (2.0%)
Number of subjects without events		2571 (98.2%)	2553 (97.8%)	5124 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.801 [0.541, 1.186]			
p-value	0.2686			
Relative Risk [b]				
RR, 95% CI	0.805 [0.548, 1.182]			
p-value	0.2687			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.012, 0.003]			
p-value	0.2677			

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

Table A2.1.186: Effect Measures of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		38 (1.5%)	40 (1.5%)	78 (1.5%)
Number of subjects without events		2579 (98.5%)	2570 (98.5%)	5149 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.947 [0.605, 1.481]			
p-value	0.8103			
Relative Risk [b]				
RR, 95% CI	0.947 [0.610, 1.472]			
p-value	0.8103			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.007, 0.006]			
p-value	0.8103			

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

Table A2.1.187: Effect Measures of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		62 (2.4%)	76 (2.9%)	138 (2.6%)
Number of subjects without events		2555 (97.6%)	2534 (97.1%)	5089 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.809 [0.576, 1.137]			
p-value	0.2218			
Relative Risk [b]				
RR, 95% CI	0.814 [0.584, 1.133]			
p-value	0.2219			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.014, 0.003]			
p-value	0.2210			

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

Table A2.1.188: Effect Measures of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		27 (1.0%)	35 (1.3%)	62 (1.2%)
Number of subjects without events		2590 (99.0%)	2575 (98.7%)	5165 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.767 [0.463, 1.271]			
p-value	0.3031			
Relative Risk [b]				
RR, 95% CI	0.769 [0.467, 1.267]			
p-value	0.3032			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.009, 0.003]			
p-value	0.3018			

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

Table A2.1.189: Effect Measures of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		44 (1.7%)	51 (2.0%)	95 (1.8%)
Number of subjects without events		2573 (98.3%)	2559 (98.0%)	5132 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.858 [0.571, 1.289]			
p-value	0.4609			
Relative Risk [b]				
RR, 95% CI	0.860 [0.577, 1.283]			
p-value	0.4610			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.005]			
p-value	0.4606			

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

Table A2.1.190: Effect Measures of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=2617)	Placebo (N=2610)	Total (N=5227)
Number of subjects at risk		2617 (100.0%)	2610 (100.0%)	5227 (100.0%)
Number of subjects with events		33 (1.3%)	43 (1.6%)	76 (1.5%)
Number of subjects without events		2584 (98.7%)	2567 (98.4%)	5151 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.762 [0.483, 1.204]			
p-value	0.2445			
Relative Risk [b]				
RR, 95% CI	0.765 [0.488, 1.201]			
p-value	0.2446			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.010, 0.003]			
p-value	0.2431			

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

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4.2 Disposition

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

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			19381
Screening failures			11944
Randomized	1377	1381	2758
GCP VIOLATIONS	18	19	37
Full analysis set	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Study drug never administered	3 (0.2%)	5 (0.4%)	8 (0.3%)
Treated	1356 (99.8%)	1357 (99.6%)	2713 (99.7%)
Did not complete treatment due COVID-19	20 (1.5%)	12 (0.9%)	32 (1.2%)
Subject decision: COVID-19 pandemic related	13 (1.0%)	7 (0.5%)	20 (0.7%)
Physician decision: COVID-19 pandemic related	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Logistical reason: COVID-19 pandemic related	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Did not complete study	2 (0.1%)	7 (0.5%)	9 (0.3%)
WITHDRAWN CONSENT	0	4 (0.3%)	4 (0.1%)
LOST TO FOLLOW-UP	2 (0.1%)	3 (0.2%)	5 (0.2%)
Completed study	1357 (99.9%)	1355 (99.5%)	2712 (99.7%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Completed epoch	904 (66.5%)	938 (68.9%)	1842 (67.7%)
Not completed	455 (33.5%)	424 (31.1%)	879 (32.3%)
Primary reason			
ADVERSE EVENT	146 (10.7%)	128 (9.4%)	274 (10.1%)
DEATH	103 (7.6%)	95 (7.0%)	198 (7.3%)
WITHDRAWAL BY SUBJECT	87 (6.4%)	91 (6.7%)	178 (6.5%)
LOST TO FOLLOW-UP	0	2 (0.1%)	2 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	6 (0.4%)	6 (0.4%)	12 (0.4%)
PHYSICIAN DECISION	74 (5.4%)	55 (4.0%)	129 (4.7%)
TECHNICAL PROBLEMS	8 (0.6%)	22 (1.6%)	30 (1.1%)
DETERIORATION OF GENERAL CONDITIONS	0	1 (<0.1%)	1 (<0.1%)
PROTOCOL DEVIATION	5 (0.4%)	5 (0.4%)	10 (0.4%)
LOGISTICAL REASON	1 (<0.1%)	0	1 (<0.1%)
SUBJECT DECISION	3 (0.2%)	2 (0.1%)	5 (0.2%)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	13 (1.0%)	7 (0.5%)	20 (0.7%)
PHYSICIAN DECISION: COVID-19 PANDEMIC RELATED	6 (0.4%)	1 (<0.1%)	7 (0.3%)
LOGISTICAL REASON: COVID-19 PANDEMIC RELATED	1 (<0.1%)	4 (0.3%)	5 (0.2%)
OTHER	2 (0.1%)	5 (0.4%)	7 (0.3%)

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4.3 Demographic characteristics

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

TEXT	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Race (N)			
WHITE	1013 (74.5%)	992 (72.8%)	2005 (73.7%)
BLACK OR AFRICAN AMERICAN	43 (3.2%)	71 (5.2%)	114 (4.2%)
ASIAN	251 (18.5%)	253 (18.6%)	504 (18.5%)
AMERICAN INDIAN OR ALASKA NATIVE	15 (1.1%)	12 (0.9%)	27 (1.0%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	3 (0.2%)	6 (0.4%)	9 (0.3%)
NOT REPORTED	3 (0.2%)	4 (0.3%)	7 (0.3%)
MULTIPLE	31 (2.3%)	24 (1.8%)	55 (2.0%)
Sex (N)			
Male	917 (67.5%)	937 (68.8%)	1854 (68.1%)
Female	442 (32.5%)	425 (31.2%)	867 (31.9%)
Age (YEARS)			
n	1359	1362	2721
Mean	69.17	69.56	69.36
SD	7.79	7.89	7.84
Min	36.0	38.0	36.0
Q1	65.00	65.00	65.00
Median	69.00	70.00	70.00
Q3	74.00	75.00	75.00
Max	89.0	93.0	93.0
Run-in age group (years) category (N)			
18 - 44 years	6 (0.4%)	6 (0.4%)	12 (0.4%)
45 - 64 years	331 (24.4%)	330 (24.2%)	661 (24.3%)
65 - 74 years	683 (50.3%)	659 (48.4%)	1342 (49.3%)
>= 75 years	339 (24.9%)	367 (26.9%)	706 (25.9%)
Age group (years) category 3 (N)			
< 65 years	337 (24.8%)	336 (24.7%)	673 (24.7%)
>= 65 years	1022 (75.2%)	1026 (75.3%)	2048 (75.3%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	1198 (88.2%)	1203 (88.3%)	2401 (88.2%)
HISPANIC OR LATINO	159 (11.7%)	154 (11.3%)	313 (11.5%)
NOT REPORTED	2 (0.1%)	5 (0.4%)	7 (0.3%)

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

TEXT	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Region (N)			
Europe	640 (47.1%)	639 (46.9%)	1279 (47.0%)
North America	267 (19.6%)	271 (19.9%)	538 (19.8%)
Asia	288 (21.2%)	292 (21.4%)	580 (21.3%)
Latin America	102 (7.5%)	101 (7.4%)	203 (7.5%)
Others	62 (4.6%)	59 (4.3%)	121 (4.4%)
Baseline Weight (kg)			
n	1357	1361	2718
Mean	87.95	87.21	87.58
SD	20.01	19.14	19.58
Min	37.6	40.3	37.6
Q1	74.10	73.50	73.90
Median	85.60	85.20	85.30
Q3	99.40	98.70	99.00
Max	170.0	171.4	171.4
Baseline weight (kg) category (N)			
missing	2 (0.1%)	1 (<0.1%)	3 (0.1%)
< 60 kg	70 (5.2%)	75 (5.5%)	145 (5.3%)
60 - < 90 kg	722 (53.1%)	733 (53.8%)	1455 (53.5%)
>= 90 kg	565 (41.6%)	553 (40.6%)	1118 (41.1%)
Baseline Height (cm)			
n	1355	1361	2716
Mean	167.29	166.71	167.00
SD	9.98	9.82	9.90
Min	136.0	140.0	136.0
Q1	160.00	160.00	160.00
Median	168.00	167.00	167.50
Q3	174.00	174.00	174.00
Max	198.1	197.0	198.1

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

TEXT	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline Body Mass Index (kg/m2)			
n	1354	1360	2714
Mean	31.25	31.26	31.25
SD	5.73	5.70	5.71
Min	15.8	18.4	15.8
Q1	27.40	27.00	27.20
Median	30.50	30.50	30.50
Q3	34.50	34.80	34.60
Max	58.3	57.2	58.3
Baseline BMI (kg/m2) category 2 (N)			
missing	5 (0.4%)	2 (0.1%)	7 (0.3%)
< 30 kg/m2	616 (45.3%)	623 (45.7%)	1239 (45.5%)
>= 30 kg/m2	738 (54.3%)	737 (54.1%)	1475 (54.2%)
Baseline BMI (kg/m2) category 3 (N)			
missing	5 (0.4%)	2 (0.1%)	7 (0.3%)
< 20 kg/m2	12 (0.9%)	5 (0.4%)	17 (0.6%)
20 - < 25 kg/m2	144 (10.6%)	159 (11.7%)	303 (11.1%)
25 - < 30 kg/m2	460 (33.8%)	459 (33.7%)	919 (33.8%)
30 - < 35 kg/m2	432 (31.8%)	409 (30.0%)	841 (30.9%)
>= 35 kg/m2	306 (22.5%)	328 (24.1%)	634 (23.3%)
Baseline Hip Circumference (cm)			
n	1350	1354	2704
Mean	107.91	108.05	107.98
SD	13.98	13.29	13.64
Min	36.0	36.0	36.0
Q1	99.00	99.50	99.00
Median	106.70	106.00	106.25
Q3	115.00	116.00	115.00
Max	185.0	171.0	185.0

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

TEXT	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline waist circumference (cm)			
n	1355	1357	2712
Mean	107.58	107.49	107.54
SD	15.01	14.60	14.80
Min	34.0	34.0	34.0
Q1	98.00	98.00	98.00
Median	106.40	107.00	106.90
Q3	117.00	117.00	117.00
Max	180.0	173.0	180.0
Baseline waist circumf. (cm) cat. (N)			
missing	4 (0.3%)	5 (0.4%)	9 (0.3%)
normal	145 (10.7%)	138 (10.1%)	283 (10.4%)
increased	213 (15.7%)	237 (17.4%)	450 (16.5%)
substantially increased	997 (73.4%)	982 (72.1%)	1979 (72.7%)
Baseline waist-hip ratio (N)			
n	1350	1354	2704
Mean	1.00	1.00	1.00
SD	0.10	0.09	0.10
Min	0.6	0.6	0.6
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.04	1.05
Max	2.1	2.2	2.2
Smoking History (N)			
NEVER	651 (47.9%)	664 (48.8%)	1315 (48.3%)
FORMER	561 (41.3%)	583 (42.8%)	1144 (42.0%)
CURRENT	147 (10.8%)	115 (8.4%)	262 (9.6%)

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

TEXT	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Alcohol Use (N)			
missing	1 (<0.1%)	0	1 (<0.1%)
ABSTINENT	825 (60.7%)	797 (58.5%)	1622 (59.6%)
LIGHT	461 (33.9%)	482 (35.4%)	943 (34.7%)
MODERATE	66 (4.9%)	80 (5.9%)	146 (5.4%)
HEAVY	6 (0.4%)	3 (0.2%)	9 (0.3%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:11
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4.4 Baseline characteristics

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline potassium (mmol/L)			
n	1359	1361	2720
Arithm. Mean	4.37	4.37	4.37
Arithm. SD	0.43	0.43	0.43
Min	2.8	3.0	2.8
Q1	4.10	4.10	4.10
Median	4.40	4.40	4.40
Q3	4.60	4.60	4.60
Max	6.3	6.1	6.3
Baseline ser. potassium (mmol/L) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.5 mmol/L	924 (68.0%)	932 (68.4%)	1856 (68.2%)
> 4.5 mmol/L	435 (32.0%)	429 (31.5%)	864 (31.8%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.8 mmol/L	1175 (86.5%)	1197 (87.9%)	2372 (87.2%)
>4.8 to <=5.0 mmol/L	104 (7.7%)	86 (6.3%)	190 (7.0%)
>5.0 mmol/L	80 (5.9%)	78 (5.7%)	158 (5.8%)
Basel. potass (mmol/L) median FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<= 4.30 mmol/L (median in FAS)	659 (48.5%)	675 (49.6%)	1334 (49.0%)
> 4.30 mmol/L (median in FAS)	700 (51.5%)	686 (50.4%)	1386 (50.9%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	388 (28.6%)	405 (29.7%)	793 (29.1%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	271 (19.9%)	270 (19.8%)	541 (19.9%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	369 (27.2%)	364 (26.7%)	733 (26.9%)
>4.6 mmol/L (>Q3 in FAS)	331 (24.4%)	322 (23.6%)	653 (24.0%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	1359	1362	2721
Arithm. Mean	134.43	134.50	134.47
Arithm. SD	14.58	14.55	14.56
Min	90.3	85.7	85.7
Q1	125.00	125.33	125.00
Median	134.00	135.33	134.67
Q3	144.67	145.00	144.67
Max	183.0	181.7	183.0
Baseline SBP (mmHg) category (N)			
< 130 mmHg	494 (36.4%)	497 (36.5%)	991 (36.4%)
130 - < 160 mmHg	831 (61.1%)	830 (60.9%)	1661 (61.0%)
>= 160 mmHg	34 (2.5%)	35 (2.6%)	69 (2.5%)
Baseline SBP (mmHg) median for FAS (N)			
<= 137.00 mmHg (median in FAS)	773 (56.9%)	764 (56.1%)	1537 (56.5%)
> 137.00 mmHg (median in FAS)	586 (43.1%)	598 (43.9%)	1184 (43.5%)
Baseline Diastolic Blood Pressure (mmHg)			
n	1359	1362	2721
Arithm. Mean	73.98	73.60	73.79
Arithm. SD	9.91	9.68	9.79
Min	34.7	45.0	34.7
Q1	67.00	67.33	67.00
Median	74.00	73.67	74.00
Q3	80.67	80.33	80.67
Max	105.0	107.7	107.7
Baseline Heart Rate (BEATS/MIN)			
n	1359	1362	2721
Arithm. Mean	71.36	70.87	71.11
Arithm. SD	11.77	11.49	11.63
Min	41.0	35.3	35.3
Q1	63.00	62.67	62.67
Median	70.33	70.00	70.00
Q3	78.00	78.33	78.33
Max	122.7	136.0	136.0

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	1359	1361	2720
Arithm. Mean	46.19	46.39	46.29
Arithm. SD	11.40	11.20	11.30
Min	17.3	17.6	17.3
Q1	37.50	38.40	37.80
Median	46.00	46.50	46.20
Q3	54.00	53.80	53.90
Max	103.5	109.5	109.5
Baseline eGFR (mL/min/1.73m2) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
< 25 mL/min/1.73m2	14 (1.0%)	12 (0.9%)	26 (1.0%)
25 - < 45 mL/min/1.73m2	618 (45.5%)	600 (44.1%)	1218 (44.8%)
45 - < 60 mL/min/1.73m2	575 (42.3%)	614 (45.1%)	1189 (43.7%)
>= 60 mL/min/1.73m2	152 (11.2%)	135 (9.9%)	287 (10.5%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
< 30 mL/min/1.73m2	96 (7.1%)	95 (7.0%)	191 (7.0%)
30 - < 60 mL/min/1.73m2	1111 (81.8%)	1131 (83.0%)	2242 (82.4%)
60 - < 90 mL/min/1.73m2	150 (11.0%)	133 (9.8%)	283 (10.4%)
>= 90 mL/min/1.73m2	2 (0.1%)	2 (0.1%)	4 (0.1%)
Screening eGFR (mL/min/1.73m2)			
n	1359	1361	2720
Arithm. Mean	44.92	45.15	45.03
Arithm. SD	9.32	9.24	9.28
Min	25.1	22.9	22.9
Q1	37.30	37.70	37.50
Median	45.70	46.10	45.90
Q3	52.90	53.00	53.00
Max	59.9	59.9	59.9
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	0	1 (<0.1%)	1 (<0.1%)
< 25 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
25 - < 45 mL/min/1.73m2	639 (47.0%)	629 (46.2%)	1268 (46.6%)
45 - < 60 mL/min/1.73m2	720 (53.0%)	731 (53.7%)	1451 (53.3%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	0	1 (<0.1%)	1 (<0.1%)
< 30 mL/min/1.73m2	99 (7.3%)	86 (6.3%)	185 (6.8%)
30 - < 60 mL/min/1.73m2	1260 (92.7%)	1275 (93.6%)	2535 (93.2%)
Baseline UACR (mg/g)			
n	1359	1362	2721
Geom. Mean	99.67	105.04	102.33
Geom. SD	2.31	2.22	2.27
Min	1.8	5.0	1.8
Q1	54.99	61.00	57.53
Median	101.00	107.80	104.48
Q3	184.08	180.87	182.46
Max	3675.4	3501.1	3675.4
Baseline albuminuria (mg/g) cat. (N)			
Normalbuminuria (UACR < 30 mg/g)	87 (6.4%)	72 (5.3%)	159 (5.8%)
High albuminuria (30 mg/g - < 300 mg/g)	1178 (86.7%)	1184 (86.9%)	2362 (86.8%)
Very high albuminuria (>= 300 mg/g)	94 (6.9%)	106 (7.8%)	200 (7.4%)
Baseline UACR (mg/g) cat. median fas (N)			
<= 514.7 mg/g (median in FAS)	1329 (97.8%)	1337 (98.2%)	2666 (98.0%)
> 514.7 mg/g (median in FAS)	30 (2.2%)	25 (1.8%)	55 (2.0%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	0	1 (<0.1%)	1 (<0.1%)
NO	1130 (83.1%)	1152 (84.6%)	2282 (83.9%)
YES	229 (16.9%)	209 (15.3%)	438 (16.1%)
Baseline Creatinine (mg/dL)			
n	1359	1361	2720
Arithm. Mean	1.47	1.46	1.47
Arithm. SD	0.36	0.36	0.36
Min	0.6	0.6	0.6
Q1	1.22	1.21	1.22
Median	1.41	1.40	1.41
Q3	1.66	1.65	1.66
Max	3.4	3.4	3.4

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Baseline Albumin (g/dL) in Serum			
n	1359	1361	2720
Arithm. Mean	4.28	4.29	4.28
Arithm. SD	0.29	0.28	0.29
Min	2.0	3.1	2.0
Q1	4.10	4.10	4.10
Median	4.30	4.30	4.30
Q3	4.50	4.50	4.50
Max	5.3	5.2	5.3
Baseline Hemoglobin (g/dL) in Blood			
n	1356	1360	2716
Arithm. Mean	13.23	13.16	13.19
Arithm. SD	1.64	1.57	1.60
Min	6.9	8.6	6.9
Q1	12.10	12.00	12.00
Median	13.30	13.20	13.20
Q3	14.30	14.30	14.30
Max	19.1	17.7	19.1
Baseline Hemoglobin A1C (%)			
n	1356	1359	2715
Arithm. Mean	7.59	7.45	7.52
Arithm. SD	1.29	1.18	1.24
Min	4.4	5.0	4.4
Q1	6.60	6.60	6.60
Median	7.40	7.30	7.40
Q3	8.30	8.10	8.20
Max	12.0	11.8	12.0
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	3 (0.2%)	3 (0.2%)	6 (0.2%)
<= 7.5%	731 (53.8%)	799 (58.7%)	1530 (56.2%)
> 7.5%	625 (46.0%)	560 (41.1%)	1185 (43.6%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	3 (0.2%)	3 (0.2%)	6 (0.2%)
<=6.7 % (<= Q1 in FAS)	388 (28.6%)	424 (31.1%)	812 (29.8%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	343 (25.2%)	375 (27.5%)	718 (26.4%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	335 (24.7%)	329 (24.2%)	664 (24.4%)
>8.5 % (>Q3 in FAS)	290 (21.3%)	231 (17.0%)	521 (19.1%)
Baseline C Reactive Protein (mg/L)			
n	1359	1362	2721
Arithm. Mean	5.14	4.74	4.94
Arithm. SD	10.17	8.87	9.54
Min	0.1	0.1	0.1
Q1	0.98	1.00	0.99
Median	2.28	2.13	2.20
Q3	5.37	4.91	5.21
Max	138.0	131.0	138.0
Basel. C Reactive Protein Quartiles (N)			
<=0.95 % (<= Q1 in FAS)	325 (23.9%)	323 (23.7%)	648 (23.8%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	341 (25.1%)	375 (27.5%)	716 (26.3%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	327 (24.1%)	340 (25.0%)	667 (24.5%)
>5.13 % (>Q3 in FAS)	366 (26.9%)	324 (23.8%)	690 (25.4%)
Stratification factor 3 (N)			
CVD present	865 (63.6%)	851 (62.5%)	1716 (63.1%)
CVD absent	494 (36.4%)	511 (37.5%)	1005 (36.9%)
Hyperkalemia (based on MLG) in MH (N)			
NO	1333 (98.1%)	1346 (98.8%)	2679 (98.5%)
YES	26 (1.9%)	16 (1.2%)	42 (1.5%)
Hepatic impairment in medical history(N)			
NO	1130 (83.1%)	1173 (86.1%)	2303 (84.6%)
YES	229 (16.9%)	189 (13.9%)	418 (15.4%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Child Pugh (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
likely Child Pugh A	1337 (98.4%)	1343 (98.6%)	2680 (98.5%)
likely Child Pugh B	20 (1.5%)	18 (1.3%)	38 (1.4%)
certain Child Pugh B	1 (<0.1%)	0	1 (<0.1%)
Duration of diabetes (in years) (N)			
n	1357	1362	2719
Arithm. Mean	16.06	16.08	16.07
Arithm. SD	9.44	9.19	9.31
Min	0.0	0.1	0.0
Q1	9.17	9.19	9.18
Median	15.15	15.24	15.18
Q3	21.20	21.27	21.24
Max	61.3	54.1	61.3
ACEI use (N)			
NO	803 (59.1%)	815 (59.8%)	1618 (59.5%)
YES	556 (40.9%)	547 (40.2%)	1103 (40.5%)
ARB use (N)			
NO	557 (41.0%)	546 (40.1%)	1103 (40.5%)
YES	802 (59.0%)	816 (59.9%)	1618 (59.5%)
Beta blocker use at baseline (N)			
NO	569 (41.9%)	597 (43.8%)	1166 (42.9%)
YES	790 (58.1%)	765 (56.2%)	1555 (57.1%)
Diuretic use at baseline (N)			
NO	581 (42.8%)	583 (42.8%)	1164 (42.8%)
YES	778 (57.2%)	779 (57.2%)	1557 (57.2%)
Statins use at baseline (N)			
NO	308 (22.7%)	291 (21.4%)	599 (22.0%)
YES	1051 (77.3%)	1071 (78.6%)	2122 (78.0%)
Anti-diabetic use at baseline (N)			
NO	49 (3.6%)	49 (3.6%)	98 (3.6%)
YES	1310 (96.4%)	1313 (96.4%)	2623 (96.4%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Insul. and analo. use at baseline (N)			
NO	621 (45.7%)	647 (47.5%)	1268 (46.6%)
YES	738 (54.3%)	715 (52.5%)	1453 (53.4%)
Dip pep 4 inhibitors use at baseline (N)			
NO	982 (72.3%)	979 (71.9%)	1961 (72.1%)
YES	377 (27.7%)	383 (28.1%)	760 (27.9%)
GLP1 agonists use at baseline (N)			
NO	1242 (91.4%)	1274 (93.5%)	2516 (92.5%)
YES	117 (8.6%)	88 (6.5%)	205 (7.5%)
SGLT-2 inhib. use at baseline (N)			
NO	1276 (93.9%)	1282 (94.1%)	2558 (94.0%)
YES	83 (6.1%)	80 (5.9%)	163 (6.0%)
Biguanides use at baseline (N)			
NO	643 (47.3%)	629 (46.2%)	1272 (46.7%)
YES	716 (52.7%)	733 (53.8%)	1449 (53.3%)
Sulfonamides use at baseline (N)			
NO	962 (70.8%)	1005 (73.8%)	1967 (72.3%)
YES	397 (29.2%)	357 (26.2%)	754 (27.7%)
Alpha gluc. inhib. use at baseline (N)			
NO	1309 (96.3%)	1307 (96.0%)	2616 (96.1%)
YES	50 (3.7%)	55 (4.0%)	105 (3.9%)
Meglitinides use at baseline (N)			
NO	1311 (96.5%)	1308 (96.0%)	2619 (96.3%)
YES	48 (3.5%)	54 (4.0%)	102 (3.7%)
Thiazolidinediones use at baseline (N)			
NO	1298 (95.5%)	1297 (95.2%)	2595 (95.4%)
YES	61 (4.5%)	65 (4.8%)	126 (4.6%)

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

	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Potassium supplement use at baseline (N)			
NO	1301 (95.7%)	1308 (96.0%)	2609 (95.9%)
YES	58 (4.3%)	54 (4.0%)	112 (4.1%)
Potassium lowering use at baseline (N)			
NO	1347 (99.1%)	1351 (99.2%)	2698 (99.2%)
YES	12 (0.9%)	11 (0.8%)	23 (0.8%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	19 (1.4%)	11 (0.8%)	30 (1.1%)
unclassified	22 (1.6%)	17 (1.2%)	39 (1.4%)
moderate	26 (1.9%)	40 (2.9%)	66 (2.4%)
weak	817 (60.1%)	844 (62.0%)	1661 (61.0%)
none	475 (35.0%)	450 (33.0%)	925 (34.0%)
Potency CYP3A4 inducer at baseline (N)			
strong	4 (0.3%)	5 (0.4%)	9 (0.3%)
unclassified	7 (0.5%)	6 (0.4%)	13 (0.5%)
moderate	8 (0.6%)	7 (0.5%)	15 (0.6%)
weak	57 (4.2%)	68 (5.0%)	125 (4.6%)
none	1283 (94.4%)	1276 (93.7%)	2559 (94.0%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
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4.5 Medical History

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Number (%) of subjects with at least one medical history finding	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Blood and lymphatic system disorders	207 (15.2%)	230 (16.9%)	437 (16.1%)
Anaemia	125 (9.2%)	142 (10.4%)	267 (9.8%)
Anaemia macrocytic	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Anaemia megaloblastic	0	1 (<0.1%)	1 (<0.1%)
Anaemia of chronic disease	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Blood loss anaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eosinophilia	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Haemolytic anaemia	0	1 (<0.1%)	1 (<0.1%)
Haemolytic uraemic syndrome	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic diathesis	1 (<0.1%)	0	1 (<0.1%)
Heparin-induced thrombocytopenia	1 (<0.1%)	0	1 (<0.1%)
Hypercoagulation	2 (0.1%)	0	2 (<0.1%)
Hypergammaglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypersplenism	0	1 (<0.1%)	1 (<0.1%)
Hypochromic anaemia	0	2 (0.1%)	2 (<0.1%)
Immune thrombocytopenia	0	2 (0.1%)	2 (<0.1%)
Increased tendency to bruise	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Iron deficiency anaemia	35 (2.6%)	37 (2.7%)	72 (2.6%)
Leukocytosis	4 (0.3%)	0	4 (0.1%)
Lymphadenopathy	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Lymphopenia	0	1 (<0.1%)	1 (<0.1%)
Macrocytosis	0	1 (<0.1%)	1 (<0.1%)
Microcytic anaemia	2 (0.1%)	2 (0.1%)	4 (0.1%)
Monoclonal B-cell lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Nephrogenic anaemia	11 (0.8%)	7 (0.5%)	18 (0.7%)
Normochromic anaemia	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Normochromic normocytic anaemia	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Normocytic anaemia	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Pancytopenia	2 (0.1%)	3 (0.2%)	5 (0.2%)
Pernicious anaemia	2 (0.1%)	2 (0.1%)	4 (0.1%)
Polycythaemia	2 (0.1%)	4 (0.3%)	6 (0.2%)
Retroperitoneal lymphadenopathy	0	1 (<0.1%)	1 (<0.1%)
Splenomegaly	4 (0.3%)	3 (0.2%)	7 (0.3%)
Thrombocytopenia	16 (1.2%)	9 (0.7%)	25 (0.9%)
Thrombocytosis	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorders	850 (62.5%)	850 (62.4%)	1700 (62.5%)
Acute coronary syndrome	1 (<0.1%)	2 (0.1%)	3 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Acute myocardial infarction	8 (0.6%)	7 (0.5%)	15 (0.6%)
Angina pectoris	82 (6.0%)	90 (6.6%)	172 (6.3%)
Angina unstable	12 (0.9%)	12 (0.9%)	24 (0.9%)
Aortic valve calcification	1 (<0.1%)	0	1 (<0.1%)
Aortic valve disease	3 (0.2%)	4 (0.3%)	7 (0.3%)
Aortic valve disease mixed	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic valve incompetence	9 (0.7%)	10 (0.7%)	19 (0.7%)
Aortic valve sclerosis	3 (0.2%)	6 (0.4%)	9 (0.3%)
Aortic valve stenosis	9 (0.7%)	7 (0.5%)	16 (0.6%)
Arrhythmia	15 (1.1%)	7 (0.5%)	22 (0.8%)
Arrhythmia supraventricular	2 (0.1%)	2 (0.1%)	4 (0.1%)
Arteriosclerosis coronary artery	15 (1.1%)	21 (1.5%)	36 (1.3%)
Atrial fibrillation	169 (12.4%)	155 (11.4%)	324 (11.9%)
Atrial flutter	19 (1.4%)	21 (1.5%)	40 (1.5%)
Atrial hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Atrial tachycardia	1 (<0.1%)	0	1 (<0.1%)
Atrioventricular block	5 (0.4%)	6 (0.4%)	11 (0.4%)
Atrioventricular block complete	9 (0.7%)	3 (0.2%)	12 (0.4%)
Atrioventricular block first degree	30 (2.2%)	35 (2.6%)	65 (2.4%)
Atrioventricular block second degree	7 (0.5%)	1 (<0.1%)	8 (0.3%)
Bifascicular block	2 (0.1%)	2 (0.1%)	4 (0.1%)
Bradyarrhythmia	0	1 (<0.1%)	1 (<0.1%)
Bradycardia	13 (1.0%)	5 (0.4%)	18 (0.7%)
Bundle branch block	0	1 (<0.1%)	1 (<0.1%)
Bundle branch block bilateral	0	1 (<0.1%)	1 (<0.1%)
Bundle branch block left	25 (1.8%)	19 (1.4%)	44 (1.6%)
Bundle branch block right	25 (1.8%)	29 (2.1%)	54 (2.0%)
Cardiac aneurysm	0	2 (0.1%)	2 (<0.1%)
Cardiac arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiac disorder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Cardiac failure	26 (1.9%)	35 (2.6%)	61 (2.2%)
Cardiac failure acute	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Cardiac failure chronic	65 (4.8%)	65 (4.8%)	130 (4.8%)
Cardiac failure congestive	28 (2.1%)	28 (2.1%)	56 (2.1%)
Cardiac hypertrophy	3 (0.2%)	0	3 (0.1%)
Cardiac tamponade	1 (<0.1%)	0	1 (<0.1%)
Cardiac valve disease	2 (0.1%)	2 (0.1%)	4 (0.1%)
Cardiac ventricular thrombosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiogenic shock	0	3 (0.2%)	3 (0.1%)
Cardiomegaly	3 (0.2%)	6 (0.4%)	9 (0.3%)
Cardiomyopathy	7 (0.5%)	8 (0.6%)	15 (0.6%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Cardiovascular disorder	1 (<0.1%)	6 (0.4%)	7 (0.3%)
Cardiovascular insufficiency	1 (<0.1%)	0	1 (<0.1%)
Carditis	0	1 (<0.1%)	1 (<0.1%)
Chronic left ventricular failure	6 (0.4%)	4 (0.3%)	10 (0.4%)
Conduction disorder	1 (<0.1%)	0	1 (<0.1%)
Congestive cardiomyopathy	4 (0.3%)	3 (0.2%)	7 (0.3%)
Cor pulmonale	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Coronary artery disease	582 (42.8%)	616 (45.2%)	1198 (44.0%)
Coronary artery insufficiency	0	1 (<0.1%)	1 (<0.1%)
Coronary artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Coronary artery stenosis	8 (0.6%)	7 (0.5%)	15 (0.6%)
Defect conduction intraventricular	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Diastolic dysfunction	8 (0.6%)	10 (0.7%)	18 (0.7%)
Dilatation atrial	1 (<0.1%)	0	1 (<0.1%)
Dressler's syndrome	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Extrasystoles	2 (0.1%)	3 (0.2%)	5 (0.2%)
Heart valve incompetence	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Hypertensive cardiomyopathy	5 (0.4%)	1 (<0.1%)	6 (0.2%)
Hypertensive heart disease	26 (1.9%)	21 (1.5%)	47 (1.7%)
Intracardiac thrombus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	4 (0.3%)	8 (0.6%)	12 (0.4%)
Left atrial dilatation	1 (<0.1%)	0	1 (<0.1%)
Left atrial enlargement	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Left ventricular dysfunction	7 (0.5%)	5 (0.4%)	12 (0.4%)
Left ventricular enlargement	1 (<0.1%)	0	1 (<0.1%)
Left ventricular failure	8 (0.6%)	11 (0.8%)	19 (0.7%)
Left ventricular hypertrophy	34 (2.5%)	30 (2.2%)	64 (2.4%)
Metabolic cardiomyopathy	2 (0.1%)	2 (0.1%)	4 (0.1%)
Microvascular coronary artery disease	1 (<0.1%)	0	1 (<0.1%)
Mitral valve calcification	2 (0.1%)	0	2 (<0.1%)
Mitral valve disease	3 (0.2%)	5 (0.4%)	8 (0.3%)
Mitral valve incompetence	35 (2.6%)	40 (2.9%)	75 (2.8%)
Mitral valve prolapse	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Mitral valve sclerosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Mitral valve stenosis	0	1 (<0.1%)	1 (<0.1%)
Myocardial fibrosis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Myocardial infarction	325 (23.9%)	317 (23.3%)	642 (23.6%)
Myocardial ischaemia	67 (4.9%)	64 (4.7%)	131 (4.8%)
Myocardial necrosis	0	1 (<0.1%)	1 (<0.1%)
Myocarditis	1 (<0.1%)	0	1 (<0.1%)
Non-obstructive cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Palpitations	5 (0.4%)	6 (0.4%)	11 (0.4%)
Pericardial cyst	1 (<0.1%)	0	1 (<0.1%)
Pericardial effusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pericarditis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Pericarditis constrictive	1 (<0.1%)	0	1 (<0.1%)
Prinzmetal angina	1 (<0.1%)	0	1 (<0.1%)
Pulmonary valve incompetence	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary valve stenosis	0	1 (<0.1%)	1 (<0.1%)
Restrictive cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Rheumatic heart disease	1 (<0.1%)	0	1 (<0.1%)
Right atrial dilatation	1 (<0.1%)	0	1 (<0.1%)
Right ventricular hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Silent myocardial infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus bradycardia	15 (1.1%)	7 (0.5%)	22 (0.8%)
Sinus node dysfunction	6 (0.4%)	3 (0.2%)	9 (0.3%)
Sinus tachycardia	3 (0.2%)	4 (0.3%)	7 (0.3%)
Stress cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Supraventricular extrasystoles	5 (0.4%)	4 (0.3%)	9 (0.3%)
Supraventricular tachyarrhythmia	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	7 (0.5%)	2 (0.1%)	9 (0.3%)
Systolic dysfunction	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Tachyarrhythmia	2 (0.1%)	0	2 (<0.1%)
Tachycardia	6 (0.4%)	2 (0.1%)	8 (0.3%)
Tachycardia induced cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Tachycardia paroxysmal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thyrotoxic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Tricuspid valve disease	0	1 (<0.1%)	1 (<0.1%)
Tricuspid valve incompetence	17 (1.3%)	20 (1.5%)	37 (1.4%)
Trifascicular block	0	1 (<0.1%)	1 (<0.1%)
Ventricular dysfunction	1 (<0.1%)	0	1 (<0.1%)
Ventricular dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Ventricular extrasystoles	13 (1.0%)	9 (0.7%)	22 (0.8%)
Ventricular fibrillation	0	1 (<0.1%)	1 (<0.1%)
Ventricular hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Ventricular hypokinesia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular remodelling	1 (<0.1%)	0	1 (<0.1%)
Ventricular tachycardia	2 (0.1%)	4 (0.3%)	6 (0.2%)
Wolff-Parkinson-White syndrome	1 (<0.1%)	0	1 (<0.1%)
Congenital, familial and genetic disorders	74 (5.4%)	60 (4.4%)	134 (4.9%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Adenomatous polyposis coli	2 (0.1%)	0	2 (<0.1%)
Atrial septal defect	2 (0.1%)	2 (0.1%)	4 (0.1%)
Bicuspid aortic valve	0	2 (0.1%)	2 (<0.1%)
Birth mark	2 (0.1%)	0	2 (<0.1%)
Breast malformation	1 (<0.1%)	0	1 (<0.1%)
Cataract congenital	1 (<0.1%)	0	1 (<0.1%)
Cerebrovascular arteriovenous malformation	0	1 (<0.1%)	1 (<0.1%)
Congenital aortic dilatation	1 (<0.1%)	0	1 (<0.1%)
Congenital cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Congenital cystic kidney disease	0	6 (0.4%)	6 (0.2%)
Congenital hepatobiliary anomaly	0	1 (<0.1%)	1 (<0.1%)
Congenital hypercoagulation	1 (<0.1%)	0	1 (<0.1%)
Congenital monorchidism	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	5 (0.4%)	2 (0.1%)	7 (0.3%)
Congenital scoliosis	0	1 (<0.1%)	1 (<0.1%)
Congenital spondylolisthesis	1 (<0.1%)	0	1 (<0.1%)
Congenital ureteric anomaly	1 (<0.1%)	0	1 (<0.1%)
Corneal dystrophy	0	1 (<0.1%)	1 (<0.1%)
Cystinuria	0	1 (<0.1%)	1 (<0.1%)
Dermoid cyst	1 (<0.1%)	0	1 (<0.1%)
Developmental hip dysplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Duane's syndrome	1 (<0.1%)	0	1 (<0.1%)
Exomphalos	1 (<0.1%)	0	1 (<0.1%)
Factor V Leiden carrier	0	1 (<0.1%)	1 (<0.1%)
Factor VIII deficiency	0	1 (<0.1%)	1 (<0.1%)
Factor X deficiency	1 (<0.1%)	0	1 (<0.1%)
Familial high density lipoprotein deficiency	1 (<0.1%)	0	1 (<0.1%)
Familial mediterranean fever	0	1 (<0.1%)	1 (<0.1%)
Familial tremor	0	2 (0.1%)	2 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	0	1 (<0.1%)	1 (<0.1%)
Hereditary ataxia	1 (<0.1%)	0	1 (<0.1%)
Hereditary neuropathy with liability to pressure palsies	0	1 (<0.1%)	1 (<0.1%)
Heterotaxia	1 (<0.1%)	0	1 (<0.1%)
Homocystinaemia	1 (<0.1%)	0	1 (<0.1%)
Homocystinuria	1 (<0.1%)	0	1 (<0.1%)
Hydrocele	3 (0.2%)	2 (0.1%)	5 (0.2%)
Hypertrophic cardiomyopathy	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Ichthyosis	2 (0.1%)	0	2 (<0.1%)
Inborn error of bilirubin metabolism	1 (<0.1%)	0	1 (<0.1%)
Intracranial lipoma	1 (<0.1%)	0	1 (<0.1%)
Macroglossia	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Methylenetetrahydrofolate reductase gene mutation	0	1 (<0.1%)	1 (<0.1%)
Phimosis	7 (0.5%)	2 (0.1%)	9 (0.3%)
Primary hypercholesterolaemia	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Renal hypoplasia	2 (0.1%)	0	2 (<0.1%)
Renal malposition	0	1 (<0.1%)	1 (<0.1%)
Retinitis pigmentosa	0	1 (<0.1%)	1 (<0.1%)
Sickle cell trait	1 (<0.1%)	0	1 (<0.1%)
Spine malformation	1 (<0.1%)	0	1 (<0.1%)
Thalassaemia	0	1 (<0.1%)	1 (<0.1%)
Thalassaemia beta	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thalassaemia minor	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Transcobalamin deficiency	1 (<0.1%)	0	1 (<0.1%)
Tuberous sclerosis complex	1 (<0.1%)	0	1 (<0.1%)
Type IIa hyperlipidaemia	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Type IIb hyperlipidaemia	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Type V hyperlipidaemia	18 (1.3%)	13 (1.0%)	31 (1.1%)
Urethral atresia	1 (<0.1%)	0	1 (<0.1%)
Urinary tract malformation	1 (<0.1%)	0	1 (<0.1%)
Vitello-intestinal duct remnant	0	3 (0.2%)	3 (0.1%)
Von Willebrand's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Welander distal myopathy	1 (<0.1%)	0	1 (<0.1%)
Ear and labyrinth disorders	111 (8.2%)	98 (7.2%)	209 (7.7%)
Auditory disorder	1 (<0.1%)	0	1 (<0.1%)
Cerumen impaction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deafness	11 (0.8%)	13 (1.0%)	24 (0.9%)
Deafness bilateral	2 (0.1%)	4 (0.3%)	6 (0.2%)
Deafness neurosensory	13 (1.0%)	7 (0.5%)	20 (0.7%)
Deafness unilateral	4 (0.3%)	3 (0.2%)	7 (0.3%)
Ear discomfort	1 (<0.1%)	0	1 (<0.1%)
Ear disorder	1 (<0.1%)	0	1 (<0.1%)
Ear pain	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Eustachian tube dysfunction	1 (<0.1%)	0	1 (<0.1%)
Hypoacusis	16 (1.2%)	16 (1.2%)	32 (1.2%)
Meniere's disease	4 (0.3%)	7 (0.5%)	11 (0.4%)
Motion sickness	0	1 (<0.1%)	1 (<0.1%)
Neurosensory hypoacusis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Otorrhoea	1 (<0.1%)	0	1 (<0.1%)
Otosclerosis	2 (0.1%)	0	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Presbyacusis	3 (0.2%)	4 (0.3%)	7 (0.3%)
Sudden hearing loss	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Tinnitus	21 (1.5%)	12 (0.9%)	33 (1.2%)
Tympanic membrane perforation	2 (0.1%)	3 (0.2%)	5 (0.2%)
Vertigo	29 (2.1%)	24 (1.8%)	53 (1.9%)
Vertigo labyrinthine	1 (<0.1%)	0	1 (<0.1%)
Vertigo positional	7 (0.5%)	3 (0.2%)	10 (0.4%)
Vestibular ataxia	3 (0.2%)	4 (0.3%)	7 (0.3%)
Vestibular disorder	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Endocrine disorders	249 (18.3%)	235 (17.3%)	484 (17.8%)
Acromegaly	1 (<0.1%)	0	1 (<0.1%)
Adrenal mass	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Androgen deficiency	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Autoimmune thyroid disorder	0	1 (<0.1%)	1 (<0.1%)
Autoimmune thyroiditis	6 (0.4%)	9 (0.7%)	15 (0.6%)
Basedow's disease	3 (0.2%)	2 (0.1%)	5 (0.2%)
Cushing's syndrome	0	1 (<0.1%)	1 (<0.1%)
Cushingoid	0	2 (0.1%)	2 (<0.1%)
Goitre	39 (2.9%)	48 (3.5%)	87 (3.2%)
Hyperaldosteronism	0	2 (0.1%)	2 (<0.1%)
Hyperparathyroidism	25 (1.8%)	11 (0.8%)	36 (1.3%)
Hyperparathyroidism primary	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperparathyroidism secondary	12 (0.9%)	19 (1.4%)	31 (1.1%)
Hyperplasia adrenal	2 (0.1%)	0	2 (<0.1%)
Hyperthyroidism	23 (1.7%)	10 (0.7%)	33 (1.2%)
Hypogonadism	4 (0.3%)	9 (0.7%)	13 (0.5%)
Hypogonadism male	3 (0.2%)	0	3 (0.1%)
Hypoparathyroidism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoparathyroidism secondary	0	1 (<0.1%)	1 (<0.1%)
Hypothyroidism	132 (9.7%)	120 (8.8%)	252 (9.3%)
Primary hyperaldosteronism	2 (0.1%)	3 (0.2%)	5 (0.2%)
Primary hypogonadism	0	1 (<0.1%)	1 (<0.1%)
Primary hypothyroidism	4 (0.3%)	3 (0.2%)	7 (0.3%)
Testicular failure	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Thyroid cyst	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Thyroid disorder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Thyroid mass	12 (0.9%)	10 (0.7%)	22 (0.8%)
Thyroiditis	0	1 (<0.1%)	1 (<0.1%)
Thyroiditis chronic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Toxic nodular goitre	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Eye disorders	628 (46.2%)	613 (45.0%)	1241 (45.6%)
Age-related macular degeneration	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Amaurosis	1 (<0.1%)	0	1 (<0.1%)
Amaurosis fugax	2 (0.1%)	0	2 (<0.1%)
Amblyopia	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Angle closure glaucoma	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerotic retinopathy	3 (0.2%)	5 (0.4%)	8 (0.3%)
Asthenopia	2 (0.1%)	6 (0.4%)	8 (0.3%)
Astigmatism	4 (0.3%)	5 (0.4%)	9 (0.3%)
Blepharitis	2 (0.1%)	3 (0.2%)	5 (0.2%)
Blindness	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Blindness transient	0	1 (<0.1%)	1 (<0.1%)
Blindness unilateral	3 (0.2%)	5 (0.4%)	8 (0.3%)
Borderline glaucoma	4 (0.3%)	2 (0.1%)	6 (0.2%)
Cataract	221 (16.3%)	242 (17.8%)	463 (17.0%)
Cataract cortical	2 (0.1%)	0	2 (<0.1%)
Cataract diabetic	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Cataract nuclear	9 (0.7%)	3 (0.2%)	12 (0.4%)
Cataract subcapsular	3 (0.2%)	0	3 (0.1%)
Chalazion	1 (<0.1%)	0	1 (<0.1%)
Cholesterolosis bulbi	0	2 (0.1%)	2 (<0.1%)
Chorioretinopathy	1 (<0.1%)	0	1 (<0.1%)
Choroidal neovascularisation	1 (<0.1%)	0	1 (<0.1%)
Ciliary body disorder	1 (<0.1%)	0	1 (<0.1%)
Conjunctival haemorrhage	0	2 (0.1%)	2 (<0.1%)
Conjunctivitis allergic	13 (1.0%)	7 (0.5%)	20 (0.7%)
Corneal degeneration	1 (<0.1%)	0	1 (<0.1%)
Corneal deposits	0	1 (<0.1%)	1 (<0.1%)
Corneal erosion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Corneal oedema	0	1 (<0.1%)	1 (<0.1%)
Cystoid macular oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dacryostenosis acquired	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Dermatochalasis	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Diabetic retinal oedema	3 (0.2%)	5 (0.4%)	8 (0.3%)
Diabetic retinopathy	387 (28.5%)	364 (26.7%)	751 (27.6%)
Diplopia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dry age-related macular degeneration	1 (<0.1%)	0	1 (<0.1%)
Dry eye	29 (2.1%)	19 (1.4%)	48 (1.8%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Ectropion	0	1 (<0.1%)	1 (<0.1%)
Entropion	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Exfoliation glaucoma	1 (<0.1%)	0	1 (<0.1%)
Extraocular muscle paresis	1 (<0.1%)	0	1 (<0.1%)
Eye allergy	0	1 (<0.1%)	1 (<0.1%)
Eye disorder	1 (<0.1%)	0	1 (<0.1%)
Eye haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Eye irritation	1 (<0.1%)	0	1 (<0.1%)
Eye pruritus	1 (<0.1%)	0	1 (<0.1%)
Eyelid ptosis	7 (0.5%)	4 (0.3%)	11 (0.4%)
Glaucoma	76 (5.6%)	77 (5.7%)	153 (5.6%)
Hypermetropia	9 (0.7%)	13 (1.0%)	22 (0.8%)
Iris disorder	1 (<0.1%)	0	1 (<0.1%)
Keratitis	2 (0.1%)	0	2 (<0.1%)
Keratoconus	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	0	2 (0.1%)	2 (<0.1%)
Lacrimation increased	2 (0.1%)	3 (0.2%)	5 (0.2%)
Lagophthalmos	1 (<0.1%)	0	1 (<0.1%)
Lenticular opacities	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	13 (1.0%)	9 (0.7%)	22 (0.8%)
Macular fibrosis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Macular hole	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Macular ischaemia	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	10 (0.7%)	9 (0.7%)	19 (0.7%)
Macular scar	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Maculopathy	6 (0.4%)	4 (0.3%)	10 (0.4%)
Meibomian gland dysfunction	0	1 (<0.1%)	1 (<0.1%)
Myopia	13 (1.0%)	9 (0.7%)	22 (0.8%)
Myopic chorioretinal degeneration	1 (<0.1%)	0	1 (<0.1%)
Narrow anterior chamber angle	0	1 (<0.1%)	1 (<0.1%)
Neovascular age-related macular degeneration	0	1 (<0.1%)	1 (<0.1%)
Non-proliferative retinopathy	0	1 (<0.1%)	1 (<0.1%)
Ocular discomfort	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Ocular hypertension	3 (0.2%)	4 (0.3%)	7 (0.3%)
Ocular ischaemic syndrome	1 (<0.1%)	0	1 (<0.1%)
Open angle glaucoma	2 (0.1%)	9 (0.7%)	11 (0.4%)
Ophthalmoplegia	2 (0.1%)	0	2 (<0.1%)
Optic atrophy	2 (0.1%)	2 (0.1%)	4 (0.1%)
Pathologic myopia	2 (0.1%)	0	2 (<0.1%)
Posterior capsule opacification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Presbyopia	12 (0.9%)	14 (1.0%)	26 (1.0%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Pterygium	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Refraction disorder	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Retinal artery embolism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal artery occlusion	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Retinal artery thrombosis	0	1 (<0.1%)	1 (<0.1%)
Retinal degeneration	1 (<0.1%)	0	1 (<0.1%)
Retinal detachment	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Retinal disorder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Retinal drusen	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Retinal haemorrhage	2 (0.1%)	4 (0.3%)	6 (0.2%)
Retinal infarction	0	1 (<0.1%)	1 (<0.1%)
Retinal oedema	1 (<0.1%)	0	1 (<0.1%)
Retinal tear	2 (0.1%)	3 (0.2%)	5 (0.2%)
Retinal vascular disorder	4 (0.3%)	4 (0.3%)	8 (0.3%)
Retinal vascular occlusion	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Retinal vein occlusion	4 (0.3%)	2 (0.1%)	6 (0.2%)
Retinal vein thrombosis	2 (0.1%)	0	2 (<0.1%)
Retinopathy	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Retinopathy hypertensive	18 (1.3%)	14 (1.0%)	32 (1.2%)
Retinoschisis	1 (<0.1%)	0	1 (<0.1%)
Rhegmatogenous retinal detachment	1 (<0.1%)	0	1 (<0.1%)
Strabismus	4 (0.3%)	2 (0.1%)	6 (0.2%)
Swelling of eyelid	0	1 (<0.1%)	1 (<0.1%)
Tractional retinal detachment	0	1 (<0.1%)	1 (<0.1%)
Trichiasis	2 (0.1%)	2 (0.1%)	4 (0.1%)
Uveitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vernal keratoconjunctivitis	0	1 (<0.1%)	1 (<0.1%)
Vision blurred	5 (0.4%)	1 (<0.1%)	6 (0.2%)
Visual acuity reduced	0	3 (0.2%)	3 (0.1%)
Visual impairment	5 (0.4%)	12 (0.9%)	17 (0.6%)
Vitreous degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitreous detachment	2 (0.1%)	3 (0.2%)	5 (0.2%)
Vitreous disorder	0	1 (<0.1%)	1 (<0.1%)
Vitreous floaters	2 (0.1%)	2 (0.1%)	4 (0.1%)
Vitreous haemorrhage	4 (0.3%)	5 (0.4%)	9 (0.3%)
Vitreous opacities	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Xerophthalmia	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorders	613 (45.1%)	565 (41.5%)	1178 (43.3%)
Abdominal discomfort	3 (0.2%)	3 (0.2%)	6 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Abdominal distension	1 (<0.1%)	0	1 (<0.1%)
Abdominal hernia	9 (0.7%)	4 (0.3%)	13 (0.5%)
Abdominal mass	1 (<0.1%)	0	1 (<0.1%)
Abdominal pain	10 (0.7%)	8 (0.6%)	18 (0.7%)
Abdominal pain upper	8 (0.6%)	3 (0.2%)	11 (0.4%)
Abdominal wall haematoma	1 (<0.1%)	0	1 (<0.1%)
Acid peptic disease	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Alcoholic pancreatitis	0	1 (<0.1%)	1 (<0.1%)
Anal fissure	3 (0.2%)	5 (0.4%)	8 (0.3%)
Anal fistula	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Anal haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Anal incontinence	2 (0.1%)	2 (0.1%)	4 (0.1%)
Anorectal discomfort	0	1 (<0.1%)	1 (<0.1%)
Aphthous ulcer	1 (<0.1%)	0	1 (<0.1%)
Ascites	0	1 (<0.1%)	1 (<0.1%)
Barrett's oesophagus	9 (0.7%)	8 (0.6%)	17 (0.6%)
Bowel movement irregularity	0	1 (<0.1%)	1 (<0.1%)
Brunner's gland hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Change of bowel habit	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	60 (4.4%)	22 (1.6%)	82 (3.0%)
Coeliac artery aneurysm	1 (<0.1%)	0	1 (<0.1%)
Coeliac disease	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Colitis	4 (0.3%)	3 (0.2%)	7 (0.3%)
Colitis erosive	0	1 (<0.1%)	1 (<0.1%)
Colitis ischaemic	2 (0.1%)	0	2 (<0.1%)
Colitis microscopic	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Colitis ulcerative	6 (0.4%)	6 (0.4%)	12 (0.4%)
Colon dysplasia	1 (<0.1%)	0	1 (<0.1%)
Constipation	92 (6.8%)	89 (6.5%)	181 (6.7%)
Crohn's disease	2 (0.1%)	3 (0.2%)	5 (0.2%)
Cyclic vomiting syndrome	0	1 (<0.1%)	1 (<0.1%)
Dental caries	3 (0.2%)	3 (0.2%)	6 (0.2%)
Diabetic gastroparesis	4 (0.3%)	3 (0.2%)	7 (0.3%)
Diaphragmatic hernia	4 (0.3%)	2 (0.1%)	6 (0.2%)
Diarrhoea	17 (1.3%)	29 (2.1%)	46 (1.7%)
Diverticular perforation	0	1 (<0.1%)	1 (<0.1%)
Diverticulum	22 (1.6%)	19 (1.4%)	41 (1.5%)
Diverticulum gastric	1 (<0.1%)	0	1 (<0.1%)
Diverticulum intestinal	24 (1.8%)	27 (2.0%)	51 (1.9%)
Diverticulum intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Diverticulum oesophageal	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Dry mouth	3 (0.2%)	2 (0.1%)	5 (0.2%)
Dumping syndrome	0	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer	16 (1.2%)	16 (1.2%)	32 (1.2%)
Duodenitis	8 (0.6%)	2 (0.1%)	10 (0.4%)
Duodenogastric reflux	3 (0.2%)	0	3 (0.1%)
Dyspepsia	43 (3.2%)	23 (1.7%)	66 (2.4%)
Dysphagia	5 (0.4%)	6 (0.4%)	11 (0.4%)
Enterocolitis	1 (<0.1%)	0	1 (<0.1%)
Epigastric discomfort	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Epiploic appendagitis	1 (<0.1%)	0	1 (<0.1%)
Erosive duodenitis	1 (<0.1%)	0	1 (<0.1%)
Erosive oesophagitis	1 (<0.1%)	0	1 (<0.1%)
Faeces soft	0	1 (<0.1%)	1 (<0.1%)
Flatulence	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Functional gastrointestinal disorder	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Gastric disorder	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Gastric haemorrhage	3 (0.2%)	2 (0.1%)	5 (0.2%)
Gastric hypermotility	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	1 (<0.1%)	0	1 (<0.1%)
Gastric mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	9 (0.7%)	11 (0.8%)	20 (0.7%)
Gastric ulcer	24 (1.8%)	18 (1.3%)	42 (1.5%)
Gastric ulcer haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Gastric ulcer perforation	0	1 (<0.1%)	1 (<0.1%)
Gastritis	49 (3.6%)	48 (3.5%)	97 (3.6%)
Gastritis erosive	9 (0.7%)	9 (0.7%)	18 (0.7%)
Gastritis haemorrhagic	0	1 (<0.1%)	1 (<0.1%)
Gastritis hypertrophic	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal angiodysplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal disorder	4 (0.3%)	2 (0.1%)	6 (0.2%)
Gastrointestinal haemorrhage	5 (0.4%)	3 (0.2%)	8 (0.3%)
Gastrointestinal hypomotility	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal motility disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal polyp	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal scarring	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal tract mucosal pigmentation	2 (0.1%)	0	2 (<0.1%)
Gastrooesophageal reflux disease	200 (14.7%)	203 (14.9%)	403 (14.8%)
Gingival bleeding	1 (<0.1%)	0	1 (<0.1%)
Gingival pain	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Gingival recession	1 (<0.1%)	0	1 (<0.1%)
Gingival swelling	0	2 (0.1%)	2 (<0.1%)
Haematochezia	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Haemorrhagic necrotic pancreatitis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoids	38 (2.8%)	36 (2.6%)	74 (2.7%)
Hernial eventration	0	1 (<0.1%)	1 (<0.1%)
Hiatus hernia	36 (2.6%)	27 (2.0%)	63 (2.3%)
Hyperchlorhydria	1 (<0.1%)	0	1 (<0.1%)
Ileus	1 (<0.1%)	0	1 (<0.1%)
Impaired gastric emptying	4 (0.3%)	5 (0.4%)	9 (0.3%)
Incarcerated umbilical hernia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Inguinal hernia	16 (1.2%)	22 (1.6%)	38 (1.4%)
Intestinal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Intestinal metaplasia	1 (<0.1%)	0	1 (<0.1%)
Intestinal obstruction	0	1 (<0.1%)	1 (<0.1%)
Intestinal perforation	0	3 (0.2%)	3 (0.1%)
Intestinal polyp	3 (0.2%)	2 (0.1%)	5 (0.2%)
Irritable bowel syndrome	19 (1.4%)	5 (0.4%)	24 (0.9%)
Large intestinal obstruction	1 (<0.1%)	0	1 (<0.1%)
Large intestine polyp	44 (3.2%)	30 (2.2%)	74 (2.7%)
Lip disorder	1 (<0.1%)	0	1 (<0.1%)
Lip erosion	1 (<0.1%)	0	1 (<0.1%)
Lip oedema	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Lumbar hernia	0	1 (<0.1%)	1 (<0.1%)
Mesenteric panniculitis	0	1 (<0.1%)	1 (<0.1%)
Nausea	10 (0.7%)	9 (0.7%)	19 (0.7%)
Obstructive pancreatitis	0	2 (0.1%)	2 (<0.1%)
Oesophageal achalasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal dysplasia	1 (<0.1%)	0	1 (<0.1%)
Oesophageal spasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal stenosis	1 (<0.1%)	0	1 (<0.1%)
Oesophageal ulcer	0	2 (0.1%)	2 (<0.1%)
Oesophagitis	11 (0.8%)	7 (0.5%)	18 (0.7%)
Oral disorder	1 (<0.1%)	0	1 (<0.1%)
Pancreatic atrophy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic calcification	0	1 (<0.1%)	1 (<0.1%)
Pancreatic cyst	5 (0.4%)	3 (0.2%)	8 (0.3%)
Pancreatic failure	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Pancreatic mass	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Pancreatic steatosis	2 (0.1%)	0	2 (<0.1%)
Pancreatitis	7 (0.5%)	6 (0.4%)	13 (0.5%)
Pancreatitis acute	8 (0.6%)	14 (1.0%)	22 (0.8%)
Pancreatitis chronic	25 (1.8%)	10 (0.7%)	35 (1.3%)
Pancreatitis relapsing	0	1 (<0.1%)	1 (<0.1%)
Pancreatolithiasis	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer	9 (0.7%)	8 (0.6%)	17 (0.6%)
Peptic ulcer haemorrhage	0	2 (0.1%)	2 (<0.1%)
Periodontal disease	72 (5.3%)	62 (4.6%)	134 (4.9%)
Pharyngo-oesophageal diverticulum	2 (0.1%)	0	2 (<0.1%)
Poor dental condition	1 (<0.1%)	0	1 (<0.1%)
Portal hypertensive gastropathy	1 (<0.1%)	0	1 (<0.1%)
Pouchitis	1 (<0.1%)	0	1 (<0.1%)
Proctalgia	1 (<0.1%)	0	1 (<0.1%)
Proctitis	1 (<0.1%)	0	1 (<0.1%)
Rectal haemorrhage	4 (0.3%)	2 (0.1%)	6 (0.2%)
Rectal polyp	2 (0.1%)	3 (0.2%)	5 (0.2%)
Rectal prolapse	0	1 (<0.1%)	1 (<0.1%)
Reflux gastritis	0	5 (0.4%)	5 (0.2%)
Retching	0	1 (<0.1%)	1 (<0.1%)
Salivary gland calculus	0	1 (<0.1%)	1 (<0.1%)
Salivary gland cyst	0	1 (<0.1%)	1 (<0.1%)
Salivary gland disorder	1 (<0.1%)	0	1 (<0.1%)
Segmental diverticular colitis	0	1 (<0.1%)	1 (<0.1%)
Small intestinal obstruction	0	1 (<0.1%)	1 (<0.1%)
Splenic artery aneurysm	1 (<0.1%)	0	1 (<0.1%)
Stomatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tongue dry	0	1 (<0.1%)	1 (<0.1%)
Tooth loss	2 (0.1%)	0	2 (<0.1%)
Toothache	1 (<0.1%)	0	1 (<0.1%)
Umbilical hernia	19 (1.4%)	14 (1.0%)	33 (1.2%)
Upper gastrointestinal haemorrhage	2 (0.1%)	2 (0.1%)	4 (0.1%)
Varices oesophageal	2 (0.1%)	2 (0.1%)	4 (0.1%)
Vomiting	6 (0.4%)	3 (0.2%)	9 (0.3%)
General disorders and administration site conditions	153 (11.3%)	156 (11.5%)	309 (11.4%)
Application site hypersensitivity	1 (<0.1%)	0	1 (<0.1%)
Asthenia	4 (0.3%)	4 (0.3%)	8 (0.3%)
Calcinosis	1 (<0.1%)	0	1 (<0.1%)
Chest discomfort	2 (0.1%)	1 (<0.1%)	3 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Chest pain	16 (1.2%)	14 (1.0%)	30 (1.1%)
Chills	1 (<0.1%)	0	1 (<0.1%)
Chronic fatigue syndrome	1 (<0.1%)	0	1 (<0.1%)
Cyst	6 (0.4%)	5 (0.4%)	11 (0.4%)
Drug intolerance	9 (0.7%)	10 (0.7%)	19 (0.7%)
Facial pain	1 (<0.1%)	0	1 (<0.1%)
Fatigue	13 (1.0%)	12 (0.9%)	25 (0.9%)
Fibrosis	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	8 (0.6%)	3 (0.2%)	11 (0.4%)
Granuloma	1 (<0.1%)	0	1 (<0.1%)
Gravitational oedema	0	1 (<0.1%)	1 (<0.1%)
Hernia	2 (0.1%)	5 (0.4%)	7 (0.3%)
Hypothermia	0	1 (<0.1%)	1 (<0.1%)
Impaired healing	0	1 (<0.1%)	1 (<0.1%)
Impaired self-care	0	1 (<0.1%)	1 (<0.1%)
Inflammation	5 (0.4%)	0	5 (0.2%)
Influenza like illness	0	2 (0.1%)	2 (<0.1%)
Injury associated with device	0	1 (<0.1%)	1 (<0.1%)
Localised oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malaise	1 (<0.1%)	0	1 (<0.1%)
Mass	0	1 (<0.1%)	1 (<0.1%)
Medical device pain	1 (<0.1%)	0	1 (<0.1%)
Oedema	15 (1.1%)	17 (1.2%)	32 (1.2%)
Oedema due to renal disease	1 (<0.1%)	0	1 (<0.1%)
Oedema peripheral	64 (4.7%)	74 (5.4%)	138 (5.1%)
Pain	9 (0.7%)	8 (0.6%)	17 (0.6%)
Peripheral swelling	5 (0.4%)	3 (0.2%)	8 (0.3%)
Polyp	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Pseudocyst	0	1 (<0.1%)	1 (<0.1%)
Pyrexia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sensation of foreign body	1 (<0.1%)	0	1 (<0.1%)
Vascular stent stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatobiliary disorders	276 (20.3%)	242 (17.8%)	518 (19.0%)
Alcoholic liver disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bile duct stone	2 (0.1%)	2 (0.1%)	4 (0.1%)
Biliary colic	0	2 (0.1%)	2 (<0.1%)
Biliary dilatation	2 (0.1%)	0	2 (<0.1%)
Biliary dyskinesia	4 (0.3%)	0	4 (0.1%)
Cholangitis	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Cholangitis acute	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis	13 (1.0%)	7 (0.5%)	20 (0.7%)
Cholecystitis acute	3 (0.2%)	4 (0.3%)	7 (0.3%)
Cholecystitis chronic	12 (0.9%)	8 (0.6%)	20 (0.7%)
Cholelithiasis	71 (5.2%)	68 (5.0%)	139 (5.1%)
Cholestasis	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Chronic hepatitis	7 (0.5%)	0	7 (0.3%)
Diabetic hepatopathy	6 (0.4%)	4 (0.3%)	10 (0.4%)
Dilatation intrahepatic duct acquired	1 (<0.1%)	0	1 (<0.1%)
Drug-induced liver injury	0	1 (<0.1%)	1 (<0.1%)
Fatty liver alcoholic	0	2 (0.1%)	2 (<0.1%)
Gallbladder cholesterolosis	2 (0.1%)	2 (0.1%)	4 (0.1%)
Gallbladder disorder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Gallbladder enlargement	1 (<0.1%)	0	1 (<0.1%)
Gallbladder polyp	5 (0.4%)	11 (0.8%)	16 (0.6%)
Granulomatous liver disease	1 (<0.1%)	0	1 (<0.1%)
Hepatic calcification	2 (0.1%)	0	2 (<0.1%)
Hepatic cirrhosis	5 (0.4%)	9 (0.7%)	14 (0.5%)
Hepatic cyst	11 (0.8%)	5 (0.4%)	16 (0.6%)
Hepatic failure	1 (<0.1%)	0	1 (<0.1%)
Hepatic fibrosis	0	2 (0.1%)	2 (<0.1%)
Hepatic function abnormal	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Hepatic lesion	0	3 (0.2%)	3 (0.1%)
Hepatic steato-fibrosis	2 (0.1%)	0	2 (<0.1%)
Hepatic steatosis	162 (11.9%)	136 (10.0%)	298 (11.0%)
Hepatitis	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Hepatocellular injury	2 (0.1%)	2 (0.1%)	4 (0.1%)
Hepatomegaly	3 (0.2%)	7 (0.5%)	10 (0.4%)
Hepatosplenomegaly	0	3 (0.2%)	3 (0.1%)
Hyperplastic cholecystopathy	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Hypertransaminasaemia	0	1 (<0.1%)	1 (<0.1%)
Ischaemic hepatitis	1 (<0.1%)	0	1 (<0.1%)
Liver disorder	11 (0.8%)	5 (0.4%)	16 (0.6%)
Liver injury	0	2 (0.1%)	2 (<0.1%)
Non-alcoholic steatohepatitis	7 (0.5%)	5 (0.4%)	12 (0.4%)
Nonalcoholic fatty liver disease	8 (0.6%)	8 (0.6%)	16 (0.6%)
Porcelain gallbladder	0	1 (<0.1%)	1 (<0.1%)
Portal hypertension	0	1 (<0.1%)	1 (<0.1%)
Sphincter of Oddi dysfunction	1 (<0.1%)	0	1 (<0.1%)
Steatohepatitis	2 (0.1%)	3 (0.2%)	5 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Subcapsular hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Immune system disorders	106 (7.8%)	116 (8.5%)	222 (8.2%)
Allergy to arthropod bite	1 (<0.1%)	0	1 (<0.1%)
Allergy to arthropod sting	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Allergy to chemicals	1 (<0.1%)	0	1 (<0.1%)
Anaphylactic reaction	1 (<0.1%)	0	1 (<0.1%)
Contrast media allergy	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Drug hypersensitivity	47 (3.5%)	45 (3.3%)	92 (3.4%)
Food allergy	2 (0.1%)	6 (0.4%)	8 (0.3%)
Hypersensitivity	6 (0.4%)	8 (0.6%)	14 (0.5%)
Immunodeficiency	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Mite allergy	0	1 (<0.1%)	1 (<0.1%)
Multiple allergies	4 (0.3%)	5 (0.4%)	9 (0.3%)
Perennial allergy	0	1 (<0.1%)	1 (<0.1%)
Rubber sensitivity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sarcoidosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Seasonal allergy	49 (3.6%)	51 (3.7%)	100 (3.7%)
Infections and infestations	326 (24.0%)	299 (22.0%)	625 (23.0%)
Abscess limb	0	1 (<0.1%)	1 (<0.1%)
Acquired immunodeficiency syndrome	0	1 (<0.1%)	1 (<0.1%)
American trypanosomiasis	0	1 (<0.1%)	1 (<0.1%)
Anal abscess	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Appendicitis	11 (0.8%)	12 (0.9%)	23 (0.8%)
Appendicitis perforated	0	1 (<0.1%)	1 (<0.1%)
Arthritis bacterial	1 (<0.1%)	0	1 (<0.1%)
Arthritis infective	1 (<0.1%)	0	1 (<0.1%)
Aspergilloma	1 (<0.1%)	0	1 (<0.1%)
Bacterial disease carrier	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bacteriuria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Body tinea	2 (0.1%)	2 (0.1%)	4 (0.1%)
Borrelia infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bronchitis	9 (0.7%)	16 (1.2%)	25 (0.9%)
Brucellosis	0	1 (<0.1%)	1 (<0.1%)
Candida infection	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Carbuncle	0	2 (0.1%)	2 (<0.1%)
Catheter site infection	1 (<0.1%)	0	1 (<0.1%)
Cellulitis	21 (1.5%)	7 (0.5%)	28 (1.0%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Cervicitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholecystitis infective	0	2 (0.1%)	2 (<0.1%)
Chronic hepatitis B	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic hepatitis C	0	5 (0.4%)	5 (0.2%)
Chronic sinusitis	8 (0.6%)	9 (0.7%)	17 (0.6%)
Chronic tonsillitis	2 (0.1%)	2 (0.1%)	4 (0.1%)
Clostridium difficile colitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coccidioidomycosis	0	1 (<0.1%)	1 (<0.1%)
Conjunctivitis	9 (0.7%)	3 (0.2%)	12 (0.4%)
Coxsackie viral infection	0	1 (<0.1%)	1 (<0.1%)
Cystitis	4 (0.3%)	4 (0.3%)	8 (0.3%)
Dental fistula	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis of nail	9 (0.7%)	9 (0.7%)	18 (0.7%)
Diabetic foot infection	0	1 (<0.1%)	1 (<0.1%)
Diabetic gangrene	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diverticulitis	14 (1.0%)	13 (1.0%)	27 (1.0%)
Ear infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Encephalitis	0	1 (<0.1%)	1 (<0.1%)
Endocarditis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Enterococcal bacteraemia	0	1 (<0.1%)	1 (<0.1%)
Epididymitis	1 (<0.1%)	0	1 (<0.1%)
Epstein-Barr virus infection	1 (<0.1%)	0	1 (<0.1%)
Erysipelas	8 (0.6%)	7 (0.5%)	15 (0.6%)
Escherichia urinary tract infection	0	2 (0.1%)	2 (<0.1%)
External ear cellulitis	0	1 (<0.1%)	1 (<0.1%)
Eye infection	1 (<0.1%)	0	1 (<0.1%)
Folliculitis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Fungal infection	1 (<0.1%)	0	1 (<0.1%)
Fungal skin infection	3 (0.2%)	2 (0.1%)	5 (0.2%)
Furuncle	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gangrene	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastritis viral	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis	2 (0.1%)	3 (0.2%)	5 (0.2%)
Gastroenteritis norovirus	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis viral	1 (<0.1%)	0	1 (<0.1%)
Genital herpes	0	2 (0.1%)	2 (<0.1%)
Genitourinary tract infection	0	1 (<0.1%)	1 (<0.1%)
Gingivitis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Groin abscess	0	1 (<0.1%)	1 (<0.1%)
Helicobacter gastritis	4 (0.3%)	0	4 (0.1%)
Helicobacter infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hepatic echinococciasis	1 (<0.1%)	0	1 (<0.1%)
Hepatitis A	2 (0.1%)	4 (0.3%)	6 (0.2%)
Hepatitis B	5 (0.4%)	1 (<0.1%)	6 (0.2%)
Hepatitis C	8 (0.6%)	2 (0.1%)	10 (0.4%)
Hepatitis infectious mononucleosis	0	1 (<0.1%)	1 (<0.1%)
Hepatitis viral	1 (<0.1%)	0	1 (<0.1%)
Herpes simplex	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Herpes zoster	13 (1.0%)	13 (1.0%)	26 (1.0%)
Herpes zoster reactivation	1 (<0.1%)	0	1 (<0.1%)
Hordeolum	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infected bite	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	1 (<0.1%)	0	1 (<0.1%)
Infectious mononucleosis	1 (<0.1%)	0	1 (<0.1%)
Infective keratitis	0	1 (<0.1%)	1 (<0.1%)
Influenza	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Intestinal tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Kidney infection	1 (<0.1%)	0	1 (<0.1%)
Labyrinthitis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Laryngitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Legionella infection	0	3 (0.2%)	3 (0.1%)
Leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Lice infestation	0	1 (<0.1%)	1 (<0.1%)
Liver abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lower respiratory tract infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lyme disease	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Malaria	1 (<0.1%)	0	1 (<0.1%)
Mastitis	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	0	2 (0.1%)	2 (<0.1%)
Meningitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Meningitis aseptic	0	1 (<0.1%)	1 (<0.1%)
Meningitis bacterial	0	1 (<0.1%)	1 (<0.1%)
Mumps	0	1 (<0.1%)	1 (<0.1%)
Myocarditis infectious	0	1 (<0.1%)	1 (<0.1%)
Nail candida	0	1 (<0.1%)	1 (<0.1%)
Nasal abscess	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	14 (1.0%)	5 (0.4%)	19 (0.7%)
Necrotising fasciitis	1 (<0.1%)	0	1 (<0.1%)
Oesophageal candidiasis	0	1 (<0.1%)	1 (<0.1%)
Onychomycosis	27 (2.0%)	26 (1.9%)	53 (1.9%)
Oral candidiasis	0	1 (<0.1%)	1 (<0.1%)
Oral herpes	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Osteomyelitis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Osteomyelitis chronic	1 (<0.1%)	0	1 (<0.1%)
Otitis externa	2 (0.1%)	0	2 (<0.1%)
Otitis media	4 (0.3%)	2 (0.1%)	6 (0.2%)
Otitis media chronic	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	0	1 (<0.1%)	1 (<0.1%)
Paronychia	2 (0.1%)	0	2 (<0.1%)
Parotitis	2 (0.1%)	0	2 (<0.1%)
Periodontitis	2 (0.1%)	0	2 (<0.1%)
Peritonitis	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	3 (0.2%)	4 (0.3%)	7 (0.3%)
Pharyngotonsillitis	0	1 (<0.1%)	1 (<0.1%)
Pilonidal cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pleurisy viral	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	23 (1.7%)	19 (1.4%)	42 (1.5%)
Pneumonia bacterial	0	1 (<0.1%)	1 (<0.1%)
Pneumonia moraxella	0	1 (<0.1%)	1 (<0.1%)
Poliomyelitis	0	2 (0.1%)	2 (<0.1%)
Post procedural infection	1 (<0.1%)	0	1 (<0.1%)
Pulmonary sepsis	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculoma	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	3 (0.2%)	6 (0.4%)	9 (0.3%)
Pustule	0	1 (<0.1%)	1 (<0.1%)
Pyelonephritis	4 (0.3%)	2 (0.1%)	6 (0.2%)
Pyelonephritis acute	2 (0.1%)	5 (0.4%)	7 (0.3%)
Pyelonephritis chronic	27 (2.0%)	20 (1.5%)	47 (1.7%)
Rectal abscess	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Respiratory tract infection viral	1 (<0.1%)	0	1 (<0.1%)
Rhinitis	10 (0.7%)	9 (0.7%)	19 (0.7%)
Salpingo-oophoritis	2 (0.1%)	0	2 (<0.1%)
Scrotal abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Septic embolus	0	1 (<0.1%)	1 (<0.1%)
Septic shock	1 (<0.1%)	0	1 (<0.1%)
Sinusitis	9 (0.7%)	6 (0.4%)	15 (0.6%)
Skin infection	3 (0.2%)	2 (0.1%)	5 (0.2%)
Sternitis	0	2 (0.1%)	2 (<0.1%)
Subcutaneous abscess	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Taeniasis	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Tinea cruris	5 (0.4%)	2 (0.1%)	7 (0.3%)
Tinea infection	6 (0.4%)	6 (0.4%)	12 (0.4%)
Tinea manuum	0	1 (<0.1%)	1 (<0.1%)
Tinea pedis	20 (1.5%)	14 (1.0%)	34 (1.2%)
Tinea versicolour	2 (0.1%)	2 (0.1%)	4 (0.1%)
Tonsillitis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Tooth abscess	1 (<0.1%)	0	1 (<0.1%)
Tooth infection	0	2 (0.1%)	2 (<0.1%)
Tracheitis	1 (<0.1%)	0	1 (<0.1%)
Trichuriasis	0	1 (<0.1%)	1 (<0.1%)
Tuberculosis	10 (0.7%)	4 (0.3%)	14 (0.5%)
Upper respiratory tract infection	6 (0.4%)	13 (1.0%)	19 (0.7%)
Urinary tract infection	29 (2.1%)	37 (2.7%)	66 (2.4%)
Urinary tract infection bacterial	0	1 (<0.1%)	1 (<0.1%)
Urosepsis	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Vaginal infection	1 (<0.1%)	0	1 (<0.1%)
Varicella	0	1 (<0.1%)	1 (<0.1%)
Vascular device infection	0	1 (<0.1%)	1 (<0.1%)
Vestibular neuronitis	0	1 (<0.1%)	1 (<0.1%)
Viral diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Viral hepatitis carrier	2 (0.1%)	2 (0.1%)	4 (0.1%)
Viral infection	2 (0.1%)	0	2 (<0.1%)
Viral pericarditis	0	1 (<0.1%)	1 (<0.1%)
Viral upper respiratory tract infection	0	1 (<0.1%)	1 (<0.1%)
Vulval abscess	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginitis	0	1 (<0.1%)	1 (<0.1%)
Wound infection	1 (<0.1%)	0	1 (<0.1%)
Injury, poisoning and procedural complications	128 (9.4%)	130 (9.5%)	258 (9.5%)
Abdominal injury	1 (<0.1%)	0	1 (<0.1%)
Accident	2 (0.1%)	0	2 (<0.1%)
Acetabulum fracture	1 (<0.1%)	0	1 (<0.1%)
Ankle fracture	9 (0.7%)	8 (0.6%)	17 (0.6%)
Arterial bypass occlusion	0	1 (<0.1%)	1 (<0.1%)
Arterial bypass thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	2 (0.1%)	2 (0.1%)	4 (0.1%)
Asbestosis	0	1 (<0.1%)	1 (<0.1%)
Auricular haematoma	1 (<0.1%)	0	1 (<0.1%)
Back injury	1 (<0.1%)	0	1 (<0.1%)
Brain contusion	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Cervical vertebral fracture	1 (<0.1%)	0	1 (<0.1%)
Chest injury	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Clavicle fracture	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Compression fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Concussion	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Contusion	6 (0.4%)	4 (0.3%)	10 (0.4%)
Coronary vascular graft occlusion	1 (<0.1%)	0	1 (<0.1%)
Craniocerebral injury	0	1 (<0.1%)	1 (<0.1%)
Epicondylitis	2 (0.1%)	4 (0.3%)	6 (0.2%)
Facial bones fracture	1 (<0.1%)	0	1 (<0.1%)
Fall	3 (0.2%)	3 (0.2%)	6 (0.2%)
Femoral neck fracture	1 (<0.1%)	0	1 (<0.1%)
Femur fracture	5 (0.4%)	3 (0.2%)	8 (0.3%)
Fibula fracture	4 (0.3%)	4 (0.3%)	8 (0.3%)
Foot fracture	2 (0.1%)	7 (0.5%)	9 (0.3%)
Foreign body in eye	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fracture	1 (<0.1%)	0	1 (<0.1%)
Fractured coccyx	1 (<0.1%)	0	1 (<0.1%)
Fractured sacrum	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gun shot wound	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hand fracture	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Head injury	2 (0.1%)	0	2 (<0.1%)
Hip fracture	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Humerus fracture	3 (0.2%)	8 (0.6%)	11 (0.4%)
Incisional hernia	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Injury to brachial plexus due to birth trauma	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc injury	0	1 (<0.1%)	1 (<0.1%)
Jaw fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint dislocation	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Joint injury	2 (0.1%)	2 (0.1%)	4 (0.1%)
Ligament injury	0	1 (<0.1%)	1 (<0.1%)
Ligament rupture	3 (0.2%)	4 (0.3%)	7 (0.3%)
Ligament sprain	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Limb crushing injury	1 (<0.1%)	0	1 (<0.1%)
Limb injury	9 (0.7%)	10 (0.7%)	19 (0.7%)
Limb traumatic amputation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Lower limb fracture	1 (<0.1%)	7 (0.5%)	8 (0.3%)
Lumbar vertebral fracture	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Meniscus injury	8 (0.6%)	11 (0.8%)	19 (0.7%)
Mouth injury	0	1 (<0.1%)	1 (<0.1%)
Multiple fractures	2 (0.1%)	2 (0.1%)	4 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Multiple injuries	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle rupture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle strain	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Nerve injury	0	1 (<0.1%)	1 (<0.1%)
Optic nerve injury	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	3 (0.2%)	2 (0.1%)	5 (0.2%)
Pelvic fracture	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Penis injury	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve injury	0	1 (<0.1%)	1 (<0.1%)
Pneumonitis chemical	1 (<0.1%)	0	1 (<0.1%)
Post procedural fistula	0	1 (<0.1%)	1 (<0.1%)
Post procedural haematoma	0	1 (<0.1%)	1 (<0.1%)
Post procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypotension	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypothyroidism	5 (0.4%)	3 (0.2%)	8 (0.3%)
Post-traumatic pain	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Postoperative renal failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative thoracic procedure complication	1 (<0.1%)	0	1 (<0.1%)
Procedural pain	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Pulmonary contusion	1 (<0.1%)	0	1 (<0.1%)
Radial nerve injury	1 (<0.1%)	0	1 (<0.1%)
Radius fracture	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Rib fracture	6 (0.4%)	3 (0.2%)	9 (0.3%)
Road traffic accident	4 (0.3%)	3 (0.2%)	7 (0.3%)
Sacroiliac fracture	0	1 (<0.1%)	1 (<0.1%)
Scar	0	1 (<0.1%)	1 (<0.1%)
Silicosis	1 (<0.1%)	0	1 (<0.1%)
Skin abrasion	0	1 (<0.1%)	1 (<0.1%)
Skin injury	0	1 (<0.1%)	1 (<0.1%)
Skin laceration	1 (<0.1%)	0	1 (<0.1%)
Skin wound	0	1 (<0.1%)	1 (<0.1%)
Skull fracture	2 (0.1%)	0	2 (<0.1%)
Spinal column injury	1 (<0.1%)	0	1 (<0.1%)
Spinal compression fracture	3 (0.2%)	2 (0.1%)	5 (0.2%)
Spinal fracture	0	1 (<0.1%)	1 (<0.1%)
Stomal hernia	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Stress fracture	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous haematoma	0	1 (<0.1%)	1 (<0.1%)
Subdural haematoma	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Subdural haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Synovial rupture	0	1 (<0.1%)	1 (<0.1%)
Tendon injury	1 (<0.1%)	0	1 (<0.1%)
Tendon rupture	5 (0.4%)	5 (0.4%)	10 (0.4%)
Thermal burn	0	1 (<0.1%)	1 (<0.1%)
Thoracic vertebral fracture	1 (<0.1%)	0	1 (<0.1%)
Tibia fracture	2 (0.1%)	4 (0.3%)	6 (0.2%)
Tooth fracture	0	2 (0.1%)	2 (<0.1%)
Toxicity to various agents	1 (<0.1%)	0	1 (<0.1%)
Traumatic arthritis	0	1 (<0.1%)	1 (<0.1%)
Traumatic arthropathy	0	1 (<0.1%)	1 (<0.1%)
Traumatic fracture	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Traumatic haemothorax	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Traumatic shock	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	1 (<0.1%)	0	1 (<0.1%)
Ulna fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ulnar nerve injury	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	2 (0.1%)	8 (0.6%)	10 (0.4%)
Ureteric injury	0	1 (<0.1%)	1 (<0.1%)
Urethral stricture traumatic	0	1 (<0.1%)	1 (<0.1%)
Urinary retention postoperative	0	1 (<0.1%)	1 (<0.1%)
Vascular graft complication	0	1 (<0.1%)	1 (<0.1%)
Vascular pseudoaneurysm	1 (<0.1%)	0	1 (<0.1%)
Wound complication	1 (<0.1%)	0	1 (<0.1%)
Wound dehiscence	0	2 (0.1%)	2 (<0.1%)
Wrist fracture	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Investigations	169 (12.4%)	170 (12.5%)	339 (12.5%)
Alanine aminotransferase increased	0	1 (<0.1%)	1 (<0.1%)
Albumin urine present	0	1 (<0.1%)	1 (<0.1%)
Amylase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angiocardiogram	12 (0.9%)	15 (1.1%)	27 (1.0%)
Angiogram	8 (0.6%)	2 (0.1%)	10 (0.4%)
Angiogram cerebral	1 (<0.1%)	0	1 (<0.1%)
Ankle brachial index decreased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Anti factor VIII antibody positive	1 (<0.1%)	0	1 (<0.1%)
Anti factor XI antibody positive	0	1 (<0.1%)	1 (<0.1%)
Antinuclear antibody positive	0	1 (<0.1%)	1 (<0.1%)
Aortogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arterial bruit	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Arteriogram abnormal	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Arteriogram carotid	1 (<0.1%)	0	1 (<0.1%)
Arthroscopy	7 (0.5%)	1 (<0.1%)	8 (0.3%)
Aspartate aminotransferase increased	0	1 (<0.1%)	1 (<0.1%)
Biopsy	1 (<0.1%)	0	1 (<0.1%)
Biopsy breast	2 (0.1%)	0	2 (<0.1%)
Biopsy bronchus	0	1 (<0.1%)	1 (<0.1%)
Biopsy colon	1 (<0.1%)	0	1 (<0.1%)
Biopsy kidney	0	2 (0.1%)	2 (<0.1%)
Biopsy prostate	1 (<0.1%)	0	1 (<0.1%)
Blood alkaline phosphatase increased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Blood calcium decreased	1 (<0.1%)	0	1 (<0.1%)
Blood chloride increased	1 (<0.1%)	0	1 (<0.1%)
Blood cholesterol increased	15 (1.1%)	22 (1.6%)	37 (1.4%)
Blood creatine phosphokinase increased	9 (0.7%)	17 (1.2%)	26 (1.0%)
Blood creatinine increased	0	2 (0.1%)	2 (<0.1%)
Blood folate increased	0	1 (<0.1%)	1 (<0.1%)
Blood glucose increased	0	1 (<0.1%)	1 (<0.1%)
Blood iron decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood magnesium decreased	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Blood parathyroid hormone increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood potassium increased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Blood pressure increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood sodium decreased	0	2 (0.1%)	2 (<0.1%)
Blood testosterone decreased	2 (0.1%)	3 (0.2%)	5 (0.2%)
Blood triglycerides increased	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Blood urea increased	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Blood uric acid abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood uric acid increased	4 (0.3%)	4 (0.3%)	8 (0.3%)
Blood urine present	1 (<0.1%)	0	1 (<0.1%)
Body mass index increased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Bone densitometry	1 (<0.1%)	0	1 (<0.1%)
Brain scan abnormal	0	1 (<0.1%)	1 (<0.1%)
C-reactive protein increased	8 (0.6%)	6 (0.4%)	14 (0.5%)
Carbon dioxide decreased	1 (<0.1%)	0	1 (<0.1%)
Cardiac murmur	15 (1.1%)	15 (1.1%)	30 (1.1%)
Cardiac stress test	1 (<0.1%)	0	1 (<0.1%)
Cardiac stress test abnormal	2 (0.1%)	0	2 (<0.1%)
Cardiac ventriculogram	1 (<0.1%)	0	1 (<0.1%)
Cardiac ventriculogram left normal	1 (<0.1%)	0	1 (<0.1%)
Carotid bruit	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Catheterisation cardiac	7 (0.5%)	7 (0.5%)	14 (0.5%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Colonoscopy	2 (0.1%)	5 (0.4%)	7 (0.3%)
Computerised tomogram abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram coronary artery	0	1 (<0.1%)	1 (<0.1%)
Computerised tomogram head	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram pelvis abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram thorax abnormal	0	1 (<0.1%)	1 (<0.1%)
Culture urine positive	1 (<0.1%)	0	1 (<0.1%)
Cystoscopy	1 (<0.1%)	0	1 (<0.1%)
ECG signs of myocardial infarction	1 (<0.1%)	0	1 (<0.1%)
ECG signs of myocardial ischaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Echocardiogram	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Ejection fraction decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ejection fraction normal	0	2 (0.1%)	2 (<0.1%)
Electrocardiogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram Q wave abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram QRS complex abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram QT interval abnormal	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QT prolonged	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Electrocardiogram ST segment depression	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram ST segment elevation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram T wave abnormal	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Electrocardiogram T wave biphasic	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave inversion	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Electrocardiogram abnormal	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Electrocardiogram repolarisation abnormality	6 (0.4%)	3 (0.2%)	9 (0.3%)
Endoscopic retrograde cholangiopancreatography	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Endoscopy	1 (<0.1%)	0	1 (<0.1%)
Enzyme activity abnormal	1 (<0.1%)	0	1 (<0.1%)
False positive investigation result	0	1 (<0.1%)	1 (<0.1%)
Femoral bruit	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase abnormal	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase increased	2 (0.1%)	12 (0.9%)	14 (0.5%)
Gastric pH decreased	3 (0.2%)	3 (0.2%)	6 (0.2%)
Globulin abnormal	0	1 (<0.1%)	1 (<0.1%)
Glomerular filtration rate decreased	2 (0.1%)	0	2 (<0.1%)
Glycosylated haemoglobin increased	1 (<0.1%)	0	1 (<0.1%)
HLA-B*5801 assay positive	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Heart rate irregular	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Helicobacter test positive	2 (0.1%)	1 (<0.1%)	3 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hepatic enzyme increased	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Hepatitis C virus test positive	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure decreased	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure increased	0	2 (0.1%)	2 (<0.1%)
Light chain analysis decreased	1 (<0.1%)	0	1 (<0.1%)
Lipase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipids abnormal	0	1 (<0.1%)	1 (<0.1%)
Lipids increased	1 (<0.1%)	0	1 (<0.1%)
Lipoprotein (a) increased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Liver function test abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Liver function test increased	3 (0.2%)	6 (0.4%)	9 (0.3%)
Macroenzyme creatine kinase	1 (<0.1%)	0	1 (<0.1%)
Magnetic resonance imaging brain	1 (<0.1%)	0	1 (<0.1%)
Mammogram	1 (<0.1%)	0	1 (<0.1%)
Mammogram abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Occult blood positive	0	2 (0.1%)	2 (<0.1%)
Oxygen consumption increased	1 (<0.1%)	0	1 (<0.1%)
Pedal pulse decreased	1 (<0.1%)	0	1 (<0.1%)
Peripheral arteriogram	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Platelet aggregation decreased	1 (<0.1%)	0	1 (<0.1%)
Platelet count decreased	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Prostatic specific antigen increased	6 (0.4%)	3 (0.2%)	9 (0.3%)
Pulmonary function test decreased	1 (<0.1%)	0	1 (<0.1%)
Pulse absent	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pyeloscopy	1 (<0.1%)	0	1 (<0.1%)
QRS axis abnormal	8 (0.6%)	3 (0.2%)	11 (0.4%)
Red blood cell count increased	0	1 (<0.1%)	1 (<0.1%)
Red blood cell sedimentation rate increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scan myocardial perfusion abnormal	0	1 (<0.1%)	1 (<0.1%)
Serum ferritin increased	1 (<0.1%)	0	1 (<0.1%)
Spinal X-ray	0	1 (<0.1%)	1 (<0.1%)
Staphylococcus test positive	0	1 (<0.1%)	1 (<0.1%)
Thyroid function test normal	1 (<0.1%)	0	1 (<0.1%)
Thyroid gland scan abnormal	0	1 (<0.1%)	1 (<0.1%)
Thyroid hormones decreased	0	1 (<0.1%)	1 (<0.1%)
Total lung capacity decreased	0	1 (<0.1%)	1 (<0.1%)
Transaminases increased	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Troponin increased	0	1 (<0.1%)	1 (<0.1%)
Tuberculin test positive	0	1 (<0.1%)	1 (<0.1%)
Ultrasound abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Ultrasound kidney	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ultrasound kidney abnormal	1 (<0.1%)	0	1 (<0.1%)
Ultrasound thyroid	1 (<0.1%)	0	1 (<0.1%)
Ultrasound thyroid abnormal	0	1 (<0.1%)	1 (<0.1%)
Ureteroscopy	1 (<0.1%)	0	1 (<0.1%)
Urinary occult blood positive	1 (<0.1%)	0	1 (<0.1%)
Urine analysis abnormal	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Vitamin B12 increased	1 (<0.1%)	0	1 (<0.1%)
Vitamin D decreased	2 (0.1%)	5 (0.4%)	7 (0.3%)
Weight decreased	1 (<0.1%)	0	1 (<0.1%)
Weight increased	1 (<0.1%)	0	1 (<0.1%)
White blood cell count increased	1 (<0.1%)	2 (0.1%)	3 (0.1%)
X-ray limb	0	1 (<0.1%)	1 (<0.1%)
X-ray of pelvis and hip	0	1 (<0.1%)	1 (<0.1%)
Metabolism and nutrition disorders	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Abnormal loss of weight	0	1 (<0.1%)	1 (<0.1%)
Acidosis	1 (<0.1%)	0	1 (<0.1%)
Acquired mixed hyperlipidaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Calcium deficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Central obesity	20 (1.5%)	8 (0.6%)	28 (1.0%)
Decreased appetite	2 (0.1%)	4 (0.3%)	6 (0.2%)
Dehydration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Diabetes mellitus inadequate control	6 (0.4%)	0	6 (0.2%)
Diabetic ketoacidosis	0	1 (<0.1%)	1 (<0.1%)
Diabetic ketosis	0	2 (0.1%)	2 (<0.1%)
Diabetic metabolic decompensation	0	1 (<0.1%)	1 (<0.1%)
Disaccharidase deficiency	0	1 (<0.1%)	1 (<0.1%)
Dyslipidaemia	467 (34.4%)	453 (33.3%)	920 (33.8%)
Electrolyte imbalance	1 (<0.1%)	0	1 (<0.1%)
Fluid overload	0	2 (0.1%)	2 (<0.1%)
Fluid retention	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Folate deficiency	2 (0.1%)	2 (0.1%)	4 (0.1%)
Glucose tolerance impaired	2 (0.1%)	3 (0.2%)	5 (0.2%)
Gout	141 (10.4%)	152 (11.2%)	293 (10.8%)
Haemochromatosis	5 (0.4%)	1 (<0.1%)	6 (0.2%)
Hypercalcaemia	9 (0.7%)	8 (0.6%)	17 (0.6%)
Hypercholesterolaemia	186 (13.7%)	203 (14.9%)	389 (14.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hyperferritinaemia	1 (<0.1%)	0	1 (<0.1%)
Hyperglycaemia	3 (0.2%)	5 (0.4%)	8 (0.3%)
Hyperhomocysteinaemia	5 (0.4%)	2 (0.1%)	7 (0.3%)
Hyperinsulinaemic hypoglycaemia	1 (<0.1%)	0	1 (<0.1%)
Hyperkalaemia	25 (1.8%)	14 (1.0%)	39 (1.4%)
Hyperlipidaemia	396 (29.1%)	384 (28.2%)	780 (28.7%)
Hyperphosphataemia	2 (0.1%)	0	2 (<0.1%)
Hypertriglyceridaemia	21 (1.5%)	25 (1.8%)	46 (1.7%)
Hyperuricaemia	210 (15.5%)	229 (16.8%)	439 (16.1%)
Hypo HDL cholesterolaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoalbuminaemia	1 (<0.1%)	0	1 (<0.1%)
Hypocalcaemia	3 (0.2%)	2 (0.1%)	5 (0.2%)
Hypoglycaemia	10 (0.7%)	8 (0.6%)	18 (0.7%)
Hypokalaemia	15 (1.1%)	11 (0.8%)	26 (1.0%)
Hypomagnesaemia	11 (0.8%)	6 (0.4%)	17 (0.6%)
Hyponatraemia	7 (0.5%)	8 (0.6%)	15 (0.6%)
Hypophosphataemia	0	2 (0.1%)	2 (<0.1%)
Hypoproteinaemia	1 (<0.1%)	0	1 (<0.1%)
Hypouricaemia	1 (<0.1%)	0	1 (<0.1%)
Hypovitaminosis	0	4 (0.3%)	4 (0.1%)
Impaired fasting glucose	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Iron deficiency	15 (1.1%)	10 (0.7%)	25 (0.9%)
Lactic acidosis	0	1 (<0.1%)	1 (<0.1%)
Lactose intolerance	3 (0.2%)	2 (0.1%)	5 (0.2%)
Lipid metabolism disorder	7 (0.5%)	8 (0.6%)	15 (0.6%)
Lipomatosis	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Magnesium metabolism disorder	0	1 (<0.1%)	1 (<0.1%)
Malnutrition	0	1 (<0.1%)	1 (<0.1%)
Metabolic acidosis	5 (0.4%)	7 (0.5%)	12 (0.4%)
Metabolic syndrome	5 (0.4%)	4 (0.3%)	9 (0.3%)
Obesity	579 (42.6%)	562 (41.3%)	1141 (41.9%)
Overweight	16 (1.2%)	13 (1.0%)	29 (1.1%)
Purine metabolism disorder	2 (0.1%)	0	2 (<0.1%)
Type 2 diabetes mellitus	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Vitamin B complex deficiency	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Vitamin B1 deficiency	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 deficiency	37 (2.7%)	33 (2.4%)	70 (2.6%)
Vitamin D deficiency	121 (8.9%)	133 (9.8%)	254 (9.3%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Zinc deficiency	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal and connective tissue disorders	600 (44.2%)	587 (43.1%)	1187 (43.6%)
Ankle deformity	0	1 (<0.1%)	1 (<0.1%)
Ankylosing spondylitis	4 (0.3%)	2 (0.1%)	6 (0.2%)
Arthralgia	64 (4.7%)	47 (3.5%)	111 (4.1%)
Arthritis	27 (2.0%)	43 (3.2%)	70 (2.6%)
Arthropathy	5 (0.4%)	2 (0.1%)	7 (0.3%)
Articular calcification	1 (<0.1%)	0	1 (<0.1%)
Axillary mass	1 (<0.1%)	0	1 (<0.1%)
Back disorder	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Back pain	115 (8.5%)	111 (8.1%)	226 (8.3%)
Bone atrophy	1 (<0.1%)	0	1 (<0.1%)
Bone disorder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Bone metabolism disorder	2 (0.1%)	0	2 (<0.1%)
Bone pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bursa disorder	0	1 (<0.1%)	1 (<0.1%)
Bursitis	11 (0.8%)	8 (0.6%)	19 (0.7%)
Calcification of muscle	1 (<0.1%)	0	1 (<0.1%)
Cervical spinal stenosis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Chondrocalcinosis	0	2 (0.1%)	2 (<0.1%)
Chondromalacia	1 (<0.1%)	0	1 (<0.1%)
Chondropathy	2 (0.1%)	0	2 (<0.1%)
Chronic kidney disease-mineral and bone disorder	5 (0.4%)	0	5 (0.2%)
Coccydynia	1 (<0.1%)	0	1 (<0.1%)
Compartment syndrome	0	1 (<0.1%)	1 (<0.1%)
Diabetic amyotrophy	0	2 (0.1%)	2 (<0.1%)
Diastasis recti abdominis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Diffuse idiopathic skeletal hyperostosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Dupuytren's contracture	9 (0.7%)	7 (0.5%)	16 (0.6%)
Enthesopathy	2 (0.1%)	0	2 (<0.1%)
Exostosis	2 (0.1%)	9 (0.7%)	11 (0.4%)
Facet joint syndrome	1 (<0.1%)	0	1 (<0.1%)
Fasciitis	1 (<0.1%)	0	1 (<0.1%)
Fibromyalgia	7 (0.5%)	5 (0.4%)	12 (0.4%)
Finger deformity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Flank pain	2 (0.1%)	2 (0.1%)	4 (0.1%)
Foot deformity	6 (0.4%)	10 (0.7%)	16 (0.6%)
Gouty arthritis	21 (1.5%)	13 (1.0%)	34 (1.2%)
Gouty tophus	2 (0.1%)	1 (<0.1%)	3 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Haemarthrosis	1 (<0.1%)	0	1 (<0.1%)
Inguinal mass	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc degeneration	12 (0.9%)	9 (0.7%)	21 (0.8%)
Intervertebral disc disorder	21 (1.5%)	13 (1.0%)	34 (1.2%)
Intervertebral disc displacement	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Intervertebral disc protrusion	36 (2.6%)	39 (2.9%)	75 (2.8%)
Intervertebral disc space narrowing	1 (<0.1%)	0	1 (<0.1%)
Joint contracture	0	1 (<0.1%)	1 (<0.1%)
Joint effusion	0	1 (<0.1%)	1 (<0.1%)
Joint range of motion decreased	0	2 (0.1%)	2 (<0.1%)
Joint stiffness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint swelling	2 (0.1%)	2 (0.1%)	4 (0.1%)
Knee deformity	1 (<0.1%)	0	1 (<0.1%)
Kyphosis	1 (<0.1%)	0	1 (<0.1%)
Limb asymmetry	0	2 (0.1%)	2 (<0.1%)
Limb discomfort	0	1 (<0.1%)	1 (<0.1%)
Lumbar spinal stenosis	11 (0.8%)	14 (1.0%)	25 (0.9%)
Meniscal degeneration	0	1 (<0.1%)	1 (<0.1%)
Metatarsalgia	0	1 (<0.1%)	1 (<0.1%)
Muscle atrophy	1 (<0.1%)	0	1 (<0.1%)
Muscle spasms	39 (2.9%)	32 (2.3%)	71 (2.6%)
Muscular weakness	2 (0.1%)	5 (0.4%)	7 (0.3%)
Musculoskeletal chest pain	2 (0.1%)	0	2 (<0.1%)
Musculoskeletal pain	0	4 (0.3%)	4 (0.1%)
Musculoskeletal stiffness	0	1 (<0.1%)	1 (<0.1%)
Myalgia	22 (1.6%)	23 (1.7%)	45 (1.7%)
Myofascial pain syndrome	3 (0.2%)	0	3 (0.1%)
Myopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myositis	1 (<0.1%)	0	1 (<0.1%)
Neck mass	1 (<0.1%)	0	1 (<0.1%)
Neck pain	12 (0.9%)	12 (0.9%)	24 (0.9%)
Neuropathic arthropathy	5 (0.4%)	4 (0.3%)	9 (0.3%)
Oligoarthritis	1 (<0.1%)	0	1 (<0.1%)
Osteitis	0	2 (0.1%)	2 (<0.1%)
Osteitis deformans	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Osteoarthritis	247 (18.2%)	216 (15.9%)	463 (17.0%)
Osteoarthropathy	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Osteochondrosis	17 (1.3%)	22 (1.6%)	39 (1.4%)
Osteonecrosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Osteopenia	22 (1.6%)	8 (0.6%)	30 (1.1%)
Osteoporosis	56 (4.1%)	59 (4.3%)	115 (4.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Osteoporosis postmenopausal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteoporotic fracture	1 (<0.1%)	0	1 (<0.1%)
Osteosclerosis	2 (0.1%)	0	2 (<0.1%)
Pain in extremity	21 (1.5%)	29 (2.1%)	50 (1.8%)
Patellofemoral pain syndrome	1 (<0.1%)	0	1 (<0.1%)
Pathological fracture	1 (<0.1%)	0	1 (<0.1%)
Periarthritis	14 (1.0%)	7 (0.5%)	21 (0.8%)
Plantar fascial fibromatosis	0	1 (<0.1%)	1 (<0.1%)
Plantar fasciitis	3 (0.2%)	7 (0.5%)	10 (0.4%)
Plica syndrome	1 (<0.1%)	0	1 (<0.1%)
Polyarthritis	3 (0.2%)	4 (0.3%)	7 (0.3%)
Polymyalgia rheumatica	6 (0.4%)	4 (0.3%)	10 (0.4%)
Pseudarthrosis	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	3 (0.2%)	2 (0.1%)	5 (0.2%)
Rhabdomyolysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rheumatic disorder	4 (0.3%)	3 (0.2%)	7 (0.3%)
Rheumatoid arthritis	11 (0.8%)	11 (0.8%)	22 (0.8%)
Rotator cuff syndrome	20 (1.5%)	14 (1.0%)	34 (1.2%)
Sacroiliitis	2 (0.1%)	0	2 (<0.1%)
Scleroderma	1 (<0.1%)	0	1 (<0.1%)
Scoliosis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Senile osteoporosis	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Seronegative arthritis	0	1 (<0.1%)	1 (<0.1%)
Sjogren's syndrome	1 (<0.1%)	0	1 (<0.1%)
Soft tissue disorder	1 (<0.1%)	0	1 (<0.1%)
Soft tissue mass	0	1 (<0.1%)	1 (<0.1%)
Spinal deformity	1 (<0.1%)	0	1 (<0.1%)
Spinal disorder	3 (0.2%)	2 (0.1%)	5 (0.2%)
Spinal ligament ossification	0	1 (<0.1%)	1 (<0.1%)
Spinal osteoarthritis	67 (4.9%)	53 (3.9%)	120 (4.4%)
Spinal pain	8 (0.6%)	11 (0.8%)	19 (0.7%)
Spinal stenosis	22 (1.6%)	22 (1.6%)	44 (1.6%)
Spondylitis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Spondyloarthropathy	0	1 (<0.1%)	1 (<0.1%)
Spondylolisthesis	6 (0.4%)	5 (0.4%)	11 (0.4%)
Synovial cyst	2 (0.1%)	2 (0.1%)	4 (0.1%)
Synovitis	1 (<0.1%)	0	1 (<0.1%)
Systemic lupus erythematosus	0	2 (0.1%)	2 (<0.1%)
Temporomandibular joint syndrome	0	2 (0.1%)	2 (<0.1%)
Tendon calcification	0	1 (<0.1%)	1 (<0.1%)
Tendon disorder	1 (<0.1%)	3 (0.2%)	4 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Tendon pain	1 (<0.1%)	0	1 (<0.1%)
Tendonitis	3 (0.2%)	4 (0.3%)	7 (0.3%)
Tenosynovitis	5 (0.4%)	1 (<0.1%)	6 (0.2%)
Tenosynovitis stenosans	0	2 (0.1%)	2 (<0.1%)
Torticollis	1 (<0.1%)	0	1 (<0.1%)
Trigger finger	11 (0.8%)	7 (0.5%)	18 (0.7%)
Vertebral foraminal stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral osteophyte	4 (0.3%)	0	4 (0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	209 (15.4%)	212 (15.6%)	421 (15.5%)
Acoustic neuroma	1 (<0.1%)	0	1 (<0.1%)
Acrochordon	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Acute myeloid leukaemia	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma gastric	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma of colon	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Adenoma benign	2 (0.1%)	2 (0.1%)	4 (0.1%)
Adrenal adenoma	7 (0.5%)	3 (0.2%)	10 (0.4%)
Adrenal neoplasm	6 (0.4%)	0	6 (0.2%)
Angiomyolipoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anogenital warts	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
B-cell lymphoma	1 (<0.1%)	0	1 (<0.1%)
Basal cell carcinoma	16 (1.2%)	20 (1.5%)	36 (1.3%)
Benign breast neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign gastrointestinal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign hepatic neoplasm	2 (0.1%)	0	2 (<0.1%)
Benign laryngeal neoplasm	0	2 (0.1%)	2 (<0.1%)
Benign lung neoplasm	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Benign mediastinal neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm	2 (0.1%)	0	2 (<0.1%)
Benign neoplasm of adrenal gland	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of orbit	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of prostate	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Benign neoplasm of skin	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of thyroid gland	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Benign nipple neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign penile neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign salivary gland neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign soft tissue neoplasm	0	1 (<0.1%)	1 (<0.1%)
Bladder cancer	10 (0.7%)	10 (0.7%)	20 (0.7%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Bladder cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Bladder neoplasm	0	3 (0.2%)	3 (0.1%)
Bladder papilloma	0	1 (<0.1%)	1 (<0.1%)
Bladder transitional cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Blepharal papilloma	0	1 (<0.1%)	1 (<0.1%)
Bowen's disease	1 (<0.1%)	0	1 (<0.1%)
Breast cancer	11 (0.8%)	10 (0.7%)	21 (0.8%)
Breast cancer in situ	0	1 (<0.1%)	1 (<0.1%)
Breast fibroma	0	1 (<0.1%)	1 (<0.1%)
Bronchioloalveolar carcinoma	1 (<0.1%)	0	1 (<0.1%)
Carcinoma in situ	0	1 (<0.1%)	1 (<0.1%)
Cervix carcinoma	3 (0.2%)	0	3 (0.1%)
Cholesteatoma	1 (<0.1%)	0	1 (<0.1%)
Chronic lymphocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)
Chronic myeloid leukaemia	0	1 (<0.1%)	1 (<0.1%)
Colon adenoma	10 (0.7%)	2 (0.1%)	12 (0.4%)
Colon cancer	7 (0.5%)	12 (0.9%)	19 (0.7%)
Colon cancer stage 0	0	2 (0.1%)	2 (<0.1%)
Colon neoplasm	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dermatofibrosarcoma protuberans	0	1 (<0.1%)	1 (<0.1%)
Dysplastic naevus	0	1 (<0.1%)	1 (<0.1%)
Ear neoplasm	0	1 (<0.1%)	1 (<0.1%)
Enchondromatosis	2 (0.1%)	0	2 (<0.1%)
Endometrial cancer	1 (<0.1%)	0	1 (<0.1%)
Extranodal marginal zone B-cell lymphoma (MALT type)	0	1 (<0.1%)	1 (<0.1%)
Eye naevus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibroadenoma of breast	1 (<0.1%)	0	1 (<0.1%)
Fibromatosis	1 (<0.1%)	0	1 (<0.1%)
Fibrous histiocytoma	1 (<0.1%)	0	1 (<0.1%)
Gallbladder cancer	0	2 (0.1%)	2 (<0.1%)
Gastric cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal stromal tumour	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal tract adenoma	0	1 (<0.1%)	1 (<0.1%)
Germ cell neoplasm	1 (<0.1%)	0	1 (<0.1%)
Glomus tumour	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	2 (0.1%)	0	2 (<0.1%)
Haemangioma of bone	0	1 (<0.1%)	1 (<0.1%)
Haemangioma of liver	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Haemangioma of skin	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hair follicle tumour benign	1 (<0.1%)	0	1 (<0.1%)
Hepatic neoplasm	0	2 (0.1%)	2 (<0.1%)
Hodgkin's disease	0	1 (<0.1%)	1 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	1 (<0.1%)	0	1 (<0.1%)
Intraductal papillary mucinous neoplasm	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Invasive ductal breast carcinoma	1 (<0.1%)	0	1 (<0.1%)
Large intestine benign neoplasm	2 (0.1%)	0	2 (<0.1%)
Laryngeal cancer	0	1 (<0.1%)	1 (<0.1%)
Leukaemia	0	1 (<0.1%)	1 (<0.1%)
Lip squamous cell carcinoma	1 (<0.1%)	0	1 (<0.1%)
Lipoma	5 (0.4%)	6 (0.4%)	11 (0.4%)
Lung adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Lung neoplasm malignant	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Lymphangioma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malignant melanoma	4 (0.3%)	4 (0.3%)	8 (0.3%)
Malignant melanoma in situ	1 (<0.1%)	0	1 (<0.1%)
Malignant urinary tract neoplasm	1 (<0.1%)	0	1 (<0.1%)
Melanocytic naevus	3 (0.2%)	2 (0.1%)	5 (0.2%)
Meningioma	4 (0.3%)	3 (0.2%)	7 (0.3%)
Meningioma benign	1 (<0.1%)	0	1 (<0.1%)
Metastases to liver	0	3 (0.2%)	3 (0.1%)
Metastases to lung	0	2 (0.1%)	2 (<0.1%)
Metastatic malignant melanoma	1 (<0.1%)	0	1 (<0.1%)
Monoclonal gammopathy	2 (0.1%)	3 (0.2%)	5 (0.2%)
Myelodysplastic syndrome	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Myeloid leukaemia	1 (<0.1%)	0	1 (<0.1%)
Neoplasm	1 (<0.1%)	0	1 (<0.1%)
Neoplasm prostate	2 (0.1%)	0	2 (<0.1%)
Neoplasm skin	1 (<0.1%)	0	1 (<0.1%)
Ocular lymphoma	1 (<0.1%)	0	1 (<0.1%)
Oesophageal papilloma	1 (<0.1%)	0	1 (<0.1%)
Oral haemangioma	1 (<0.1%)	0	1 (<0.1%)
Ovarian adenoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	0	2 (0.1%)	2 (<0.1%)
Ovarian epithelial cancer	1 (<0.1%)	0	1 (<0.1%)
Ovarian neoplasm	1 (<0.1%)	0	1 (<0.1%)
Pancreatic neoplasm	2 (0.1%)	0	2 (<0.1%)
Paraproteinaemia	0	1 (<0.1%)	1 (<0.1%)
Parathyroid tumour benign	3 (0.2%)	2 (0.1%)	5 (0.2%)
Pituitary tumour benign	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Plasma cell myeloma	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Plasma cell myeloma in remission	0	1 (<0.1%)	1 (<0.1%)
Pleomorphic adenoma	0	1 (<0.1%)	1 (<0.1%)
Polycythaemia vera	0	1 (<0.1%)	1 (<0.1%)
Prostate cancer	27 (2.0%)	35 (2.6%)	62 (2.3%)
Prostate cancer recurrent	1 (<0.1%)	0	1 (<0.1%)
Prostatic adenoma	6 (0.4%)	4 (0.3%)	10 (0.4%)
Rectal cancer	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Rectosigmoid cancer	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	4 (0.3%)	3 (0.2%)	7 (0.3%)
Renal cell carcinoma	3 (0.2%)	5 (0.4%)	8 (0.3%)
Renal hamartoma	0	3 (0.2%)	3 (0.1%)
Renal neoplasm	0	3 (0.2%)	3 (0.1%)
Renal oncocytoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland adenoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland neoplasm	1 (<0.1%)	0	1 (<0.1%)
Seborrhoeic keratosis	9 (0.7%)	12 (0.9%)	21 (0.8%)
Seminoma	0	1 (<0.1%)	1 (<0.1%)
Skin cancer	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Skin papilloma	3 (0.2%)	3 (0.2%)	6 (0.2%)
Small intestine carcinoma	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma	2 (0.1%)	5 (0.4%)	7 (0.3%)
Squamous cell carcinoma of pharynx	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma of skin	2 (0.1%)	3 (0.2%)	5 (0.2%)
Superficial spreading melanoma stage unspecified	0	1 (<0.1%)	1 (<0.1%)
Testis cancer	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Throat cancer	0	1 (<0.1%)	1 (<0.1%)
Thyroid adenoma	1 (<0.1%)	0	1 (<0.1%)
Thyroid cancer	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Tongue neoplasm benign	1 (<0.1%)	0	1 (<0.1%)
Transitional cell cancer of the renal pelvis and ureter	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Transitional cell carcinoma urethra	1 (<0.1%)	0	1 (<0.1%)
Uterine cancer	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Uterine leiomyoma	13 (1.0%)	15 (1.1%)	28 (1.0%)
Nervous system disorders	735 (54.1%)	735 (54.0%)	1470 (54.0%)
Acoustic neuritis	0	2 (0.1%)	2 (<0.1%)
Allodynia	0	3 (0.2%)	3 (0.1%)
Amnesia	5 (0.4%)	7 (0.5%)	12 (0.4%)
Aphasia	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Arachnoid cyst	1 (<0.1%)	0	1 (<0.1%)
Arachnoiditis	1 (<0.1%)	0	1 (<0.1%)
Areflexia	3 (0.2%)	2 (0.1%)	5 (0.2%)
Ataxia	1 (<0.1%)	0	1 (<0.1%)
Autoimmune neuropathy	0	1 (<0.1%)	1 (<0.1%)
Autonomic nervous system imbalance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Autonomic neuropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Balance disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal ganglia infarction	1 (<0.1%)	0	1 (<0.1%)
Basilar artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Basilar artery stenosis	0	1 (<0.1%)	1 (<0.1%)
Brain stem infarction	0	1 (<0.1%)	1 (<0.1%)
Carotid arteriosclerosis	31 (2.3%)	26 (1.9%)	57 (2.1%)
Carotid artery aneurysm	2 (0.1%)	0	2 (<0.1%)
Carotid artery disease	4 (0.3%)	7 (0.5%)	11 (0.4%)
Carotid artery occlusion	4 (0.3%)	5 (0.4%)	9 (0.3%)
Carotid artery stenosis	40 (2.9%)	30 (2.2%)	70 (2.6%)
Carpal tunnel syndrome	33 (2.4%)	23 (1.7%)	56 (2.1%)
Central nervous system lesion	0	1 (<0.1%)	1 (<0.1%)
Cerebellar ataxia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar atrophy	0	1 (<0.1%)	1 (<0.1%)
Cerebral arteriosclerosis	6 (0.4%)	12 (0.9%)	18 (0.7%)
Cerebral artery embolism	1 (<0.1%)	0	1 (<0.1%)
Cerebral artery occlusion	0	3 (0.2%)	3 (0.1%)
Cerebral artery stenosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Cerebral atrophy	5 (0.4%)	5 (0.4%)	10 (0.4%)
Cerebral haemorrhage	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Cerebral infarction	14 (1.0%)	5 (0.4%)	19 (0.7%)
Cerebral ischaemia	11 (0.8%)	6 (0.4%)	17 (0.6%)
Cerebral microangiopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cerebral small vessel ischaemic disease	2 (0.1%)	0	2 (<0.1%)
Cerebrovascular accident	19 (1.4%)	10 (0.7%)	29 (1.1%)
Cerebrovascular disorder	18 (1.3%)	19 (1.4%)	37 (1.4%)
Cerebrovascular stenosis	1 (<0.1%)	0	1 (<0.1%)
Cervical radiculopathy	4 (0.3%)	3 (0.2%)	7 (0.3%)
Cervicobrachial syndrome	5 (0.4%)	3 (0.2%)	8 (0.3%)
Circadian rhythm sleep disorder	0	1 (<0.1%)	1 (<0.1%)
Clonus	1 (<0.1%)	0	1 (<0.1%)
Cluster headache	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cognitive disorder	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Cogwheel rigidity	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Decreased vibratory sense	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Dementia	4 (0.3%)	4 (0.3%)	8 (0.3%)
Dementia Alzheimer's type	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Diabetic autonomic neuropathy	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Diabetic coma	0	1 (<0.1%)	1 (<0.1%)
Diabetic encephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic neuropathy	326 (24.0%)	318 (23.3%)	644 (23.7%)
Diplegia	0	1 (<0.1%)	1 (<0.1%)
Dizziness	30 (2.2%)	23 (1.7%)	53 (1.9%)
Dizziness postural	0	4 (0.3%)	4 (0.1%)
Dysaesthesia	0	1 (<0.1%)	1 (<0.1%)
Dysarthria	3 (0.2%)	0	3 (0.1%)
Dyslalia	0	1 (<0.1%)	1 (<0.1%)
Dysmetria	1 (<0.1%)	0	1 (<0.1%)
Embolic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Encephalopathy	14 (1.0%)	11 (0.8%)	25 (0.9%)
Epilepsy	4 (0.3%)	3 (0.2%)	7 (0.3%)
Essential tremor	6 (0.4%)	10 (0.7%)	16 (0.6%)
Facial nerve disorder	2 (0.1%)	0	2 (<0.1%)
Facial paralysis	5 (0.4%)	9 (0.7%)	14 (0.5%)
Facial paresis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fine motor skill dysfunction	1 (<0.1%)	0	1 (<0.1%)
Guillain-Barre syndrome	0	2 (0.1%)	2 (<0.1%)
Haemorrhage intracranial	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic stroke	2 (0.1%)	2 (0.1%)	4 (0.1%)
Headache	32 (2.4%)	26 (1.9%)	58 (2.1%)
Hemianaesthesia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	0	2 (0.1%)	2 (<0.1%)
Hemiparesis	8 (0.6%)	9 (0.7%)	17 (0.6%)
Hemiplegia	2 (0.1%)	2 (0.1%)	4 (0.1%)
Horner's syndrome	1 (<0.1%)	0	1 (<0.1%)
Hydrocephalus	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Hyperaesthesia	0	1 (<0.1%)	1 (<0.1%)
Hyperreflexia	0	1 (<0.1%)	1 (<0.1%)
Hypersomnia	0	1 (<0.1%)	1 (<0.1%)
Hypertensive encephalopathy	2 (0.1%)	3 (0.2%)	5 (0.2%)
Hypertonia	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Hypoaesthesia	16 (1.2%)	9 (0.7%)	25 (0.9%)
Hyporeflexia	0	1 (<0.1%)	1 (<0.1%)
Hyposmia	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hypoxic-ischaemic encephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
IIIrd nerve paralysis	0	1 (<0.1%)	1 (<0.1%)
IIIrd nerve paresis	1 (<0.1%)	0	1 (<0.1%)
Intellectual disability	0	1 (<0.1%)	1 (<0.1%)
Intention tremor	0	1 (<0.1%)	1 (<0.1%)
Internal capsule infarction	0	1 (<0.1%)	1 (<0.1%)
Intracranial aneurysm	2 (0.1%)	0	2 (<0.1%)
Intraventricular haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Ischaemic cerebral infarction	1 (<0.1%)	0	1 (<0.1%)
Ischaemic stroke	230 (16.9%)	212 (15.6%)	442 (16.2%)
Lacunar infarction	9 (0.7%)	1 (<0.1%)	10 (0.4%)
Loss of consciousness	0	1 (<0.1%)	1 (<0.1%)
Lumbar radiculopathy	4 (0.3%)	3 (0.2%)	7 (0.3%)
Lumbosacral plexopathy	1 (<0.1%)	0	1 (<0.1%)
Lumbosacral plexus lesion	0	2 (0.1%)	2 (<0.1%)
Lumbosacral radiculopathy	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Memory impairment	6 (0.4%)	5 (0.4%)	11 (0.4%)
Meralgia paraesthetica	0	1 (<0.1%)	1 (<0.1%)
Metabolic encephalopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Migraine	4 (0.3%)	11 (0.8%)	15 (0.6%)
Migraine with aura	0	1 (<0.1%)	1 (<0.1%)
Migraine without aura	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Monoplegia	0	1 (<0.1%)	1 (<0.1%)
Morton's neuralgia	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Multiple sclerosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Muscle contractions involuntary	2 (0.1%)	0	2 (<0.1%)
Muscle spasticity	0	1 (<0.1%)	1 (<0.1%)
Muscle tone disorder	1 (<0.1%)	0	1 (<0.1%)
Myasthenia gravis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myelomalacia	1 (<0.1%)	0	1 (<0.1%)
Myelopathy	5 (0.4%)	2 (0.1%)	7 (0.3%)
Myoclonus	0	1 (<0.1%)	1 (<0.1%)
Nerve compression	2 (0.1%)	3 (0.2%)	5 (0.2%)
Nervous system disorder	1 (<0.1%)	0	1 (<0.1%)
Neuralgia	10 (0.7%)	5 (0.4%)	15 (0.6%)
Neuralgic amyotrophy	1 (<0.1%)	0	1 (<0.1%)
Neuritis	1 (<0.1%)	0	1 (<0.1%)
Neuritis cranial	1 (<0.1%)	0	1 (<0.1%)
Neurological symptom	1 (<0.1%)	0	1 (<0.1%)
Neuropathy peripheral	70 (5.2%)	70 (5.1%)	140 (5.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Occipital neuralgia	0	1 (<0.1%)	1 (<0.1%)
Optic neuritis	2 (0.1%)	0	2 (<0.1%)
Orthostatic intolerance	0	1 (<0.1%)	1 (<0.1%)
Paraesthesia	12 (0.9%)	8 (0.6%)	20 (0.7%)
Paralysis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	3 (0.2%)	10 (0.7%)	13 (0.5%)
Parkinsonian rest tremor	0	1 (<0.1%)	1 (<0.1%)
Parkinsonism	0	2 (0.1%)	2 (<0.1%)
Partial seizures	0	1 (<0.1%)	1 (<0.1%)
Perineurial cyst	1 (<0.1%)	0	1 (<0.1%)
Periodic limb movement disorder	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve lesion	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve paresis	0	1 (<0.1%)	1 (<0.1%)
Peripheral sensorimotor neuropathy	4 (0.3%)	0	4 (0.1%)
Peripheral sensory neuropathy	3 (0.2%)	3 (0.2%)	6 (0.2%)
Peroneal nerve palsy	1 (<0.1%)	0	1 (<0.1%)
Phantom limb syndrome	2 (0.1%)	2 (0.1%)	4 (0.1%)
Piriformis syndrome	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	24 (1.8%)	33 (2.4%)	57 (2.1%)
Poor quality sleep	0	1 (<0.1%)	1 (<0.1%)
Post herpetic neuralgia	4 (0.3%)	3 (0.2%)	7 (0.3%)
Post polio syndrome	1 (<0.1%)	0	1 (<0.1%)
Post stroke epilepsy	1 (<0.1%)	0	1 (<0.1%)
Precerebral arteriosclerosis	1 (<0.1%)	0	1 (<0.1%)
Precerebral artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Presyncope	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Quadriplegia	1 (<0.1%)	0	1 (<0.1%)
Radial nerve palsy	1 (<0.1%)	0	1 (<0.1%)
Radicular pain	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Radiculopathy	3 (0.2%)	3 (0.2%)	6 (0.2%)
Resting tremor	0	1 (<0.1%)	1 (<0.1%)
Restless legs syndrome	11 (0.8%)	8 (0.6%)	19 (0.7%)
Sciatica	24 (1.8%)	21 (1.5%)	45 (1.7%)
Seizure	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Sensory disturbance	0	1 (<0.1%)	1 (<0.1%)
Somnolence	1 (<0.1%)	0	1 (<0.1%)
Spinal claudication	0	1 (<0.1%)	1 (<0.1%)
Spinal cord compression	1 (<0.1%)	0	1 (<0.1%)
Spondylitic myelopathy	0	2 (0.1%)	2 (<0.1%)
Stupor	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	3 (0.2%)	2 (0.1%)	5 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Syncope	12 (0.9%)	11 (0.8%)	23 (0.8%)
Tardive dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Tension headache	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Thalamic infarction	1 (<0.1%)	0	1 (<0.1%)
Thoracic outlet syndrome	1 (<0.1%)	0	1 (<0.1%)
Transient ischaemic attack	30 (2.2%)	31 (2.3%)	61 (2.2%)
Tremor	6 (0.4%)	7 (0.5%)	13 (0.5%)
Trigeminal neuralgia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper motor neurone lesion	1 (<0.1%)	0	1 (<0.1%)
VIth nerve paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular encephalopathy	10 (0.7%)	10 (0.7%)	20 (0.7%)
Vascular headache	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Vertebral artery stenosis	1 (<0.1%)	5 (0.4%)	6 (0.2%)
Vertebrobasilar dolichoectasia	0	1 (<0.1%)	1 (<0.1%)
Vertebrobasilar insufficiency	3 (0.2%)	2 (0.1%)	5 (0.2%)
Visual field defect	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Vocal cord paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord paresis	1 (<0.1%)	0	1 (<0.1%)
Pregnancy, puerperium and perinatal conditions	3 (0.2%)	5 (0.4%)	8 (0.3%)
Cephalo-pelvic disproportion	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Gestational diabetes	0	1 (<0.1%)	1 (<0.1%)
Pre-eclampsia	1 (<0.1%)	0	1 (<0.1%)
Ruptured ectopic pregnancy	1 (<0.1%)	0	1 (<0.1%)
Product issues	0	2 (0.1%)	2 (<0.1%)
Device dislocation	0	2 (0.1%)	2 (<0.1%)
Psychiatric disorders	257 (18.9%)	248 (18.2%)	505 (18.6%)
Adjustment disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Adjustment disorder with depressed mood	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Affective disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Alcohol abuse	3 (0.2%)	2 (0.1%)	5 (0.2%)
Alcoholism	0	3 (0.2%)	3 (0.1%)
Antisocial personality disorder	0	1 (<0.1%)	1 (<0.1%)
Anxiety	48 (3.5%)	56 (4.1%)	104 (3.8%)
Anxiety disorder	7 (0.5%)	6 (0.4%)	13 (0.5%)
Behaviour disorder	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Bipolar disorder	4 (0.3%)	4 (0.3%)	8 (0.3%)
Breathing-related sleep disorder	1 (<0.1%)	0	1 (<0.1%)
Bruxism	0	1 (<0.1%)	1 (<0.1%)
Conversion disorder	1 (<0.1%)	0	1 (<0.1%)
Delirium	0	1 (<0.1%)	1 (<0.1%)
Depressed mood	2 (0.1%)	4 (0.3%)	6 (0.2%)
Depression	118 (8.7%)	98 (7.2%)	216 (7.9%)
Depressive symptom	0	1 (<0.1%)	1 (<0.1%)
Drug dependence	1 (<0.1%)	0	1 (<0.1%)
Epileptic psychosis	0	1 (<0.1%)	1 (<0.1%)
Factitious disorder	0	1 (<0.1%)	1 (<0.1%)
Genito-pelvic pain/penetration disorder	1 (<0.1%)	0	1 (<0.1%)
Hallucination	0	1 (<0.1%)	1 (<0.1%)
Illness anxiety disorder	1 (<0.1%)	0	1 (<0.1%)
Initial insomnia	0	2 (0.1%)	2 (<0.1%)
Insomnia	85 (6.3%)	85 (6.2%)	170 (6.2%)
Major depression	7 (0.5%)	5 (0.4%)	12 (0.4%)
Mental disorder	0	1 (<0.1%)	1 (<0.1%)
Mixed anxiety and depressive disorder	3 (0.2%)	2 (0.1%)	5 (0.2%)
Mood disorder due to a general medical condition	0	2 (0.1%)	2 (<0.1%)
Neurosis	3 (0.2%)	0	3 (0.1%)
Nicotine dependence	0	1 (<0.1%)	1 (<0.1%)
Panic disorder	1 (<0.1%)	0	1 (<0.1%)
Persistent depressive disorder	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic stress disorder	9 (0.7%)	5 (0.4%)	14 (0.5%)
Pseudodementia	0	1 (<0.1%)	1 (<0.1%)
Schizophrenia	2 (0.1%)	0	2 (<0.1%)
Sleep disorder	13 (1.0%)	16 (1.2%)	29 (1.1%)
Somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Stress	2 (0.1%)	2 (0.1%)	4 (0.1%)
Substance abuse	1 (<0.1%)	0	1 (<0.1%)
Tic	1 (<0.1%)	0	1 (<0.1%)
Tobacco abuse	3 (0.2%)	3 (0.2%)	6 (0.2%)
Renal and urinary disorders	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Acquired cystic kidney disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acute kidney injury	18 (1.3%)	15 (1.1%)	33 (1.2%)
Albuminuria	73 (5.4%)	65 (4.8%)	138 (5.1%)
Azotaemia	0	2 (0.1%)	2 (<0.1%)
Bladder dysfunction	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Bladder mass	1 (<0.1%)	0	1 (<0.1%)
Bladder outlet obstruction	0	1 (<0.1%)	1 (<0.1%)
Bladder prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
C3 glomerulopathy	0	1 (<0.1%)	1 (<0.1%)
Calculus bladder	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Calculus urethral	0	1 (<0.1%)	1 (<0.1%)
Calculus urinary	18 (1.3%)	10 (0.7%)	28 (1.0%)
Chronic kidney disease	1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Crystalluria	0	1 (<0.1%)	1 (<0.1%)
Cystitis interstitial	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Detrusor sphincter dyssynergia	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	104 (7.7%)	112 (8.2%)	216 (7.9%)
Dysuria	6 (0.4%)	6 (0.4%)	12 (0.4%)
Focal segmental glomerulosclerosis	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	1 (<0.1%)	0	1 (<0.1%)
Glomerulonephritis chronic	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Glomerulonephritis membranoproliferative	1 (<0.1%)	0	1 (<0.1%)
Glomerulonephritis membranous	1 (<0.1%)	0	1 (<0.1%)
Glomerulosclerosis	0	1 (<0.1%)	1 (<0.1%)
Haematuria	18 (1.3%)	16 (1.2%)	34 (1.2%)
Hydronephrosis	10 (0.7%)	5 (0.4%)	15 (0.6%)
Hypertensive nephropathy	10 (0.7%)	8 (0.6%)	18 (0.7%)
Hypertonic bladder	7 (0.5%)	7 (0.5%)	14 (0.5%)
Hyperuricosuria	1 (<0.1%)	0	1 (<0.1%)
Hypocitraturia	0	1 (<0.1%)	1 (<0.1%)
IgA nephropathy	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Incontinence	5 (0.4%)	2 (0.1%)	7 (0.3%)
Intercapillary glomerulosclerosis	2 (0.1%)	0	2 (<0.1%)
Kidney small	1 (<0.1%)	0	1 (<0.1%)
Leukocyturia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lower urinary tract symptoms	4 (0.3%)	2 (0.1%)	6 (0.2%)
Microalbuminuria	50 (3.7%)	52 (3.8%)	102 (3.7%)
Micturition disorder	0	1 (<0.1%)	1 (<0.1%)
Micturition urgency	2 (0.1%)	3 (0.2%)	5 (0.2%)
Nephritis	3 (0.2%)	2 (0.1%)	5 (0.2%)
Nephroangiosclerosis	5 (0.4%)	0	5 (0.2%)
Nephrocalcinosis	3 (0.2%)	0	3 (0.1%)
Nephrolithiasis	101 (7.4%)	101 (7.4%)	202 (7.4%)
Nephropathy	8 (0.6%)	6 (0.4%)	14 (0.5%)
Nephroptosis	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Nephrosclerosis	3 (0.2%)	3 (0.2%)	6 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Nephrotic syndrome	0	2 (0.1%)	2 (<0.1%)
Neurogenic bladder	4 (0.3%)	5 (0.4%)	9 (0.3%)
Nocturia	15 (1.1%)	16 (1.2%)	31 (1.1%)
Oedematous kidney	2 (0.1%)	0	2 (<0.1%)
Pollakiuria	2 (0.1%)	6 (0.4%)	8 (0.3%)
Polyuria	0	3 (0.2%)	3 (0.1%)
Proteinuria	50 (3.7%)	63 (4.6%)	113 (4.2%)
Reduced bladder capacity	1 (<0.1%)	0	1 (<0.1%)
Renal artery arteriosclerosis	0	1 (<0.1%)	1 (<0.1%)
Renal artery fibromuscular dysplasia	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	4 (0.3%)	5 (0.4%)	9 (0.3%)
Renal atrophy	8 (0.6%)	4 (0.3%)	12 (0.4%)
Renal colic	13 (1.0%)	4 (0.3%)	17 (0.6%)
Renal cyst	91 (6.7%)	83 (6.1%)	174 (6.4%)
Renal disorder	3 (0.2%)	2 (0.1%)	5 (0.2%)
Renal failure	8 (0.6%)	9 (0.7%)	17 (0.6%)
Renal hypertension	0	1 (<0.1%)	1 (<0.1%)
Renal impairment	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Renal mass	3 (0.2%)	2 (0.1%)	5 (0.2%)
Renal tubular acidosis	1 (<0.1%)	0	1 (<0.1%)
Renal tubular necrosis	2 (0.1%)	0	2 (<0.1%)
Renal vessel disorder	1 (<0.1%)	0	1 (<0.1%)
Single functional kidney	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Stag horn calculus	0	1 (<0.1%)	1 (<0.1%)
Stress urinary incontinence	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Subcapsular renal haematoma	1 (<0.1%)	0	1 (<0.1%)
Trigonitis	0	1 (<0.1%)	1 (<0.1%)
Tubulointerstitial nephritis	1 (<0.1%)	0	1 (<0.1%)
Urate nephropathy	0	1 (<0.1%)	1 (<0.1%)
Ureteric stenosis	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	7 (0.5%)	5 (0.4%)	12 (0.4%)
Urethral stenosis	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Urge incontinence	1 (<0.1%)	0	1 (<0.1%)
Urinary hesitation	2 (0.1%)	0	2 (<0.1%)
Urinary incontinence	24 (1.8%)	23 (1.7%)	47 (1.7%)
Urinary retention	1 (<0.1%)	6 (0.4%)	7 (0.3%)
Urinary tract disorder	0	1 (<0.1%)	1 (<0.1%)
Urinary tract obstruction	0	1 (<0.1%)	1 (<0.1%)
Urine abnormality	2 (0.1%)	0	2 (<0.1%)
Urine flow decreased	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Urine odour abnormal	1 (<0.1%)	0	1 (<0.1%)
Reproductive system and breast disorders	318 (23.4%)	320 (23.5%)	638 (23.4%)
Artificial menopause	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrophic vulvovaginitis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Balanoposthitis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Bartholin's cyst	0	1 (<0.1%)	1 (<0.1%)
Benign prostatic hyperplasia	202 (14.9%)	209 (15.3%)	411 (15.1%)
Breast calcifications	1 (<0.1%)	0	1 (<0.1%)
Breast cyst	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Breast fibrosis	0	1 (<0.1%)	1 (<0.1%)
Breast haematoma	0	1 (<0.1%)	1 (<0.1%)
Breast mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Calculus prostatic	1 (<0.1%)	0	1 (<0.1%)
Cervical polyp	1 (<0.1%)	0	1 (<0.1%)
Cystocele	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Dysfunctional uterine bleeding	1 (<0.1%)	0	1 (<0.1%)
Dysmenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Endocervicosis	0	1 (<0.1%)	1 (<0.1%)
Endometrial hyperplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Endometriosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Epididymal cyst	0	1 (<0.1%)	1 (<0.1%)
Erectile dysfunction	69 (5.1%)	72 (5.3%)	141 (5.2%)
Female genital tract fistula	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Fibrocystic breast disease	0	2 (0.1%)	2 (<0.1%)
Genital prolapse	1 (<0.1%)	0	1 (<0.1%)
Gynaecomastia	3 (0.2%)	3 (0.2%)	6 (0.2%)
Hydrometra	0	1 (<0.1%)	1 (<0.1%)
Hydrosalpinx	1 (<0.1%)	0	1 (<0.1%)
Infertility	0	2 (0.1%)	2 (<0.1%)
Menopausal disorder	1 (<0.1%)	0	1 (<0.1%)
Menopausal symptoms	1 (<0.1%)	0	1 (<0.1%)
Menorrhagia	2 (0.1%)	0	2 (<0.1%)
Organic erectile dysfunction	5 (0.4%)	2 (0.1%)	7 (0.3%)
Ovarian cyst	3 (0.2%)	2 (0.1%)	5 (0.2%)
Ovarian mass	0	1 (<0.1%)	1 (<0.1%)
Pelvic cyst	1 (<0.1%)	0	1 (<0.1%)
Pelvic prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penile rash	0	1 (<0.1%)	1 (<0.1%)
Peyronie's disease	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Polycystic ovaries	0	2 (0.1%)	2 (<0.1%)
Postmenopausal haemorrhage	2 (0.1%)	0	2 (<0.1%)
Prostatic calcification	2 (0.1%)	0	2 (<0.1%)
Prostatic disorder	5 (0.4%)	2 (0.1%)	7 (0.3%)
Prostatic dysplasia	1 (<0.1%)	0	1 (<0.1%)
Prostatism	7 (0.5%)	5 (0.4%)	12 (0.4%)
Prostatitis	10 (0.7%)	15 (1.1%)	25 (0.9%)
Prostatomegaly	16 (1.2%)	16 (1.2%)	32 (1.2%)
Pruritus genital	1 (<0.1%)	0	1 (<0.1%)
Sexual dysfunction	4 (0.3%)	0	4 (0.1%)
Uterine fibrosis	1 (<0.1%)	0	1 (<0.1%)
Uterine polyp	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Uterine prolapse	2 (0.1%)	0	2 (<0.1%)
Vaginal prolapse	2 (0.1%)	4 (0.3%)	6 (0.2%)
Varicocele	0	2 (0.1%)	2 (<0.1%)
Vulval disorder	0	1 (<0.1%)	1 (<0.1%)
Vulvar squamous cell hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal dryness	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal pruritus	2 (0.1%)	0	2 (<0.1%)
Respiratory, thoracic and mediastinal disorders	382 (28.1%)	363 (26.7%)	745 (27.4%)
Acquired diaphragmatic eventration	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	3 (0.2%)	3 (0.2%)	6 (0.2%)
Acute respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Allergic cough	0	1 (<0.1%)	1 (<0.1%)
Allergic sinusitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Asthma	71 (5.2%)	58 (4.3%)	129 (4.7%)
Asthma late onset	1 (<0.1%)	0	1 (<0.1%)
Asthma-chronic obstructive pulmonary disease overlap syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atelectasis	1 (<0.1%)	0	1 (<0.1%)
Atopic cough	0	1 (<0.1%)	1 (<0.1%)
Bronchial hyperreactivity	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Bronchiectasis	5 (0.4%)	3 (0.2%)	8 (0.3%)
Bronchitis chronic	16 (1.2%)	11 (0.8%)	27 (1.0%)
Bronchospasm	1 (<0.1%)	0	1 (<0.1%)
Chronic obstructive pulmonary disease	100 (7.4%)	98 (7.2%)	198 (7.3%)
Chronic respiratory failure	2 (0.1%)	0	2 (<0.1%)
Cough	14 (1.0%)	19 (1.4%)	33 (1.2%)
Diaphragmatic disorder	1 (<0.1%)	0	1 (<0.1%)
Dysphonia	3 (0.2%)	1 (<0.1%)	4 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Dyspnoea	19 (1.4%)	22 (1.6%)	41 (1.5%)
Dyspnoea exertional	14 (1.0%)	8 (0.6%)	22 (0.8%)
Emphysema	7 (0.5%)	7 (0.5%)	14 (0.5%)
Epistaxis	4 (0.3%)	6 (0.4%)	10 (0.4%)
Haemothorax	0	1 (<0.1%)	1 (<0.1%)
Hypercapnia	1 (<0.1%)	0	1 (<0.1%)
Hyperventilation	1 (<0.1%)	0	1 (<0.1%)
Hypoventilation	0	1 (<0.1%)	1 (<0.1%)
Increased upper airway secretion	0	1 (<0.1%)	1 (<0.1%)
Interstitial lung disease	3 (0.2%)	2 (0.1%)	5 (0.2%)
Laryngeal leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Lung infiltration	0	1 (<0.1%)	1 (<0.1%)
Nasal congestion	2 (0.1%)	0	2 (<0.1%)
Nasal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nasal polyps	3 (0.2%)	3 (0.2%)	6 (0.2%)
Nasal septum deviation	4 (0.3%)	5 (0.4%)	9 (0.3%)
Nocturnal dyspnoea	0	1 (<0.1%)	1 (<0.1%)
Obliterative bronchiolitis	1 (<0.1%)	0	1 (<0.1%)
Obstructive airways disorder	2 (0.1%)	0	2 (<0.1%)
Oropharyngeal pain	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Paranasal cyst	1 (<0.1%)	0	1 (<0.1%)
Paranasal sinus hypersecretion	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal polyp	0	1 (<0.1%)	1 (<0.1%)
Pickwickian syndrome	0	1 (<0.1%)	1 (<0.1%)
Pleural calcification	0	1 (<0.1%)	1 (<0.1%)
Pleural effusion	2 (0.1%)	4 (0.3%)	6 (0.2%)
Pleurisy	0	2 (0.1%)	2 (<0.1%)
Pneumothorax	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Productive cough	3 (0.2%)	2 (0.1%)	5 (0.2%)
Pulmonary arterial hypertension	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	11 (0.8%)	6 (0.4%)	17 (0.6%)
Pulmonary fibrosis	3 (0.2%)	5 (0.4%)	8 (0.3%)
Pulmonary granuloma	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Pulmonary hypertension	9 (0.7%)	10 (0.7%)	19 (0.7%)
Pulmonary mass	11 (0.8%)	6 (0.4%)	17 (0.6%)
Pulmonary oedema	2 (0.1%)	3 (0.2%)	5 (0.2%)
Pulmonary sarcoidosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary thrombosis	1 (<0.1%)	0	1 (<0.1%)
Rales	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory disorder	1 (<0.1%)	0	1 (<0.1%)
Respiratory failure	2 (0.1%)	2 (0.1%)	4 (0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Restrictive pulmonary disease	2 (0.1%)	0	2 (<0.1%)
Rhinitis allergic	30 (2.2%)	26 (1.9%)	56 (2.1%)
Rhinitis hypertrophic	1 (<0.1%)	0	1 (<0.1%)
Rhinitis perennial	0	1 (<0.1%)	1 (<0.1%)
Rhinorrhoea	4 (0.3%)	1 (<0.1%)	5 (0.2%)
Sinus congestion	1 (<0.1%)	0	1 (<0.1%)
Sinus disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus polyp	2 (0.1%)	0	2 (<0.1%)
Sleep apnoea syndrome	143 (10.5%)	139 (10.2%)	282 (10.4%)
Snoring	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Throat irritation	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper-airway cough syndrome	1 (<0.1%)	0	1 (<0.1%)
Vasomotor rhinitis	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Vocal cord cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord polyp	0	2 (0.1%)	2 (<0.1%)
Wheezing	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Skin and subcutaneous tissue disorders	225 (16.6%)	219 (16.1%)	444 (16.3%)
Acne	0	2 (0.1%)	2 (<0.1%)
Actinic cheilitis	1 (<0.1%)	0	1 (<0.1%)
Actinic keratosis	12 (0.9%)	7 (0.5%)	19 (0.7%)
Alopecia	3 (0.2%)	3 (0.2%)	6 (0.2%)
Alopecia areata	0	1 (<0.1%)	1 (<0.1%)
Alopecia scarring	0	1 (<0.1%)	1 (<0.1%)
Androgenetic alopecia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angioedema	2 (0.1%)	0	2 (<0.1%)
Asteatosis	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Blister	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood blister	0	1 (<0.1%)	1 (<0.1%)
Cutaneous lupus erythematosus	1 (<0.1%)	0	1 (<0.1%)
Decubitus ulcer	1 (<0.1%)	0	1 (<0.1%)
Dermal cyst	5 (0.4%)	3 (0.2%)	8 (0.3%)
Dermatitis	9 (0.7%)	12 (0.9%)	21 (0.8%)
Dermatitis allergic	0	3 (0.2%)	3 (0.1%)
Dermatitis atopic	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Dermatitis contact	5 (0.4%)	9 (0.7%)	14 (0.5%)
Dermatitis diaper	0	1 (<0.1%)	1 (<0.1%)
Diabetic cheiroarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic foot	26 (1.9%)	23 (1.7%)	49 (1.8%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Diabetic ulcer	0	1 (<0.1%)	1 (<0.1%)
Drug eruption	0	2 (0.1%)	2 (<0.1%)
Dry skin	19 (1.4%)	15 (1.1%)	34 (1.2%)
Dyshidrotic eczema	1 (<0.1%)	0	1 (<0.1%)
Eczema	27 (2.0%)	24 (1.8%)	51 (1.9%)
Eczema asteatotic	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Eczema nummular	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eosinophilic cellulitis	0	1 (<0.1%)	1 (<0.1%)
Erythema	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Erythematotelangiectatic rosacea	1 (<0.1%)	0	1 (<0.1%)
Granuloma annulare	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Hand dermatitis	1 (<0.1%)	0	1 (<0.1%)
Hirsutism	0	3 (0.2%)	3 (0.1%)
Hyperkeratosis	10 (0.7%)	11 (0.8%)	21 (0.8%)
Hypersensitivity vasculitis	1 (<0.1%)	0	1 (<0.1%)
Idiopathic urticaria	1 (<0.1%)	0	1 (<0.1%)
Ingrowing nail	6 (0.4%)	1 (<0.1%)	7 (0.3%)
Intertrigo	1 (<0.1%)	0	1 (<0.1%)
Leukoderma	1 (<0.1%)	0	1 (<0.1%)
Lichen planus	1 (<0.1%)	0	1 (<0.1%)
Lichen sclerosus	1 (<0.1%)	0	1 (<0.1%)
Lipodystrophy acquired	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Lipohypertrophy	2 (0.1%)	0	2 (<0.1%)
Miliaria	0	1 (<0.1%)	1 (<0.1%)
Myxoid cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Necrobiosis lipoidica diabeticorum	0	2 (0.1%)	2 (<0.1%)
Neurodermatitis	5 (0.4%)	5 (0.4%)	10 (0.4%)
Neuropathic ulcer	1 (<0.1%)	0	1 (<0.1%)
Onychogryphosis	3 (0.2%)	0	3 (0.1%)
Palmoplantar keratoderma	2 (0.1%)	0	2 (<0.1%)
Parapsoriasis	1 (<0.1%)	0	1 (<0.1%)
Pemphigoid	0	1 (<0.1%)	1 (<0.1%)
Pigmentation disorder	1 (<0.1%)	0	1 (<0.1%)
Prurigo	0	1 (<0.1%)	1 (<0.1%)
Pruritus	17 (1.3%)	16 (1.2%)	33 (1.2%)
Pseudofolliculitis	0	1 (<0.1%)	1 (<0.1%)
Psoriasis	28 (2.1%)	29 (2.1%)	57 (2.1%)
Purpura	1 (<0.1%)	0	1 (<0.1%)
Purpura senile	0	1 (<0.1%)	1 (<0.1%)
Pyoderma gangrenosum	1 (<0.1%)	0	1 (<0.1%)
Rash	8 (0.6%)	10 (0.7%)	18 (0.7%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Rash erythematous	0	1 (<0.1%)	1 (<0.1%)
Rash pruritic	1 (<0.1%)	0	1 (<0.1%)
Rosacea	2 (0.1%)	3 (0.2%)	5 (0.2%)
Scab	0	1 (<0.1%)	1 (<0.1%)
Seborrhoeic dermatitis	12 (0.9%)	6 (0.4%)	18 (0.7%)
Senile xerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin atrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin discolouration	0	1 (<0.1%)	1 (<0.1%)
Skin disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin exfoliation	0	1 (<0.1%)	1 (<0.1%)
Skin hyperpigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	2 (0.1%)	4 (0.3%)	6 (0.2%)
Skin mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin necrosis	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	22 (1.6%)	15 (1.1%)	37 (1.4%)
Solar dermatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Solar lentigo	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	5 (0.4%)	9 (0.7%)	14 (0.5%)
Telangiectasia	0	1 (<0.1%)	1 (<0.1%)
Urticaria	15 (1.1%)	5 (0.4%)	20 (0.7%)
Urticarial vasculitis	0	1 (<0.1%)	1 (<0.1%)
Vascular purpura	0	1 (<0.1%)	1 (<0.1%)
Vitiligo	1 (<0.1%)	0	1 (<0.1%)
Xeroderma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Social circumstances	80 (5.9%)	79 (5.8%)	159 (5.8%)
Cardiac assistance device user	0	1 (<0.1%)	1 (<0.1%)
Corrective lens user	1 (<0.1%)	0	1 (<0.1%)
Disease risk factor	1 (<0.1%)	0	1 (<0.1%)
Edentulous	2 (0.1%)	0	2 (<0.1%)
Ex-tobacco user	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Limb prosthesis user	0	1 (<0.1%)	1 (<0.1%)
Loss of personal independence in daily activities	0	1 (<0.1%)	1 (<0.1%)
Menopause	47 (3.5%)	45 (3.3%)	92 (3.4%)
Organ donor	2 (0.1%)	0	2 (<0.1%)
Passive smoking	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	20 (1.5%)	25 (1.8%)	45 (1.7%)
Tobacco user	6 (0.4%)	4 (0.3%)	10 (0.4%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Surgical and medical procedures	620 (45.6%)	607 (44.6%)	1227 (45.1%)
Abdominal hernia repair	3 (0.2%)	6 (0.4%)	9 (0.3%)
Abdominoplasty	2 (0.1%)	0	2 (<0.1%)
Abscess drainage	2 (0.1%)	2 (0.1%)	4 (0.1%)
Acrochordon excision	1 (<0.1%)	0	1 (<0.1%)
Adenoidectomy	0	1 (<0.1%)	1 (<0.1%)
Adenotonsillectomy	1 (<0.1%)	0	1 (<0.1%)
Adrenalectomy	0	2 (0.1%)	2 (<0.1%)
Angioplasty	13 (1.0%)	13 (1.0%)	26 (1.0%)
Ankle arthroplasty	1 (<0.1%)	0	1 (<0.1%)
Ankle operation	1 (<0.1%)	0	1 (<0.1%)
Anorectal operation	1 (<0.1%)	0	1 (<0.1%)
Anticoagulant therapy	0	1 (<0.1%)	1 (<0.1%)
Aortic anastomosis	0	2 (0.1%)	2 (<0.1%)
Aortic aneurysm repair	4 (0.3%)	2 (0.1%)	6 (0.2%)
Aortic bypass	2 (0.1%)	4 (0.3%)	6 (0.2%)
Aortic stent insertion	1 (<0.1%)	0	1 (<0.1%)
Aortic valve repair	2 (0.1%)	2 (0.1%)	4 (0.1%)
Aortic valve replacement	15 (1.1%)	15 (1.1%)	30 (1.1%)
Appendicectomy	48 (3.5%)	65 (4.8%)	113 (4.2%)
Arterial repair	0	1 (<0.1%)	1 (<0.1%)
Arterial stent insertion	2 (0.1%)	3 (0.2%)	5 (0.2%)
Arterial therapeutic procedure	1 (<0.1%)	0	1 (<0.1%)
Arthrectomy	0	1 (<0.1%)	1 (<0.1%)
Arthrodesis	1 (<0.1%)	3 (0.2%)	4 (0.1%)
Atrial appendage closure	0	1 (<0.1%)	1 (<0.1%)
Atrial septal defect repair	1 (<0.1%)	0	1 (<0.1%)
Benign breast lump removal	0	1 (<0.1%)	1 (<0.1%)
Bentall procedure	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	3 (0.2%)	0	3 (0.1%)
Bladder neoplasm surgery	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder operation	1 (<0.1%)	0	1 (<0.1%)
Blepharoplasty	1 (<0.1%)	0	1 (<0.1%)
Bone lesion excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone operation	0	1 (<0.1%)	1 (<0.1%)
Breast conserving surgery	3 (0.2%)	5 (0.4%)	8 (0.3%)
Breast cyst excision	1 (<0.1%)	0	1 (<0.1%)
Breast reconstruction	1 (<0.1%)	0	1 (<0.1%)
Bunion operation	2 (0.1%)	1 (<0.1%)	3 (0.1%)
CSF shunt operation	1 (<0.1%)	0	1 (<0.1%)
Caesarean section	11 (0.8%)	10 (0.7%)	21 (0.8%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Cancer surgery	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Cardiac ablation	3 (0.2%)	3 (0.2%)	6 (0.2%)
Cardiac aneurysm repair	0	1 (<0.1%)	1 (<0.1%)
Cardiac operation	2 (0.1%)	0	2 (<0.1%)
Cardiac pacemaker insertion	38 (2.8%)	30 (2.2%)	68 (2.5%)
Cardiac pacemaker replacement	0	1 (<0.1%)	1 (<0.1%)
Cardiac resynchronisation therapy	2 (0.1%)	0	2 (<0.1%)
Cardiopulmonary bypass	1 (<0.1%)	0	1 (<0.1%)
Cardiovascular event prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Cardioversion	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Carotid artery bypass	0	2 (0.1%)	2 (<0.1%)
Carotid artery stent insertion	3 (0.2%)	0	3 (0.1%)
Carotid endarterectomy	23 (1.7%)	28 (2.1%)	51 (1.9%)
Carpal tunnel decompression	10 (0.7%)	11 (0.8%)	21 (0.8%)
Cartilage operation	1 (<0.1%)	0	1 (<0.1%)
Cataract operation	71 (5.2%)	79 (5.8%)	150 (5.5%)
Catheter placement	1 (<0.1%)	0	1 (<0.1%)
Cervical conisation	1 (<0.1%)	0	1 (<0.1%)
Cervical laser therapy	0	1 (<0.1%)	1 (<0.1%)
Cervical polypectomy	2 (0.1%)	2 (0.1%)	4 (0.1%)
Cholangiostomy	1 (<0.1%)	0	1 (<0.1%)
Cholecystectomy	92 (6.8%)	85 (6.2%)	177 (6.5%)
Cholecystostomy	1 (<0.1%)	0	1 (<0.1%)
Circumcision	3 (0.2%)	2 (0.1%)	5 (0.2%)
Closed fracture manipulation	0	1 (<0.1%)	1 (<0.1%)
Colectomy	4 (0.3%)	7 (0.5%)	11 (0.4%)
Colectomy total	1 (<0.1%)	0	1 (<0.1%)
Colon operation	0	2 (0.1%)	2 (<0.1%)
Continuous positive airway pressure	1 (<0.1%)	0	1 (<0.1%)
Corneal lesion removal	0	1 (<0.1%)	1 (<0.1%)
Corneal transplant	1 (<0.1%)	0	1 (<0.1%)
Coronary angioplasty	26 (1.9%)	33 (2.4%)	59 (2.2%)
Coronary arterial stent insertion	70 (5.2%)	54 (4.0%)	124 (4.6%)
Coronary artery bypass	96 (7.1%)	84 (6.2%)	180 (6.6%)
Coronary revascularisation	2 (0.1%)	2 (0.1%)	4 (0.1%)
Cranial nerve decompression	1 (<0.1%)	0	1 (<0.1%)
Craniotomy	0	1 (<0.1%)	1 (<0.1%)
Cyst removal	2 (0.1%)	4 (0.3%)	6 (0.2%)
Cystocele repair	0	1 (<0.1%)	1 (<0.1%)
Cystoprostatectomy	0	1 (<0.1%)	1 (<0.1%)
Dacryocystorhinostomy	0	1 (<0.1%)	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Debridement	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Dental implantation	0	2 (0.1%)	2 (<0.1%)
Dental prosthesis placement	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Dermatofibroma removal	1 (<0.1%)	0	1 (<0.1%)
Dialysis	1 (<0.1%)	0	1 (<0.1%)
Dupuytren's contracture operation	0	1 (<0.1%)	1 (<0.1%)
Ear operation	1 (<0.1%)	0	1 (<0.1%)
Elbow operation	0	1 (<0.1%)	1 (<0.1%)
Endoscopic sleeve gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Endovenous ablation	0	1 (<0.1%)	1 (<0.1%)
Enterostomy	1 (<0.1%)	0	1 (<0.1%)
Exeresis	0	1 (<0.1%)	1 (<0.1%)
Eye excision	0	2 (0.1%)	2 (<0.1%)
Eye laser surgery	2 (0.1%)	3 (0.2%)	5 (0.2%)
Eye operation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Eye prosthesis insertion	0	1 (<0.1%)	1 (<0.1%)
Eyelid operation	1 (<0.1%)	0	1 (<0.1%)
Facetectomy	0	1 (<0.1%)	1 (<0.1%)
Fasciectomy	0	1 (<0.1%)	1 (<0.1%)
Fasciotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Female genital operation	1 (<0.1%)	0	1 (<0.1%)
Female sterilisation	9 (0.7%)	9 (0.7%)	18 (0.7%)
Finger amputation	3 (0.2%)	4 (0.3%)	7 (0.3%)
Foot amputation	4 (0.3%)	6 (0.4%)	10 (0.4%)
Functional endoscopic sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Gallbladder operation	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Gastrectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric banding	6 (0.4%)	3 (0.2%)	9 (0.3%)
Gastric bypass	3 (0.2%)	2 (0.1%)	5 (0.2%)
Gastric operation	1 (<0.1%)	0	1 (<0.1%)
Gastric polypectomy	0	1 (<0.1%)	1 (<0.1%)
Gastric stapling	0	1 (<0.1%)	1 (<0.1%)
Gastroenterostomy	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorder prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal endoscopic therapy	0	1 (<0.1%)	1 (<0.1%)
Glaucoma surgery	0	1 (<0.1%)	1 (<0.1%)
Haemangioma removal	0	1 (<0.1%)	1 (<0.1%)
Haemodialysis	0	2 (0.1%)	2 (<0.1%)
Haemorrhoid operation	5 (0.4%)	7 (0.5%)	12 (0.4%)
Hand repair operation	0	1 (<0.1%)	1 (<0.1%)
Heart valve replacement	4 (0.3%)	1 (<0.1%)	5 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Hepatectomy	0	1 (<0.1%)	1 (<0.1%)
Hernia repair	6 (0.4%)	10 (0.7%)	16 (0.6%)
High frequency ablation	0	1 (<0.1%)	1 (<0.1%)
Hip arthroplasty	19 (1.4%)	19 (1.4%)	38 (1.4%)
Hip surgery	0	3 (0.2%)	3 (0.1%)
Hydrocele operation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Hysterectomy	45 (3.3%)	60 (4.4%)	105 (3.9%)
Hysterosalpingo-oophorectomy	5 (0.4%)	2 (0.1%)	7 (0.3%)
Hysterotomy	1 (<0.1%)	0	1 (<0.1%)
Ileostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Implantable cardiac monitor insertion	1 (<0.1%)	0	1 (<0.1%)
Implantable defibrillator insertion	5 (0.4%)	7 (0.5%)	12 (0.4%)
Implantable defibrillator replacement	0	1 (<0.1%)	1 (<0.1%)
Incisional drainage	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia repair	1 (<0.1%)	0	1 (<0.1%)
Infection prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	12 (0.9%)	12 (0.9%)	24 (0.9%)
Internal fixation of fracture	5 (0.4%)	2 (0.1%)	7 (0.3%)
Internal fixation of spine	1 (<0.1%)	0	1 (<0.1%)
Internal limiting membrane peeling	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc operation	11 (0.8%)	7 (0.5%)	18 (0.7%)
Intestinal polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intra-aortic balloon placement	1 (<0.1%)	0	1 (<0.1%)
Intra-cerebral aneurysm operation	0	1 (<0.1%)	1 (<0.1%)
Intra-ocular injection	0	2 (0.1%)	2 (<0.1%)
Intraocular lens implant	13 (1.0%)	19 (1.4%)	32 (1.2%)
Iridotomy	2 (0.1%)	0	2 (<0.1%)
Joint arthroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Knee arthroplasty	27 (2.0%)	27 (2.0%)	54 (2.0%)
Knee operation	0	8 (0.6%)	8 (0.3%)
Lacrimal duct procedure	0	1 (<0.1%)	1 (<0.1%)
Lacrimal gland operation	0	1 (<0.1%)	1 (<0.1%)
Large intestinal polypectomy	15 (1.1%)	9 (0.7%)	24 (0.9%)
Large intestine anastomosis	0	1 (<0.1%)	1 (<0.1%)
Laryngeal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Leg amputation	5 (0.4%)	9 (0.7%)	14 (0.5%)
Lens capsulotomy	1 (<0.1%)	0	1 (<0.1%)
Lens extraction	0	4 (0.3%)	4 (0.1%)
Ligament operation	0	2 (0.1%)	2 (<0.1%)
Limb amputation	1 (<0.1%)	0	1 (<0.1%)
Limb operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Lipectomy	1 (<0.1%)	0	1 (<0.1%)
Lithotripsy	6 (0.4%)	5 (0.4%)	11 (0.4%)
Liver transplant	0	1 (<0.1%)	1 (<0.1%)
Lung lobectomy	3 (0.2%)	3 (0.2%)	6 (0.2%)
Lymphadenectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mammoplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mastectomy	5 (0.4%)	2 (0.1%)	7 (0.3%)
Mastoidectomy	1 (<0.1%)	0	1 (<0.1%)
Maxillary antrum operation	1 (<0.1%)	0	1 (<0.1%)
Medical diet	1 (<0.1%)	0	1 (<0.1%)
Meningioma surgery	0	1 (<0.1%)	1 (<0.1%)
Meniscus operation	5 (0.4%)	3 (0.2%)	8 (0.3%)
Meniscus removal	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Metabolic surgery	0	1 (<0.1%)	1 (<0.1%)
Mitral valve repair	2 (0.1%)	3 (0.2%)	5 (0.2%)
Mitral valve replacement	3 (0.2%)	2 (0.1%)	5 (0.2%)
Mole excision	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Multiple drug therapy	0	2 (0.1%)	2 (<0.1%)
Myomectomy	2 (0.1%)	3 (0.2%)	5 (0.2%)
Nail operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nasal polypectomy	2 (0.1%)	0	2 (<0.1%)
Nasal septal operation	4 (0.3%)	3 (0.2%)	7 (0.3%)
Neobladder surgery	1 (<0.1%)	0	1 (<0.1%)
Nephrectomy	14 (1.0%)	12 (0.9%)	26 (1.0%)
Nephrostomy	1 (<0.1%)	0	1 (<0.1%)
Nephroureterectomy	1 (<0.1%)	0	1 (<0.1%)
Neurectomy	1 (<0.1%)	0	1 (<0.1%)
Oesophageal operation	1 (<0.1%)	0	1 (<0.1%)
Oophorectomy	8 (0.6%)	3 (0.2%)	11 (0.4%)
Oophorectomy bilateral	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Ophthalmic fluid-air exchange procedure	0	1 (<0.1%)	1 (<0.1%)
Orchidectomy	1 (<0.1%)	0	1 (<0.1%)
Osteotomy	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Pancreatectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreaticoduodenectomy	0	1 (<0.1%)	1 (<0.1%)
Pancreaticogastrostomy	1 (<0.1%)	0	1 (<0.1%)
Parathyroidectomy	7 (0.5%)	1 (<0.1%)	8 (0.3%)
Parotidectomy	0	1 (<0.1%)	1 (<0.1%)
Partial cystectomy	1 (<0.1%)	0	1 (<0.1%)
Penile prosthesis insertion	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Percutaneous coronary intervention	18 (1.3%)	24 (1.8%)	42 (1.5%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Pericardial drainage	0	1 (<0.1%)	1 (<0.1%)
Perineoplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral artery angioplasty	11 (0.8%)	10 (0.7%)	21 (0.8%)
Peripheral artery bypass	7 (0.5%)	11 (0.8%)	18 (0.7%)
Peripheral artery stent insertion	12 (0.9%)	5 (0.4%)	17 (0.6%)
Peripheral endarterectomy	2 (0.1%)	3 (0.2%)	5 (0.2%)
Peripheral nerve operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral revascularisation	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phlebectomy	5 (0.4%)	3 (0.2%)	8 (0.3%)
Phlebotomy	1 (<0.1%)	0	1 (<0.1%)
Polypectomy	3 (0.2%)	3 (0.2%)	6 (0.2%)
Proctocolectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prostate ablation	0	1 (<0.1%)	1 (<0.1%)
Prostatectomy	4 (0.3%)	16 (1.2%)	20 (0.7%)
Prostatic operation	0	4 (0.3%)	4 (0.1%)
Pterygium operation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Pulmonary resection	2 (0.1%)	0	2 (<0.1%)
Radical cystectomy	1 (<0.1%)	0	1 (<0.1%)
Radical prostatectomy	2 (0.1%)	2 (0.1%)	4 (0.1%)
Radioactive iodine therapy	0	1 (<0.1%)	1 (<0.1%)
Radiotherapy	1 (<0.1%)	0	1 (<0.1%)
Rectal polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal prolapse repair	0	1 (<0.1%)	1 (<0.1%)
Removal of foreign body from eyelids	0	1 (<0.1%)	1 (<0.1%)
Renal artery stent placement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal stone removal	10 (0.7%)	10 (0.7%)	20 (0.7%)
Renal surgery	2 (0.1%)	0	2 (<0.1%)
Renal transplant	1 (<0.1%)	0	1 (<0.1%)
Retinal laser coagulation	5 (0.4%)	4 (0.3%)	9 (0.3%)
Retinopexy	0	1 (<0.1%)	1 (<0.1%)
Revascularisation procedure	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Rhinoplasty	2 (0.1%)	2 (0.1%)	4 (0.1%)
Rotator cuff repair	3 (0.2%)	8 (0.6%)	11 (0.4%)
Routine health maintenance	1 (<0.1%)	0	1 (<0.1%)
Roux loop conversion	1 (<0.1%)	0	1 (<0.1%)
Salivary gland resection	0	1 (<0.1%)	1 (<0.1%)
Salpingo-oophorectomy	0	1 (<0.1%)	1 (<0.1%)
Salpingo-oophorectomy bilateral	1 (<0.1%)	0	1 (<0.1%)
Salpingo-oophorectomy unilateral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scrotal operation	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Sebaceous cyst excision	1 (<0.1%)	0	1 (<0.1%)
Shoulder arthroplasty	3 (0.2%)	2 (0.1%)	5 (0.2%)
Shoulder operation	3 (0.2%)	3 (0.2%)	6 (0.2%)
Sigmoidectomy	2 (0.1%)	0	2 (<0.1%)
Sinuplasty	1 (<0.1%)	0	1 (<0.1%)
Sinus operation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Skin cryotherapy	1 (<0.1%)	0	1 (<0.1%)
Skin graft	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin lesion removal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin neoplasm excision	4 (0.3%)	7 (0.5%)	11 (0.4%)
Spinal corpectomy	1 (<0.1%)	0	1 (<0.1%)
Spinal decompression	0	2 (0.1%)	2 (<0.1%)
Spinal fusion surgery	4 (0.3%)	4 (0.3%)	8 (0.3%)
Spinal laminectomy	7 (0.5%)	4 (0.3%)	11 (0.4%)
Spinal operation	6 (0.4%)	7 (0.5%)	13 (0.5%)
Stent placement	19 (1.4%)	11 (0.8%)	30 (1.1%)
Sterilisation	1 (<0.1%)	0	1 (<0.1%)
Subdural haematoma evacuation	1 (<0.1%)	0	1 (<0.1%)
Synovectomy	1 (<0.1%)	0	1 (<0.1%)
Synovial cyst removal	0	1 (<0.1%)	1 (<0.1%)
Tendon sheath incision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tenoplasty	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Therapeutic embolisation	0	1 (<0.1%)	1 (<0.1%)
Thoracic cavity drainage	0	1 (<0.1%)	1 (<0.1%)
Thoracotomy	1 (<0.1%)	0	1 (<0.1%)
Thrombectomy	0	1 (<0.1%)	1 (<0.1%)
Thromboembolectomy	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Thyroid adenoma removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid nodule removal	1 (<0.1%)	0	1 (<0.1%)
Thyroid operation	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Thyroidectomy	14 (1.0%)	17 (1.2%)	31 (1.1%)
Toe amputation	26 (1.9%)	20 (1.5%)	46 (1.7%)
Toe operation	0	1 (<0.1%)	1 (<0.1%)
Tongue operation	1 (<0.1%)	0	1 (<0.1%)
Tonsillectomy	18 (1.3%)	28 (2.1%)	46 (1.7%)
Tooth extraction	2 (0.1%)	0	2 (<0.1%)
Transurethral bladder resection	3 (0.2%)	0	3 (0.1%)
Transurethral incision of prostate	1 (<0.1%)	0	1 (<0.1%)
Transurethral prostatectomy	8 (0.6%)	7 (0.5%)	15 (0.6%)
Tricuspid valve repair	0	2 (0.1%)	2 (<0.1%)
Tricuspid valve replacement	1 (<0.1%)	0	1 (<0.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Tumour excision	0	1 (<0.1%)	1 (<0.1%)
Turbinoplasty	1 (<0.1%)	0	1 (<0.1%)
Tympanoplasty	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Umbilical hernia repair	4 (0.3%)	9 (0.7%)	13 (0.5%)
Ureteral stent insertion	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Ureteric calculus removal	1 (<0.1%)	0	1 (<0.1%)
Ureterolithotomy	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Urethral repair	1 (<0.1%)	0	1 (<0.1%)
Urethral stent insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethrotomy	1 (<0.1%)	0	1 (<0.1%)
Urinary bladder suspension	6 (0.4%)	3 (0.2%)	9 (0.3%)
Urinary cystectomy	1 (<0.1%)	0	1 (<0.1%)
Urinary tract operation	0	1 (<0.1%)	1 (<0.1%)
Urostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine dilation and curettage	3 (0.2%)	1 (<0.1%)	4 (0.1%)
Uterine operation	1 (<0.1%)	0	1 (<0.1%)
Uterine polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uvulopalatopharyngoplasty	0	2 (0.1%)	2 (<0.1%)
Uvuloplasty	0	1 (<0.1%)	1 (<0.1%)
Vaginoperineoplasty	1 (<0.1%)	0	1 (<0.1%)
Vagotomy	1 (<0.1%)	0	1 (<0.1%)
Varicose vein operation	2 (0.1%)	3 (0.2%)	5 (0.2%)
Vascular anastomosis	1 (<0.1%)	0	1 (<0.1%)
Vascular graft	8 (0.6%)	3 (0.2%)	11 (0.4%)
Vascular stent insertion	6 (0.4%)	2 (0.1%)	8 (0.3%)
Vasectomy	0	7 (0.5%)	7 (0.3%)
Vena cava filter insertion	0	2 (0.1%)	2 (<0.1%)
Venous angioplasty	1 (<0.1%)	0	1 (<0.1%)
Ventriculo-peritoneal shunt	0	1 (<0.1%)	1 (<0.1%)
Vertebroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitrectomy	5 (0.4%)	7 (0.5%)	12 (0.4%)
Vocal cord operation	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polypectomy	0	1 (<0.1%)	1 (<0.1%)
Volvulus repair	0	1 (<0.1%)	1 (<0.1%)
Vascular disorders	1340 (98.6%)	1347 (98.9%)	2687 (98.8%)
Accelerated hypertension	0	1 (<0.1%)	1 (<0.1%)
Aneurysm	1 (<0.1%)	0	1 (<0.1%)
Angiopathy	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Aortic aneurysm	15 (1.1%)	16 (1.2%)	31 (1.1%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Aortic arteriosclerosis	19 (1.4%)	23 (1.7%)	42 (1.5%)
Aortic dilatation	2 (0.1%)	4 (0.3%)	6 (0.2%)
Aortic disorder	0	1 (<0.1%)	1 (<0.1%)
Aortic stenosis	13 (1.0%)	14 (1.0%)	27 (1.0%)
Arterial disorder	2 (0.1%)	0	2 (<0.1%)
Arterial occlusive disease	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerosis	30 (2.2%)	20 (1.5%)	50 (1.8%)
Arteriosclerosis Moenckeberg-type	2 (0.1%)	0	2 (<0.1%)
Arteritis	0	1 (<0.1%)	1 (<0.1%)
Brachiocephalic arteriosclerosis	3 (0.2%)	2 (0.1%)	5 (0.2%)
Brachiocephalic artery stenosis	2 (0.1%)	0	2 (<0.1%)
Cyanosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deep vein thrombosis	15 (1.1%)	8 (0.6%)	23 (0.8%)
Diabetic macroangiopathy	4 (0.3%)	3 (0.2%)	7 (0.3%)
Diabetic microangiopathy	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Diabetic vascular disorder	18 (1.3%)	15 (1.1%)	33 (1.2%)
Embolism	0	1 (<0.1%)	1 (<0.1%)
Embolism venous	0	1 (<0.1%)	1 (<0.1%)
Essential hypertension	50 (3.7%)	49 (3.6%)	99 (3.6%)
Granulomatosis with polyangiitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma	1 (<0.1%)	0	1 (<0.1%)
Hot flush	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Hyperaemia	3 (0.2%)	0	3 (0.1%)
Hypertension	1275 (93.8%)	1280 (94.0%)	2555 (93.9%)
Hypertensive angiopathy	3 (0.2%)	3 (0.2%)	6 (0.2%)
Hypertensive crisis	0	1 (<0.1%)	1 (<0.1%)
Hypertensive end-organ damage	1 (<0.1%)	0	1 (<0.1%)
Hypotension	2 (0.1%)	3 (0.2%)	5 (0.2%)
Iliac artery stenosis	0	1 (<0.1%)	1 (<0.1%)
Infarction	0	1 (<0.1%)	1 (<0.1%)
Intermittent claudication	16 (1.2%)	25 (1.8%)	41 (1.5%)
Labile hypertension	1 (<0.1%)	0	1 (<0.1%)
Lymphocele	1 (<0.1%)	0	1 (<0.1%)
Lymphoedema	2 (0.1%)	6 (0.4%)	8 (0.3%)
Macroangiopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Microangiopathy	2 (0.1%)	2 (0.1%)	4 (0.1%)
Obstructive shock	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	9 (0.7%)	2 (0.1%)	11 (0.4%)
Peripheral arterial occlusive disease	282 (20.8%)	280 (20.6%)	562 (20.7%)
Peripheral artery aneurysm	2 (0.1%)	0	2 (<0.1%)
Peripheral artery occlusion	1 (<0.1%)	4 (0.3%)	5 (0.2%)

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

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Peripheral artery stenosis	1 (<0.1%)	4 (0.3%)	5 (0.2%)
Peripheral artery thrombosis	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Peripheral coldness	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	0	2 (0.1%)	2 (<0.1%)
Peripheral ischaemia	4 (0.3%)	5 (0.4%)	9 (0.3%)
Peripheral vascular disorder	13 (1.0%)	17 (1.2%)	30 (1.1%)
Peripheral venous disease	34 (2.5%)	28 (2.1%)	62 (2.3%)
Phlebitis	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Phlebitis deep	1 (<0.1%)	0	1 (<0.1%)
Poor peripheral circulation	0	1 (<0.1%)	1 (<0.1%)
Post thrombotic syndrome	1 (<0.1%)	0	1 (<0.1%)
Raynaud's phenomenon	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Renovascular hypertension	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery stenosis	2 (0.1%)	2 (0.1%)	4 (0.1%)
Thrombophlebitis	5 (0.4%)	7 (0.5%)	12 (0.4%)
Thrombosis	2 (0.1%)	2 (0.1%)	4 (0.1%)
Varicose ulceration	1 (<0.1%)	2 (0.1%)	3 (0.1%)
Varicose vein	42 (3.1%)	38 (2.8%)	80 (2.9%)
Vascular stenosis	1 (<0.1%)	0	1 (<0.1%)
Vasoconstriction	0	1 (<0.1%)	1 (<0.1%)
Vasodilatation	0	1 (<0.1%)	1 (<0.1%)
Vena cava thrombosis	0	1 (<0.1%)	1 (<0.1%)
Venous hypertension	1 (<0.1%)	0	1 (<0.1%)
Venous thrombosis	2 (0.1%)	0	2 (<0.1%)
Venous thrombosis limb	0	1 (<0.1%)	1 (<0.1%)
White coat hypertension	3 (0.2%)	5 (0.4%)	8 (0.3%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
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4.6 Concomitant medication

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

Drug grouping	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	1103 (81.2%)	1114 (81.8%)	2217 (81.5%)
ACEI	210 (15.5%)	225 (16.5%)	435 (16.0%)
ARB	349 (25.7%)	366 (26.9%)	715 (26.3%)
RAS-inhibitors	513 (37.7%)	547 (40.2%)	1060 (39.0%)
Beta-blocker	395 (29.1%)	407 (29.9%)	802 (29.5%)
Diuretics	538 (39.6%)	576 (42.3%)	1114 (40.9%)
Loop diuretics	374 (27.5%)	408 (30.0%)	782 (28.7%)
Thiazide diuretics	134 (9.9%)	158 (11.6%)	292 (10.7%)
Potassium supplements	98 (7.2%)	123 (9.0%)	221 (8.1%)
Potassium lowering agents (including binders)	98 (7.2%)	56 (4.1%)	154 (5.7%)
Alpha blocking agents	363 (26.7%)	379 (27.8%)	742 (27.3%)
Calcium channel blockers	392 (28.8%)	445 (32.7%)	837 (30.8%)
Centrally acting antihypertensives	73 (5.4%)	82 (6.0%)	155 (5.7%)
Strong CYP3A4 inhibitors	80 (5.9%)	70 (5.1%)	150 (5.5%)
Moderate CYP3A4 inhibitors	216 (15.9%)	192 (14.1%)	408 (15.0%)
Weak CYP3A4 inhibitors	509 (37.5%)	534 (39.2%)	1043 (38.3%)
Unclassified CYP3A4 inhibitors	74 (5.4%)	65 (4.8%)	139 (5.1%)
Strong CYP3A4 inducers	19 (1.4%)	20 (1.5%)	39 (1.4%)
Moderate CYP3A4 inducers	103 (7.6%)	108 (7.9%)	211 (7.8%)
Weak CYP3A4 inducers	111 (8.2%)	114 (8.4%)	225 (8.3%)
Unclassified CYP3A4 inducers	66 (4.9%)	52 (3.8%)	118 (4.3%)
Oral anticoagulants	163 (12.0%)	161 (11.8%)	324 (11.9%)
Acetylsalycylic acid and its salts	225 (16.6%)	243 (17.8%)	468 (17.2%)
Statins	393 (28.9%)	413 (30.3%)	806 (29.6%)
Erythropoeitin stimulating agents	30 (2.2%)	22 (1.6%)	52 (1.9%)
NSAIDS (excluding acetylsalicylic acid)	439 (32.3%)	407 (29.9%)	846 (31.1%)
ARNIs	2 (0.1%)	1 (<0.1%)	3 (0.1%)
Potassium-sparing diuretics	77 (5.7%)	81 (5.9%)	158 (5.8%)
Platelet aggregation inhibitors (excluding heparin)	345 (25.4%)	339 (24.9%)	684 (25.1%)
Trimethoprim and derivatives	57 (4.2%)	45 (3.3%)	102 (3.7%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:12
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=1359 (100%)	Placebo N=1362 (100%)	Total N=2721 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	884 (65.0%)	875 (64.2%)	1759 (64.6%)
Insulins and analogues	616 (45.3%)	585 (43.0%)	1201 (44.1%)
Dipeptidyl peptidase 4 inhibitors	247 (18.2%)	235 (17.3%)	482 (17.7%)
Glucagon-like peptide-1(GLP1) agonists	165 (12.1%)	171 (12.6%)	336 (12.3%)
SGLT-2 inhibitors	173 (12.7%)	154 (11.3%)	327 (12.0%)
Biguanides	312 (23.0%)	306 (22.5%)	618 (22.7%)
Sulfonylureas	189 (13.9%)	176 (12.9%)	365 (13.4%)
Alpha glucosidase inhibitors	42 (3.1%)	36 (2.6%)	78 (2.9%)
Meglitinides	48 (3.5%)	54 (4.0%)	102 (3.7%)
Thiazolidinediones	45 (3.3%)	50 (3.7%)	95 (3.5%)

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

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

		BAY 94-8862 (N=1359)	Placebo (N=1362)	Total (N=2721)
Study duration (months)	n	1359	1362	2721
	Nmiss	0	0	0
	Mean	40.634	40.724	40.679
	SD	11.574	11.726	11.648
	Min	0.85	0.36	0.36
	Median	42.809	43.039	42.875
	Max	60.16	60.55	60.55

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

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

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	167 (12.3%)	159 (11.7%)
Number (%) of subjects censored	1192 (87.7%)	1203 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.05 [0.85; 1.31]	
two-sided p-value from stratified logrank test	0.6480	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	167 (12.3%)	159 (11.7%)
Number (%) of subjects censored	1192 (87.7%)	1203 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.85; 1.32]	
two-sided p-value from unstratified logrank test	0.6088	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	133 (9.8%)	114 (8.4%)
Number (%) of subjects censored	1226 (90.2%)	1248 (91.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.18 [0.92; 1.51]	
two-sided p-value from stratified logrank test	0.2002	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 4: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	35 (2.6%)	31 (2.3%)
Number (%) of subjects censored	1324 (97.4%)	1331 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.15 [0.71; 1.87]	
two-sided p-value from stratified logrank test	0.5689	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 5: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	35 (2.6%)	31 (2.3%)
Number (%) of subjects censored	1324 (97.4%)	1331 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.14 [0.70; 1.85]	
two-sided p-value from unstratified logrank test	0.5973	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 6: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	29 (2.1%)	22 (1.6%)
Number (%) of subjects censored	1330 (97.9%)	1340 (98.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.37 [0.79; 2.39]	
two-sided p-value from stratified logrank test	0.2654	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 7: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	24 (1.8%)	24 (1.8%)
Number (%) of subjects censored	1335 (98.2%)	1338 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.54; 1.70]	
two-sided p-value from stratified logrank test	0.8874	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 8: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	24 (1.8%)	24 (1.8%)
Number (%) of subjects censored	1335 (98.2%)	1338 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.57; 1.77]	
two-sided p-value from unstratified logrank test	0.9801	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 9: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	20 (1.5%)	16 (1.2%)
Number (%) of subjects censored	1339 (98.5%)	1346 (98.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.28 [0.66; 2.48]	
two-sided p-value from stratified logrank test	0.4609	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 10: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	15 (1.1%)	15 (1.1%)
Number (%) of subjects censored	1344 (98.9%)	1347 (98.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.48; 2.01]	
two-sided p-value from stratified logrank test	0.9640	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 11: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	16 (1.2%)	17 (1.2%)
Number (%) of subjects censored	1343 (98.8%)	1345 (98.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.45; 1.81]	
two-sided p-value from stratified logrank test	0.7720	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 12: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	21 (1.5%)	19 (1.4%)
Number (%) of subjects censored	1338 (98.5%)	1343 (98.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.59; 2.07]	
two-sided p-value from stratified logrank test	0.7463	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 13: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	0	1 (<0.1%)
Number (%) of subjects censored	1359 (100.0%)	1361 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.00 [0.00;]	
two-sided p-value from stratified logrank test	0.2963	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 14: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	104 (7.7%)	81 (5.9%)
Number (%) of subjects censored	1255 (92.3%)	1281 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.30 [0.97; 1.75]	
two-sided p-value from stratified logrank test	0.0744	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 15: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	195 (14.3%)	228 (16.7%)
Number (%) of subjects censored	1164 (85.7%)	1134 (83.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.69; 1.02]	
two-sided p-value from stratified logrank test	0.0715	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 16: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	195 (14.3%)	228 (16.7%)
Number (%) of subjects censored	1164 (85.7%)	1134 (83.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.70; 1.03]	
two-sided p-value from unstratified logrank test	0.0949	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 17: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	146 (10.7%)	179 (13.1%)
Number (%) of subjects censored	1213 (89.3%)	1183 (86.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.66; 1.02]	
two-sided p-value from stratified logrank test	0.0772	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 18: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	89 (6.5%)	90 (6.6%)
Number (%) of subjects censored	1270 (93.5%)	1272 (93.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.74; 1.32]	
two-sided p-value from stratified logrank test	0.9321	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 19: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	48 (3.5%)	53 (3.9%)
Number (%) of subjects censored	1311 (96.5%)	1309 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.60; 1.31]	
two-sided p-value from stratified logrank test	0.5482	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 20: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	32 (2.4%)	46 (3.4%)
Number (%) of subjects censored	1327 (97.6%)	1316 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.44; 1.10]	
two-sided p-value from stratified logrank test	0.1158	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 21: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	58 (4.3%)	72 (5.3%)
Number (%) of subjects censored	1301 (95.7%)	1290 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.56; 1.12]	
two-sided p-value from stratified logrank test	0.1867	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 22: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	51 (3.8%)	58 (4.3%)
Number (%) of subjects censored	1308 (96.2%)	1304 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.59; 1.26]	
two-sided p-value from stratified logrank test	0.4448	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 23: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	51 (3.8%)	58 (4.3%)
Number (%) of subjects censored	1308 (96.2%)	1304 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.60; 1.28]	
two-sided p-value from unstratified logrank test	0.5059	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 24: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	46 (3.4%)	52 (3.8%)
Number (%) of subjects censored	1313 (96.6%)	1310 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.60; 1.34]	
two-sided p-value from stratified logrank test	0.5933	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 25: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	38 (2.8%)	54 (4.0%)
Number (%) of subjects censored	1321 (97.2%)	1308 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.46; 1.07]	
two-sided p-value from stratified logrank test	0.0962	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 26: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	38 (2.8%)	54 (4.0%)
Number (%) of subjects censored	1321 (97.2%)	1308 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.46; 1.06]	
two-sided p-value from unstratified logrank test	0.0932	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
End of table

Table 1.1.2 / 27: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	30 (2.2%)	44 (3.2%)
Number (%) of subjects censored	1329 (97.8%)	1318 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.44; 1.11]	
two-sided p-value from stratified logrank test	0.1287	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 28: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	58 (4.3%)	76 (5.6%)
Number (%) of subjects censored	1301 (95.7%)	1286 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.53; 1.06]	
two-sided p-value from stratified logrank test	0.1006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 29: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	58 (4.3%)	76 (5.6%)
Number (%) of subjects censored	1301 (95.7%)	1286 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.54; 1.07]	
two-sided p-value from unstratified logrank test	0.1210	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 30: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	43 (3.2%)	63 (4.6%)
Number (%) of subjects censored	1316 (96.8%)	1299 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.46; 1.01]	
two-sided p-value from stratified logrank test	0.0543	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 31: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	670 (49.3%)	687 (50.4%)
Number (%) of subjects censored	689 (50.7%)	675 (49.6%)
Median Time to event (month) [95 % CI]	43.200 [39.433;49.133]	41.200 [37.467;45.700]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.87; 1.07]	
two-sided p-value from stratified logrank test	0.5209	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 32: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	670 (49.3%)	687 (50.4%)
Number (%) of subjects censored	689 (50.7%)	675 (49.6%)
Median Time to event (month) [95 % CI]	43.200 [39.433;49.133]	41.200 [37.467;45.700]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.87; 1.08]	
two-sided p-value from unstratified logrank test	0.6174	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 33: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	1359 (100.0%)	1362 (100.0%)
Number (%) of subjects with event	605 (44.5%)	626 (46.0%)
Number (%) of subjects censored	754 (55.5%)	736 (54.0%)
Median Time to event (month) [95 % CI]	44.367 [39.433;50.100]	41.567 [38.033;46.600]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.87; 1.09]	
two-sided p-value from stratified logrank test	0.5990	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / history of CV disease.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_fig_s1.sas 06FEB2023 16:00
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Table 1.1.2 / 34: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.84; 1.09]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.5384

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 06FEB2023 16:04
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Figure 1.1.2 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

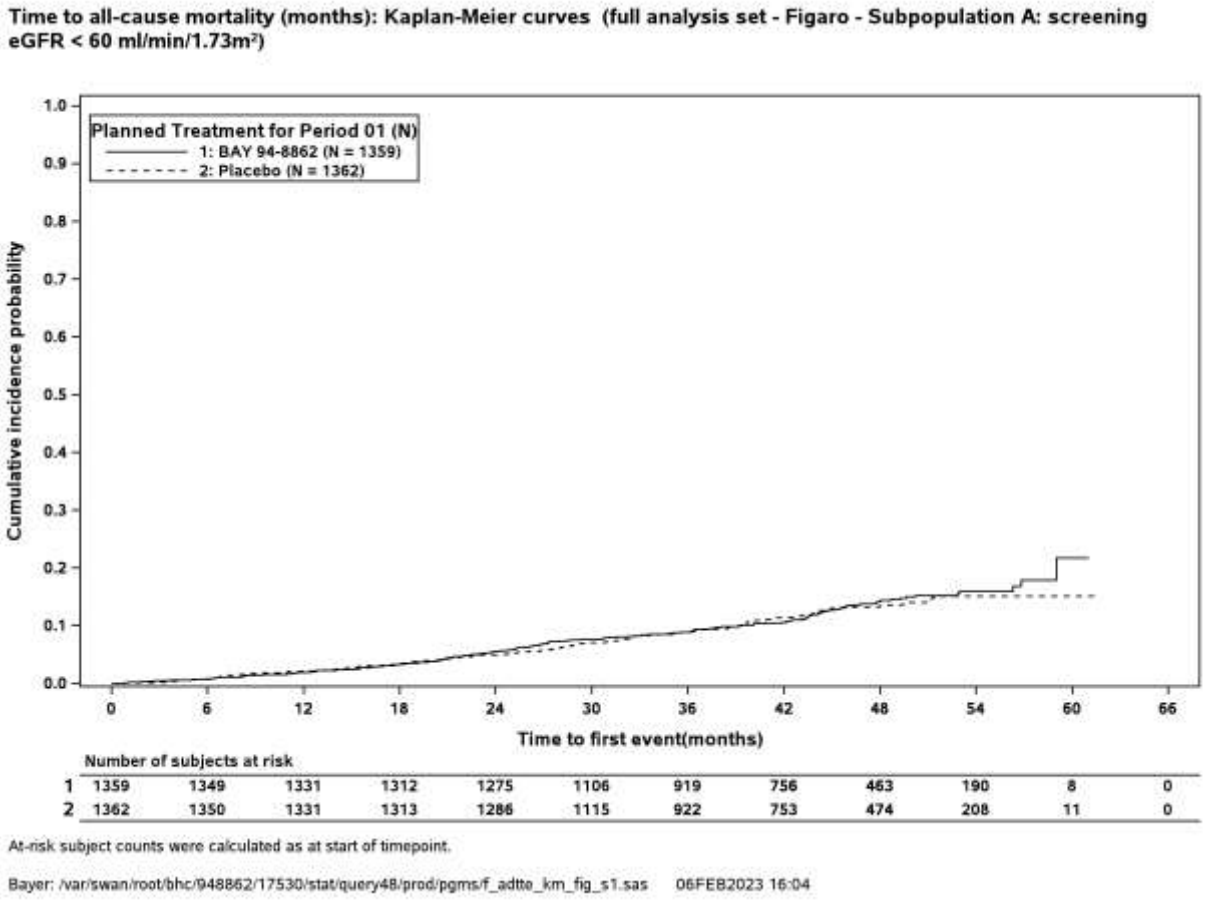


Figure 1.1.2 / 2: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

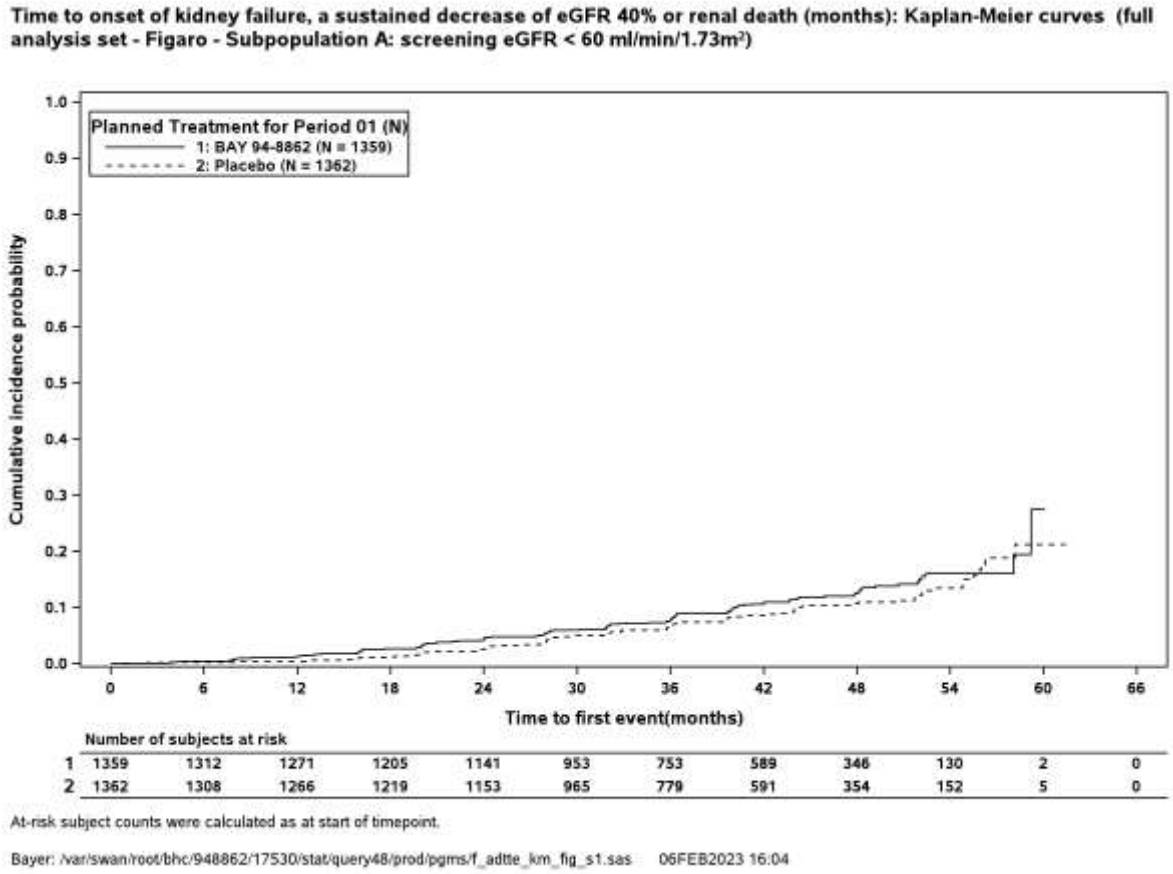


Figure 1.1.2 / 3: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

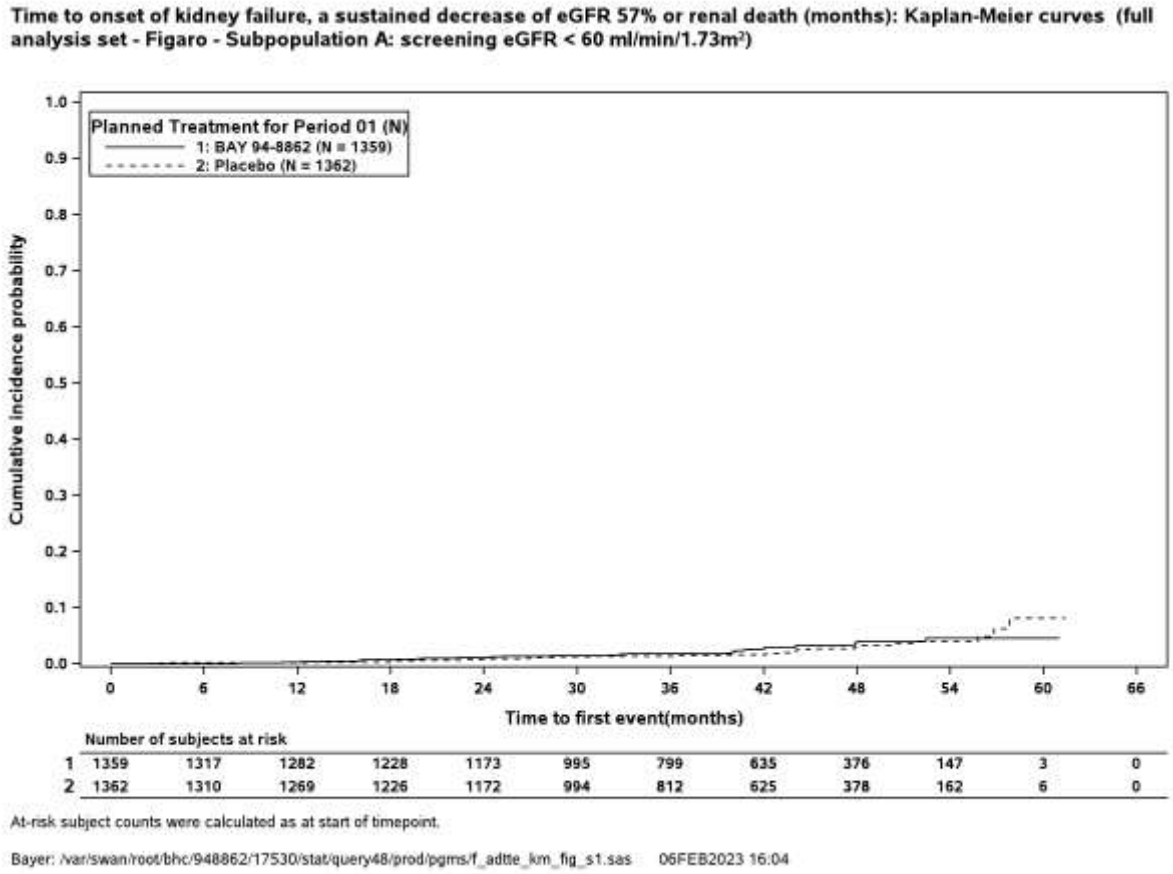


Figure 1.1.2 / 4: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

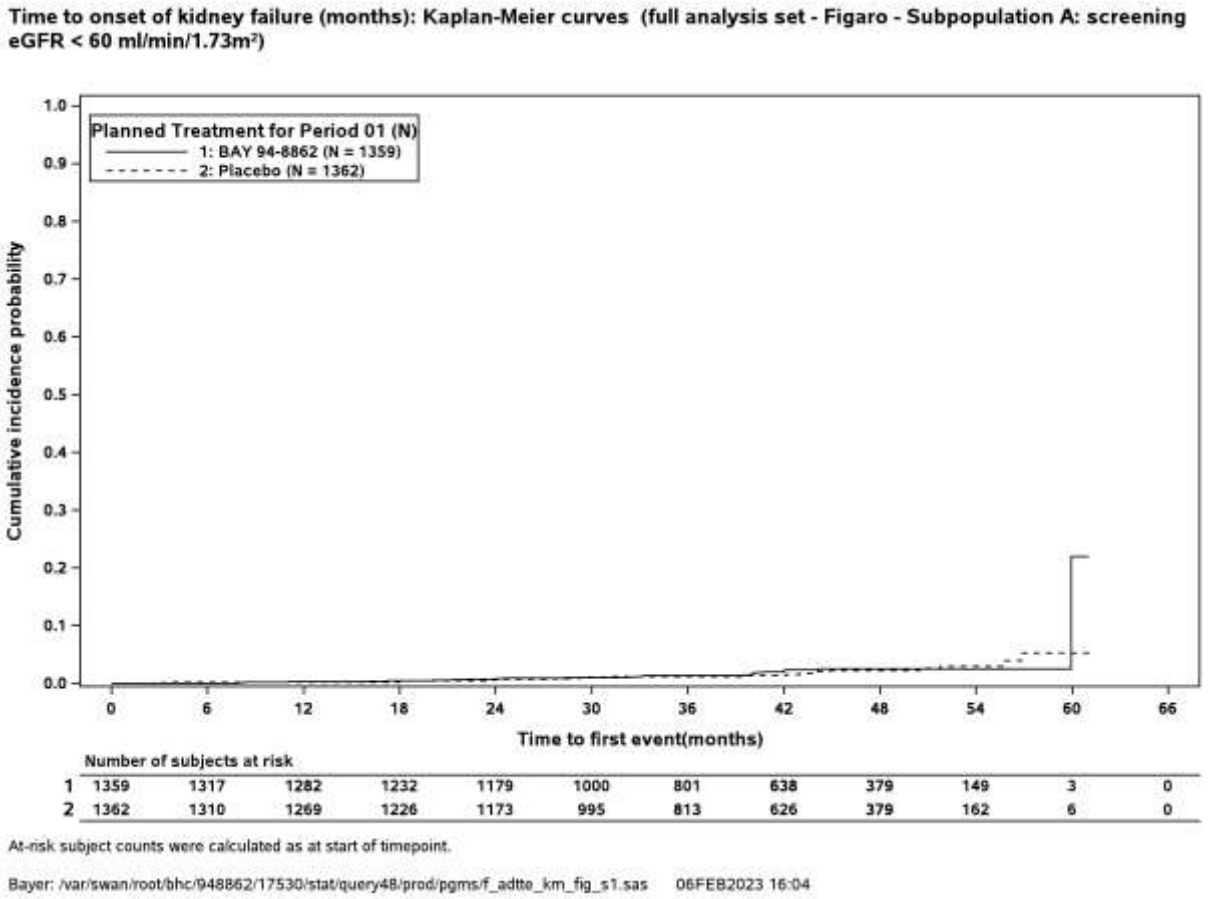
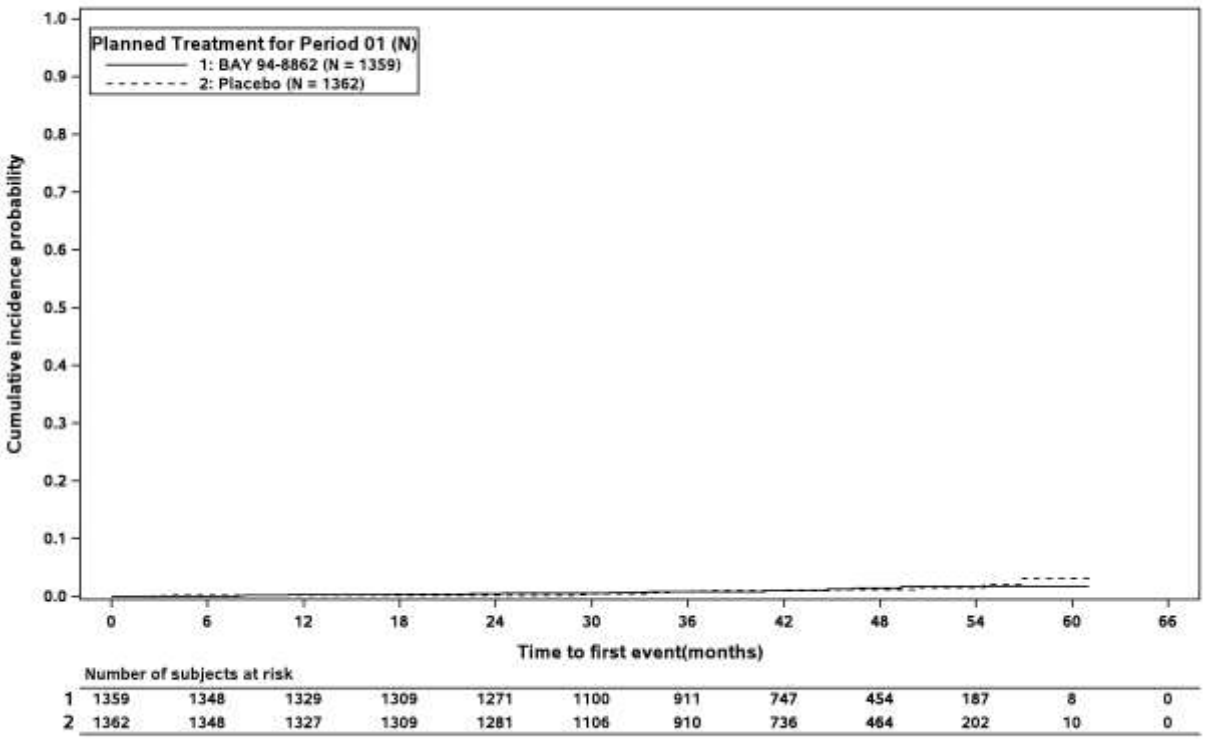


Figure 1.1.2 / 5: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Number of subjects at risk

1	1359	1348	1329	1309	1271	1100	911	747	454	187	8	0
2	1362	1348	1327	1309	1281	1106	910	736	464	202	10	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_fig_s1.sas 06FEB2023 16:04

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

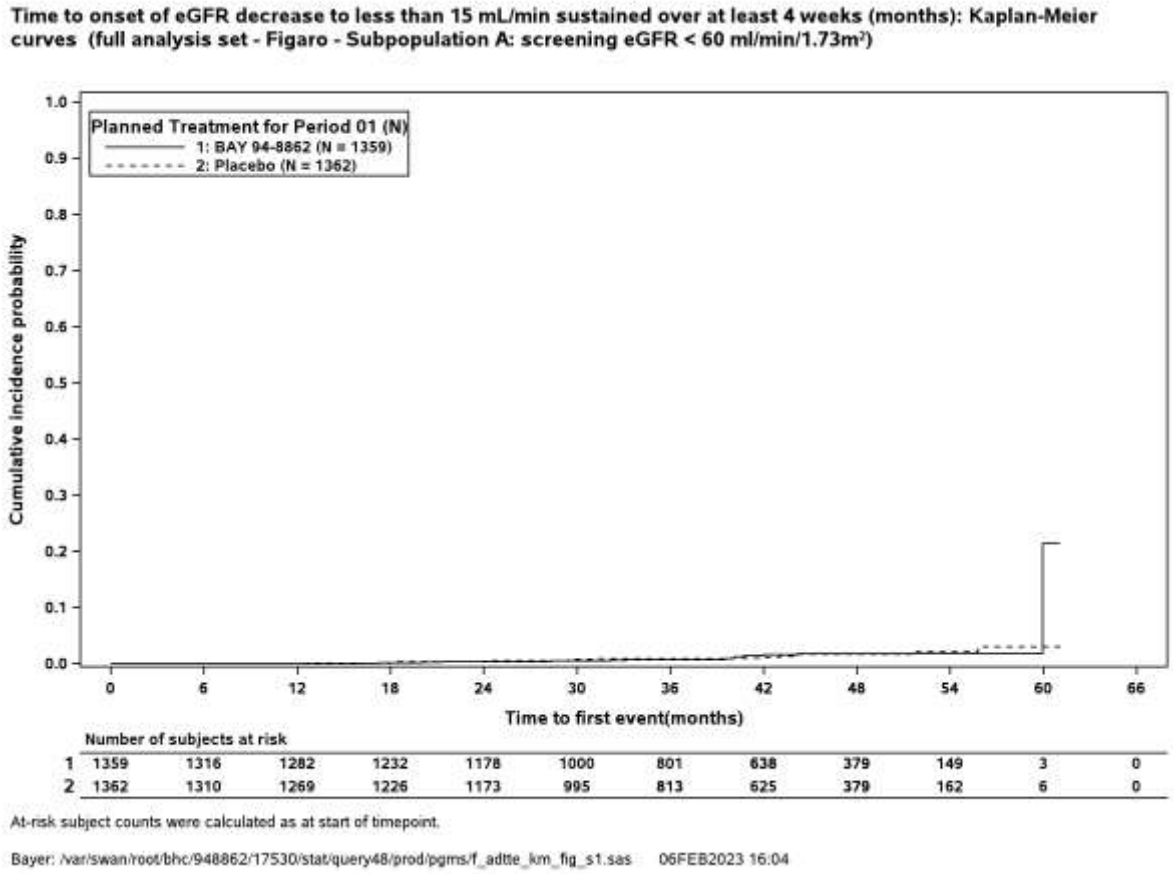


Figure 1.1.2 / 7: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

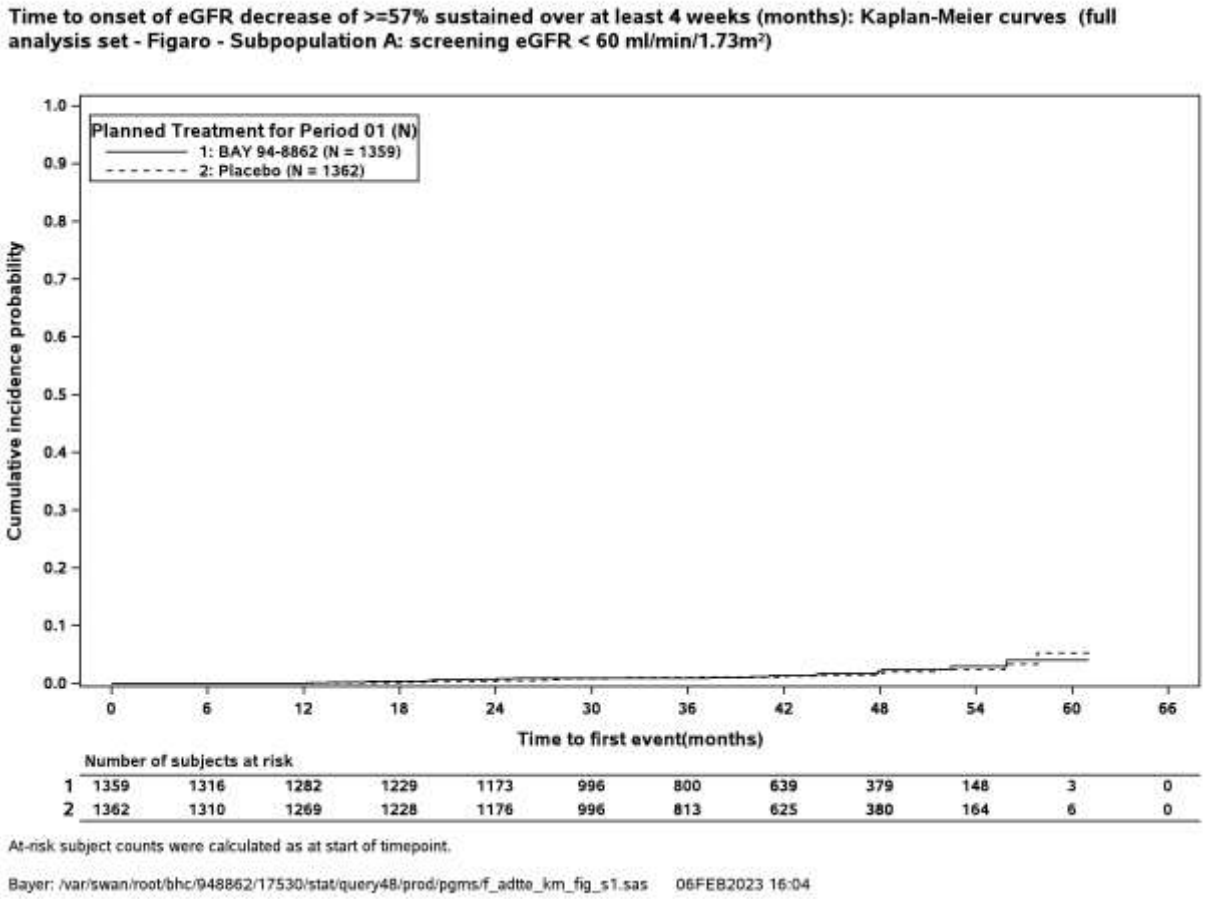


Figure 1.1.2 / 8: Time to renal death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

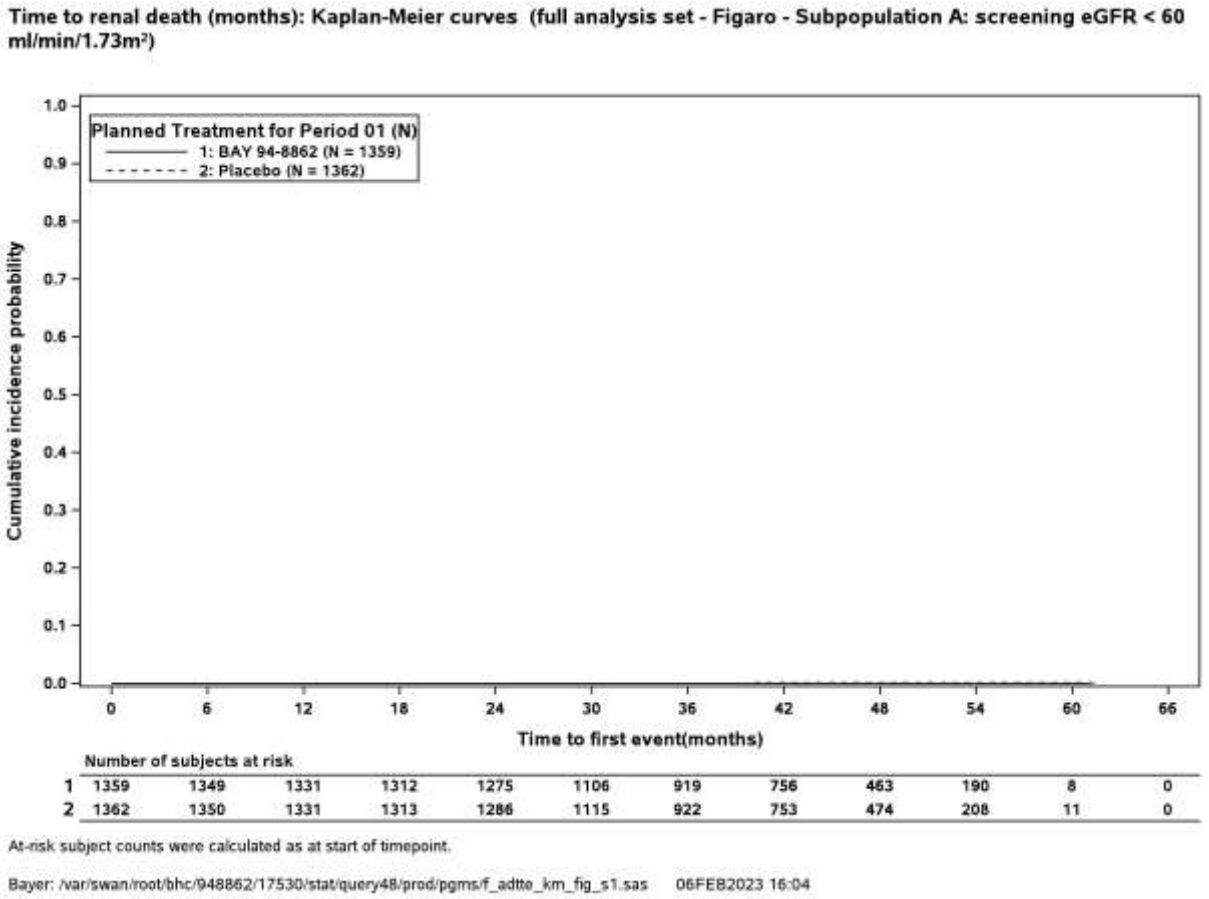


Figure 1.1.2 / 9: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

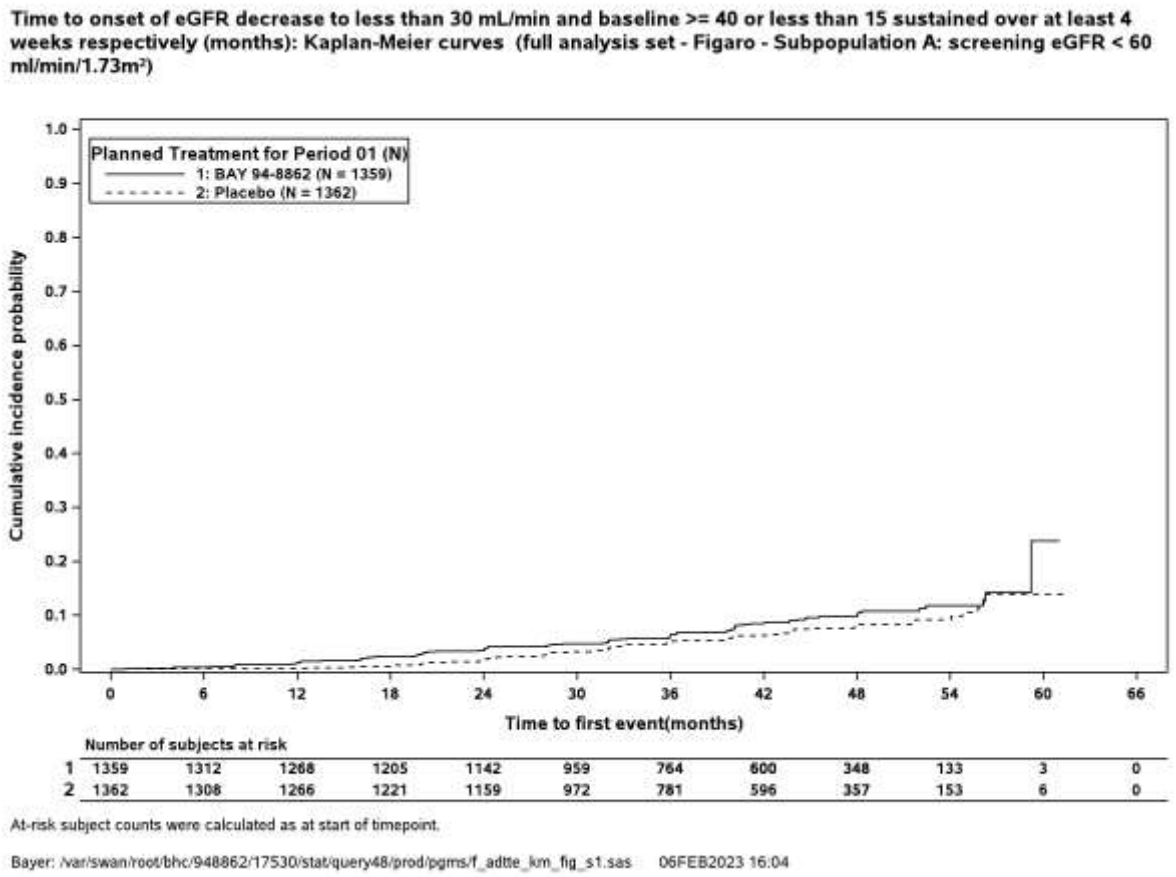


Figure 1.1.2 / 10: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

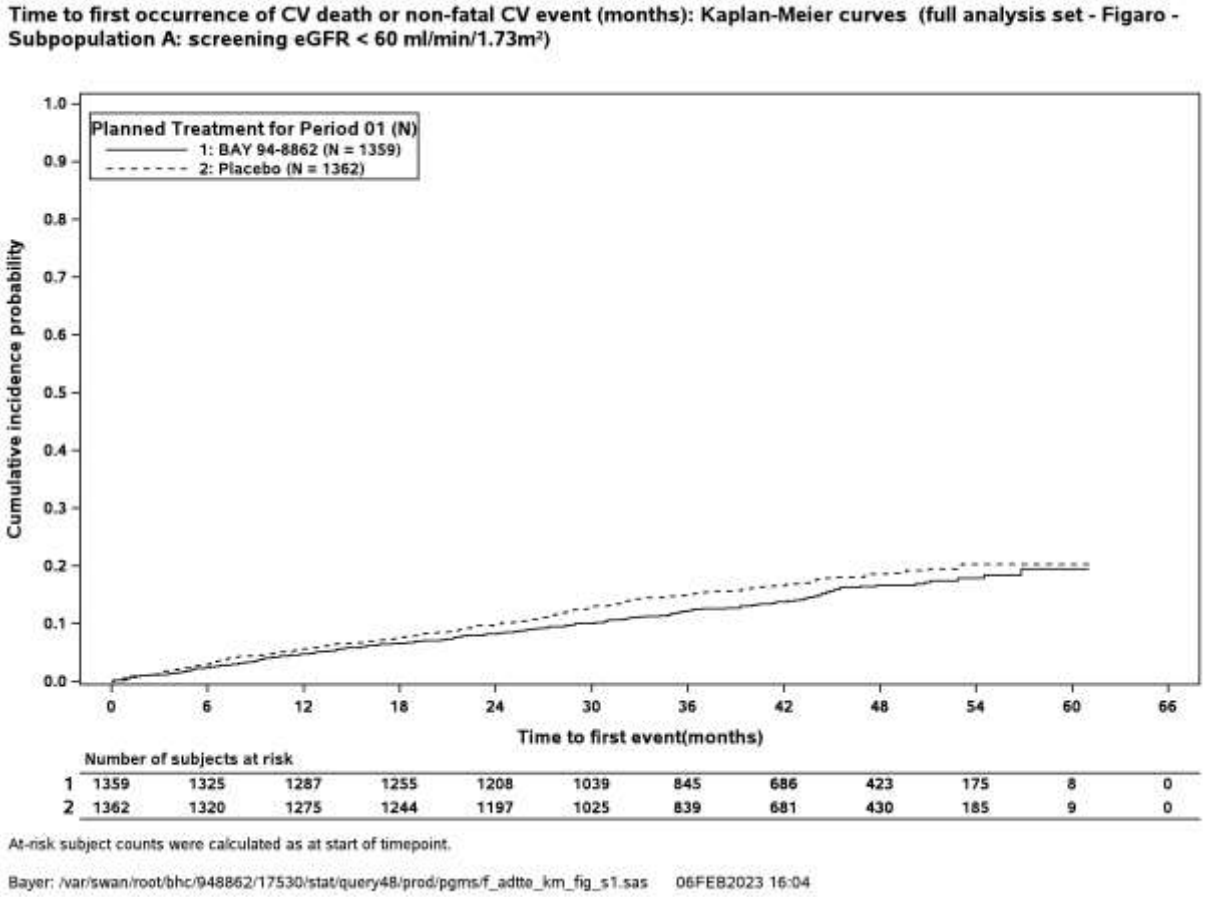


Figure 1.1.2 / 11: Time to CV death (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

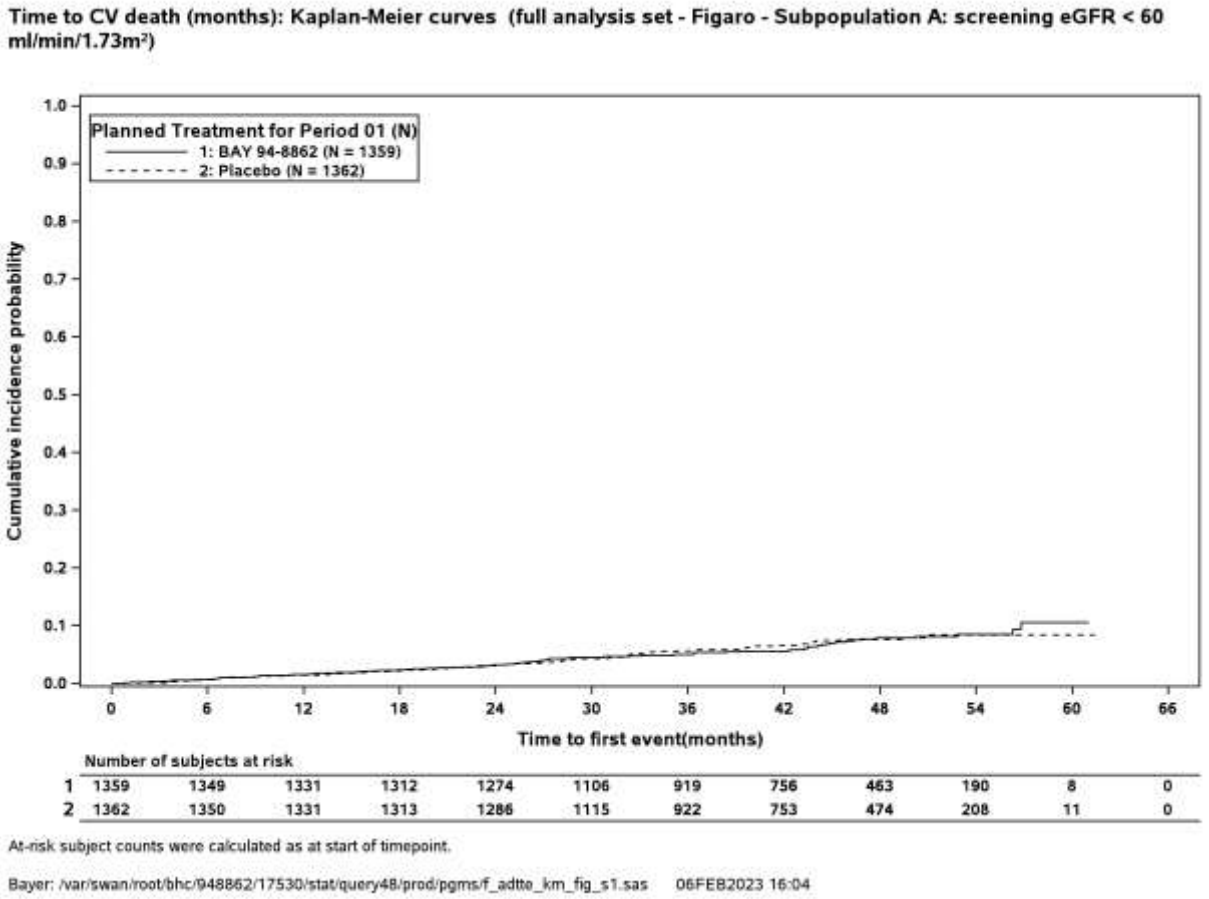


Figure 1.1.2 / 12: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

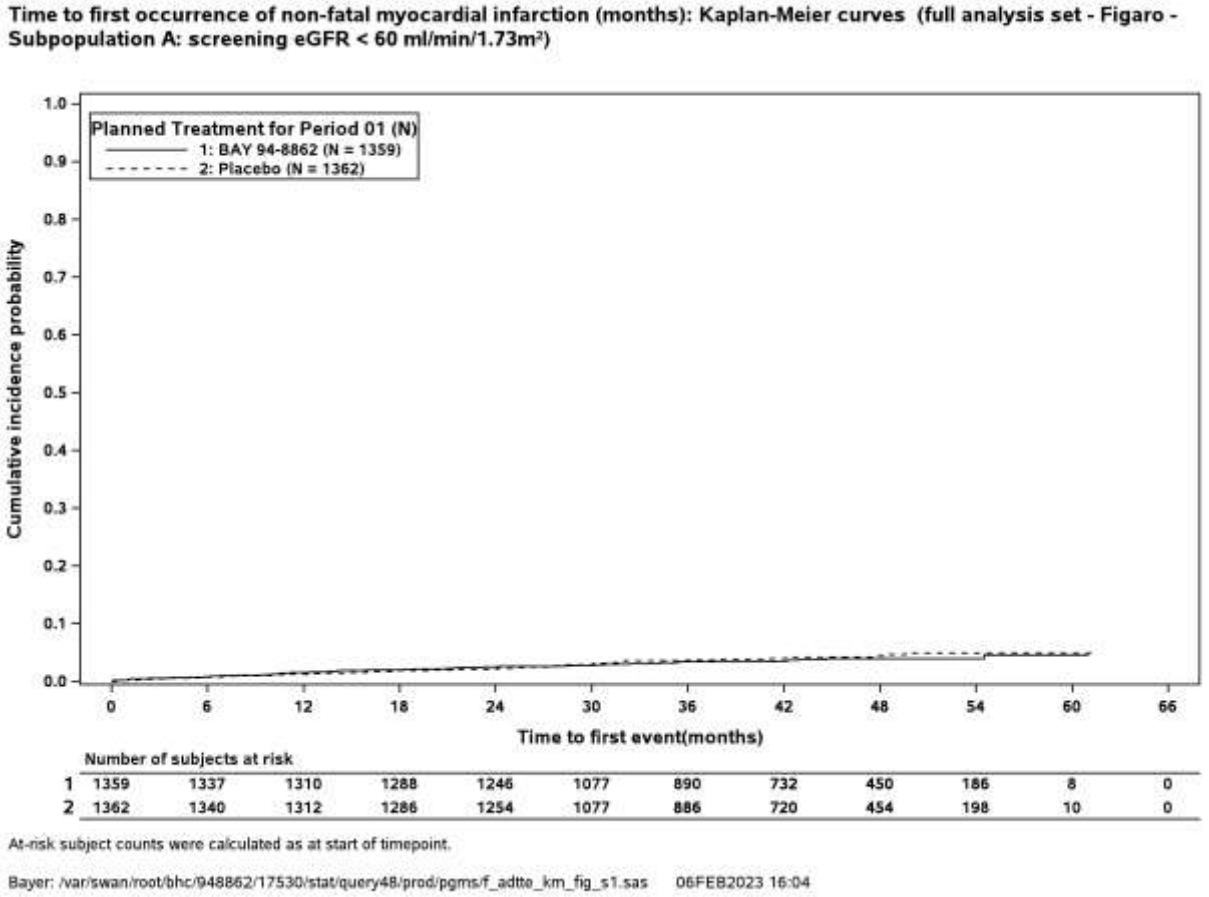


Figure 1.1.2 / 13: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

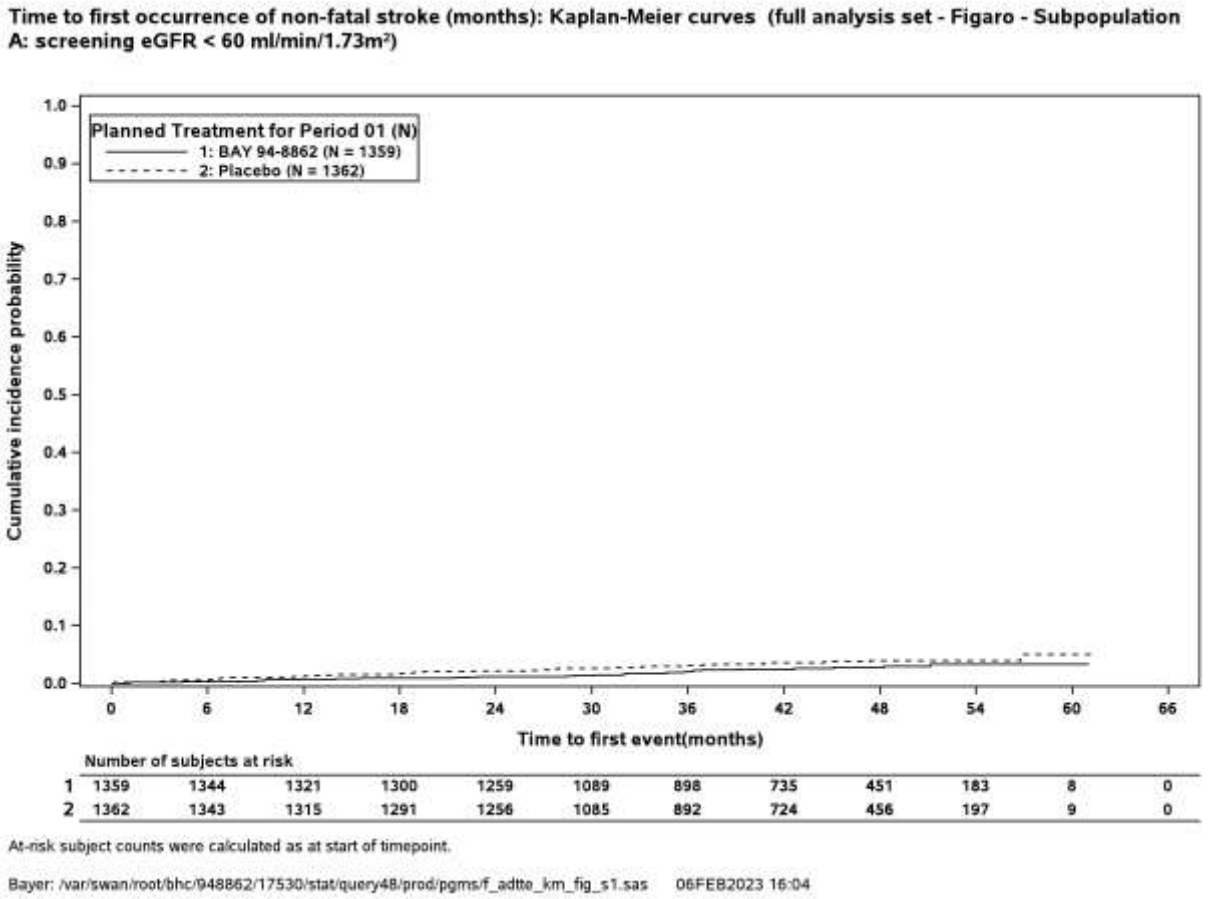


Figure 1.1.2 / 14: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

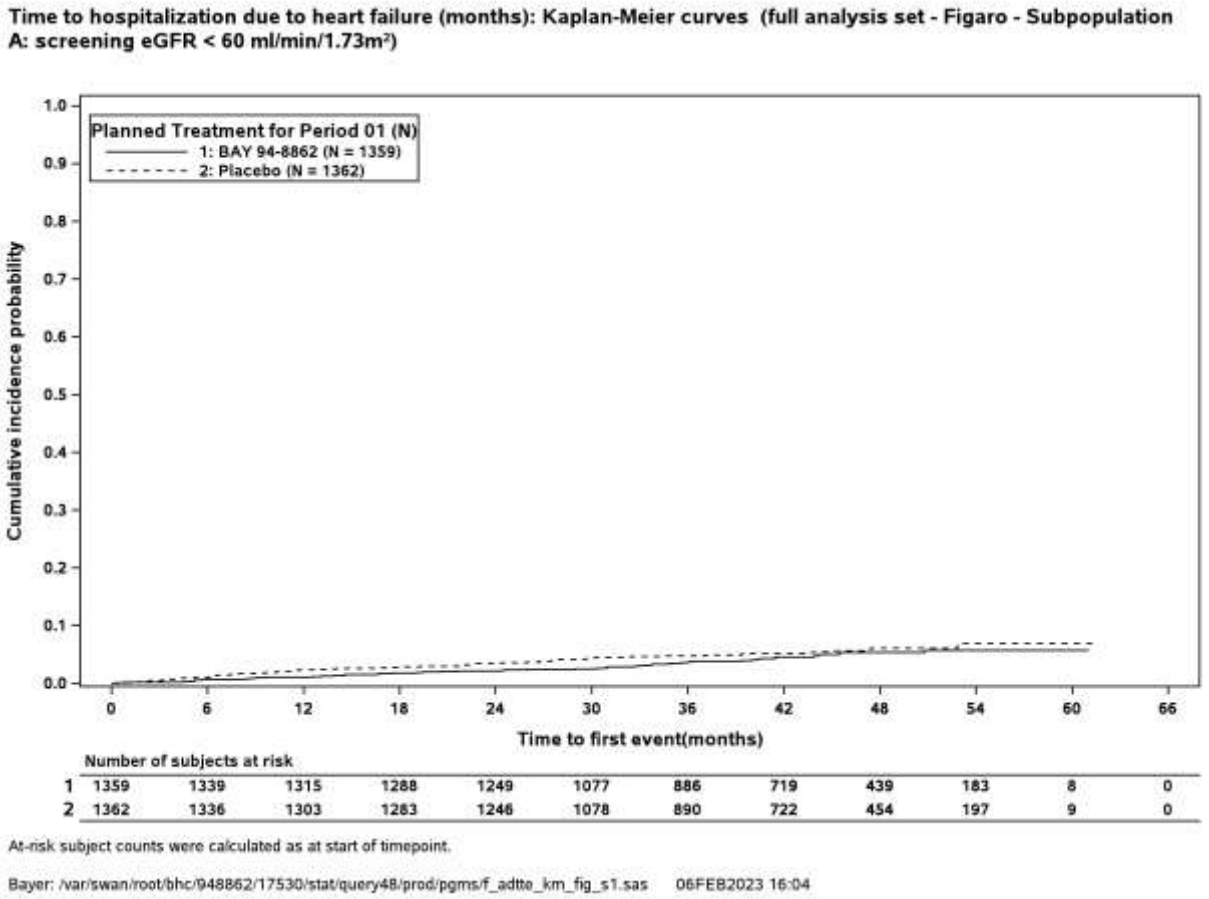


Figure 1.1.2 / 15: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

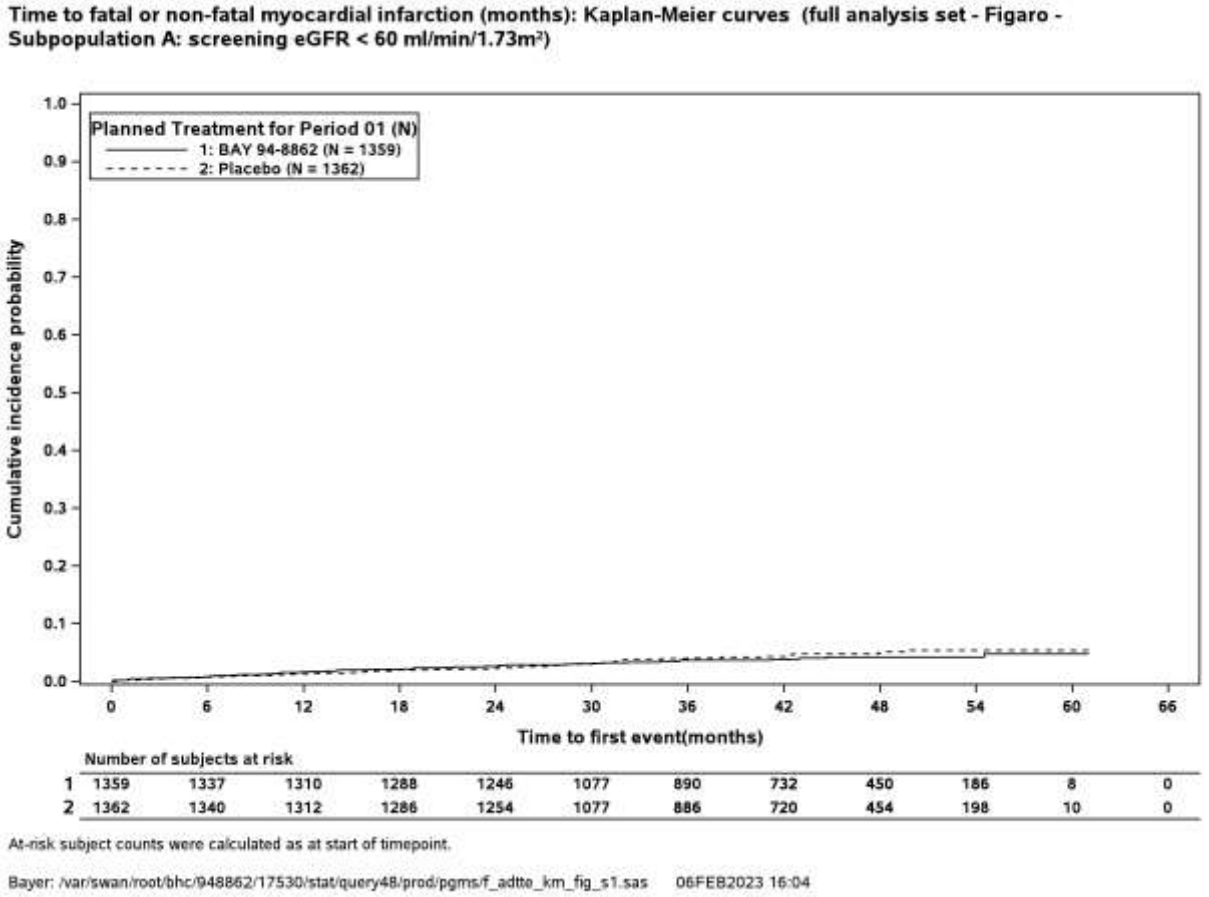


Figure 1.1.2 / 16: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

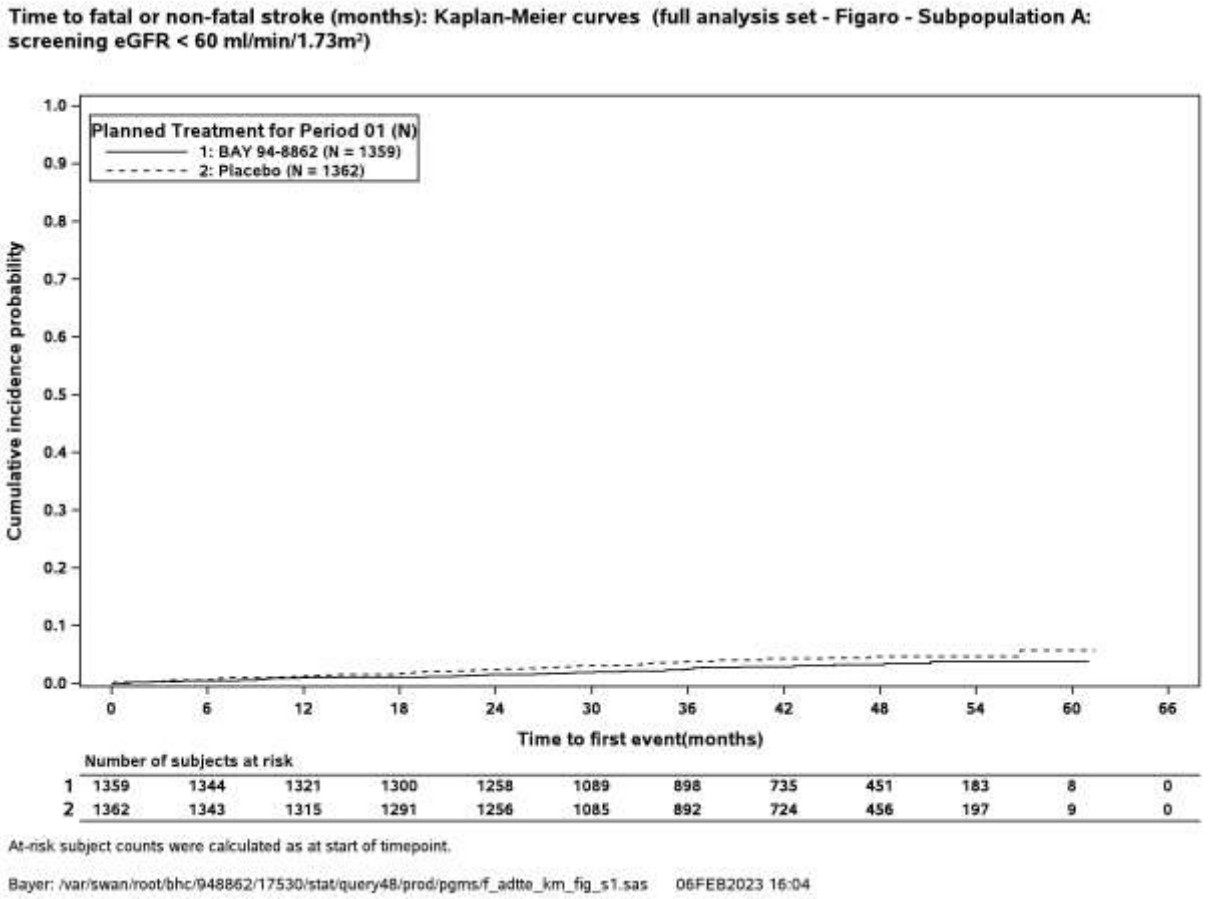


Figure 1.1.2 / 17: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

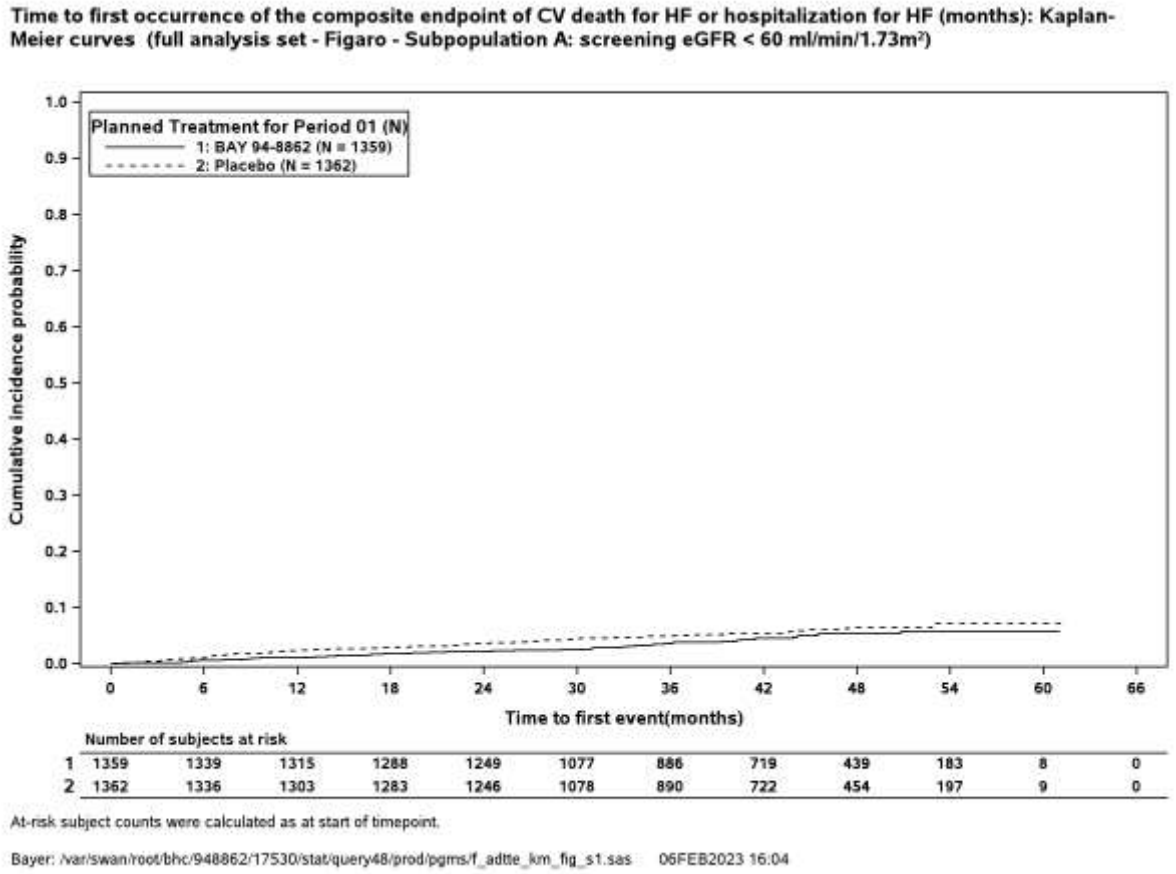


Figure 1.1.2 / 18: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Figaro - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

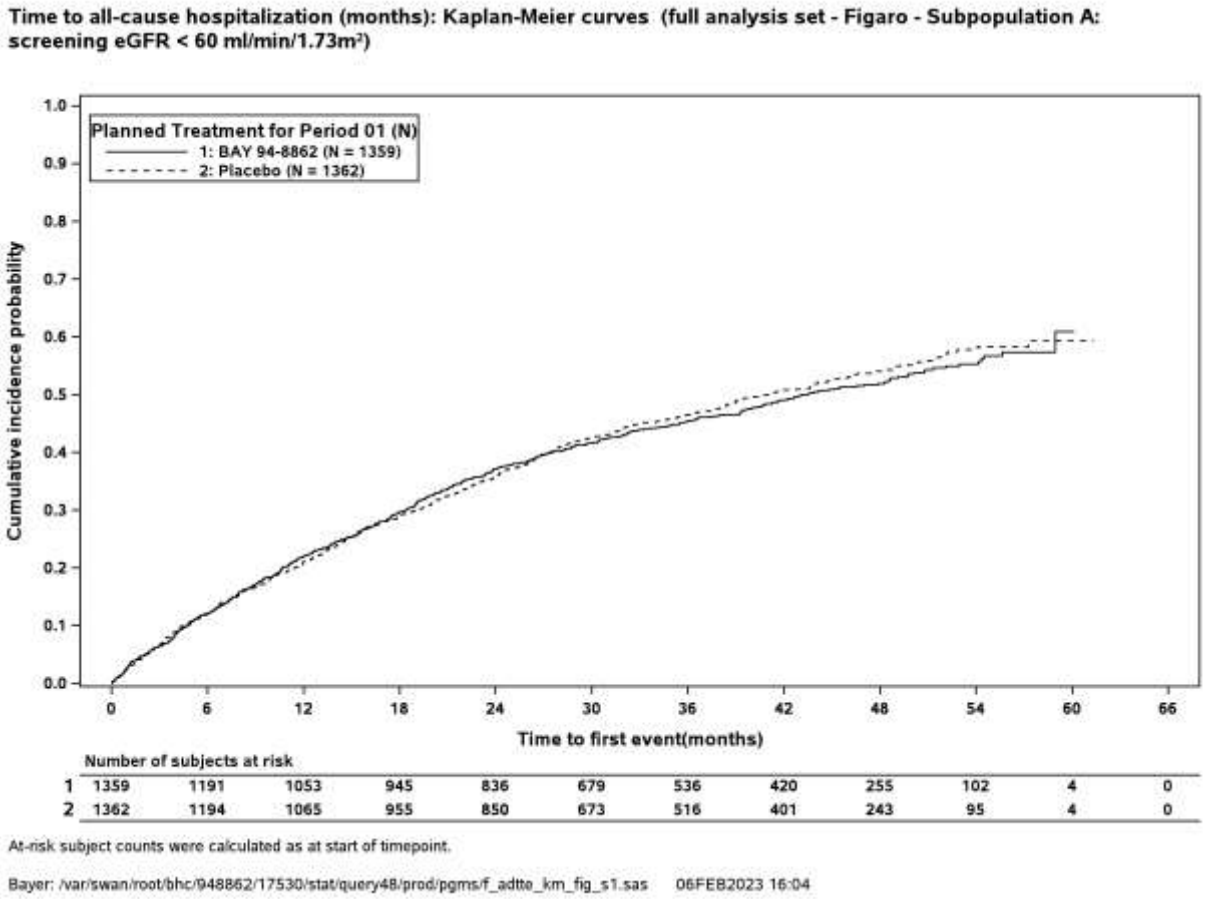


Table A3.1.1: EQ-5D VAS - Return Rate - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1326	1359	97.6%	1330	1362	97.7%	2656	2721	97.6%
Baseline	1326	1359	97.6%	1330	1362	97.7%	2656	2721	97.6%
Visit 5	1234	1359	90.8%	1235	1362	90.7%	2469	2721	90.7%
Visit 8	1112	1359	81.8%	1107	1362	81.3%	2219	2721	81.6%
Visit 11	732	1359	53.9%	732	1362	53.7%	1464	2721	53.8%
Visit 14	320	1359	23.5%	308	1362	22.6%	628	2721	23.1%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1185	1359	87.2%	1212	1362	89.0%	2397	2721	88.1%
Premature discontinuation	52	1359	3.8%	70	1362	5.1%	122	2721	4.5%
End of Study Visit	1006	1359	74.0%	986	1362	72.4%	1992	2721	73.2%

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

Table A3.1.2: KDQoL-36 - Return Rate of Physical Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Baseline	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Visit 5	1228	1359	90.4%	1225	1362	89.9%	2453	2721	90.2%
Visit 8	1110	1359	81.7%	1103	1362	81.0%	2213	2721	81.3%
Visit 11	729	1359	53.6%	729	1362	53.5%	1458	2721	53.6%
Visit 14	316	1359	23.3%	304	1362	22.3%	620	2721	22.8%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1185	1359	87.2%	1211	1362	88.9%	2396	2721	88.1%
Premature discontinuation	51	1359	3.8%	70	1362	5.1%	121	2721	4.4%
End of Study Visit	1000	1359	73.6%	977	1362	71.7%	1977	2721	72.7%

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

Table A3.1.3: KDQoL-36 - Return Rate of Mental Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Baseline	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Visit 5	1228	1359	90.4%	1225	1362	89.9%	2453	2721	90.2%
Visit 8	1110	1359	81.7%	1103	1362	81.0%	2213	2721	81.3%
Visit 11	729	1359	53.6%	729	1362	53.5%	1458	2721	53.6%
Visit 14	316	1359	23.3%	304	1362	22.3%	620	2721	22.8%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1185	1359	87.2%	1211	1362	88.9%	2396	2721	88.1%
Premature discontinuation	51	1359	3.8%	70	1362	5.1%	121	2721	4.4%
End of Study Visit	1000	1359	73.6%	977	1362	71.7%	1977	2721	72.7%

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

Table A3.1.4: KDQoL-36 - Return Rate of Burden of Kidney Disease - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1327	1359	97.6%	1333	1362	97.9%	2660	2721	97.8%
Baseline	1327	1359	97.6%	1333	1362	97.9%	2660	2721	97.8%
Visit 5	1235	1359	90.9%	1231	1362	90.4%	2466	2721	90.6%
Visit 8	1115	1359	82.0%	1110	1362	81.5%	2225	2721	81.8%
Visit 11	732	1359	53.9%	732	1362	53.7%	1464	2721	53.8%
Visit 14	320	1359	23.5%	308	1362	22.6%	628	2721	23.1%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1185	1359	87.2%	1211	1362	88.9%	2396	2721	88.1%
Premature discontinuation	51	1359	3.8%	71	1362	5.2%	122	2721	4.5%
End of Study Visit	1007	1359	74.1%	987	1362	72.5%	1994	2721	73.3%

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

Table A3.1.5: KDQoL-36 - Return Rate of Symptoms and Problems - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1329	1359	97.8%	1335	1362	98.0%	2664	2721	97.9%
Baseline	1329	1359	97.8%	1335	1362	98.0%	2664	2721	97.9%
Visit 5	1235	1359	90.9%	1236	1362	90.7%	2471	2721	90.8%
Visit 8	1113	1359	81.9%	1111	1362	81.6%	2224	2721	81.7%
Visit 11	733	1359	53.9%	732	1362	53.7%	1465	2721	53.8%
Visit 14	320	1359	23.5%	308	1362	22.6%	628	2721	23.1%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1185	1359	87.2%	1212	1362	89.0%	2397	2721	88.1%
Premature discontinuation	52	1359	3.8%	71	1362	5.2%	123	2721	4.5%
End of Study Visit	1006	1359	74.0%	989	1362	72.6%	1995	2721	73.3%

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

Table A3.1.6: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)	Subjects with assessment available	Subjects in subset of FAS	Return rate (%)
Visit 1	1328	1359	97.7%	1333	1362	97.9%	2661	2721	97.8%
Baseline	1328	1359	97.7%	1333	1362	97.9%	2661	2721	97.8%
Visit 5	1236	1359	90.9%	1227	1362	90.1%	2463	2721	90.5%
Visit 8	1112	1359	81.8%	1111	1362	81.6%	2223	2721	81.7%
Visit 11	730	1359	53.7%	732	1362	53.7%	1462	2721	53.7%
Visit 14	320	1359	23.5%	307	1362	22.5%	627	2721	23.0%
Visit 17	1	1359	0.1%	2	1362	0.1%	3	2721	0.1%
Last on-treatment	1184	1359	87.1%	1212	1362	89.0%	2396	2721	88.1%
Premature discontinuation	52	1359	3.8%	70	1362	5.1%	122	2721	4.5%
End of Study Visit	1006	1359	74.0%	985	1362	72.3%	1991	2721	73.2%

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

Table A3.1.7: EQ-5D VAS - Return Rate (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1326	1359	97.6%	1330	1362	97.7%	2656	2721	97.6%
Visit 5	1234	1310	94.2%	1235	1295	95.4%	2469	2605	94.8%
Visit 8	1112	1229	90.5%	1107	1236	89.6%	2219	2465	90.0%
Visit 11	732	852	85.9%	732	860	85.1%	1464	1712	85.5%
Visit 14	320	401	79.8%	308	408	75.5%	628	809	77.6%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	52	65	80.0%	70	77	90.9%	122	142	85.9%
End of Study Visit	1006	1143	88.0%	986	1143	86.3%	1992	2286	87.1%

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

Table A3.1.8: KDQoL-36 - Return Rate of Physical Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Visit 5	1228	1310	93.7%	1225	1295	94.6%	2453	2605	94.2%
Visit 8	1110	1229	90.3%	1103	1236	89.2%	2213	2465	89.8%
Visit 11	729	852	85.6%	729	860	84.8%	1458	1712	85.2%
Visit 14	316	401	78.8%	304	408	74.5%	620	809	76.6%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	51	65	78.5%	70	77	90.9%	121	142	85.2%
End of Study Visit	1000	1143	87.5%	977	1143	85.5%	1977	2286	86.5%

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

Table A3.1.9: KDQoL-36 - Return Rate of Mental Component Summary (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1316	1359	96.8%	1322	1362	97.1%	2638	2721	96.9%
Visit 5	1228	1310	93.7%	1225	1295	94.6%	2453	2605	94.2%
Visit 8	1110	1229	90.3%	1103	1236	89.2%	2213	2465	89.8%
Visit 11	729	852	85.6%	729	860	84.8%	1458	1712	85.2%
Visit 14	316	401	78.8%	304	408	74.5%	620	809	76.6%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	51	65	78.5%	70	77	90.9%	121	142	85.2%
End of Study Visit	1000	1143	87.5%	977	1143	85.5%	1977	2286	86.5%

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

Table A3.1.10: KDQoL-36 - Return Rate of Burden of Kidney Disease (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1327	1359	97.6%	1333	1362	97.9%	2660	2721	97.8%
Visit 5	1235	1310	94.3%	1231	1295	95.1%	2466	2605	94.7%
Visit 8	1115	1229	90.7%	1110	1236	89.8%	2225	2465	90.3%
Visit 11	732	852	85.9%	732	860	85.1%	1464	1712	85.5%
Visit 14	320	401	79.8%	308	408	75.5%	628	809	77.6%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	51	65	78.5%	71	77	92.2%	122	142	85.9%
End of Study Visit	1007	1143	88.1%	987	1143	86.4%	1994	2286	87.2%

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

Table A3.1.11: KDQoL-36 - Return Rate of Symptoms and Problems (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1329	1359	97.8%	1335	1362	98.0%	2664	2721	97.9%
Visit 5	1235	1310	94.3%	1236	1295	95.4%	2471	2605	94.9%
Visit 8	1113	1229	90.6%	1111	1236	89.9%	2224	2465	90.2%
Visit 11	733	852	86.0%	732	860	85.1%	1465	1712	85.6%
Visit 14	320	401	79.8%	308	408	75.5%	628	809	77.6%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	52	65	80.0%	71	77	92.2%	123	142	86.6%
End of Study Visit	1006	1143	88.0%	989	1143	86.5%	1995	2286	87.3%

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

Table A3.1.12: KDQoL-36 - Return Rate of Effects of Kidney Disease on Daily Life (based on subject visits) - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone			Placebo			Total		
	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)	Subjects with assessment available	Subjects with available visit	Return rate (%)
Visit 1	1328	1359	97.7%	1333	1362	97.9%	2661	2721	97.8%
Visit 5	1236	1310	94.4%	1227	1295	94.7%	2463	2605	94.5%
Visit 8	1112	1229	90.5%	1111	1236	89.9%	2223	2465	90.2%
Visit 11	730	852	85.7%	732	860	85.1%	1462	1712	85.4%
Visit 14	320	401	79.8%	307	408	75.2%	627	809	77.5%
Visit 17	1	1	100.0%	2	2	100.0%	3	3	100.0%
Premature discontinuation	52	65	80.0%	70	77	90.9%	122	142	85.9%
End of Study Visit	1006	1143	88.0%	985	1143	86.2%	1991	2286	87.1%

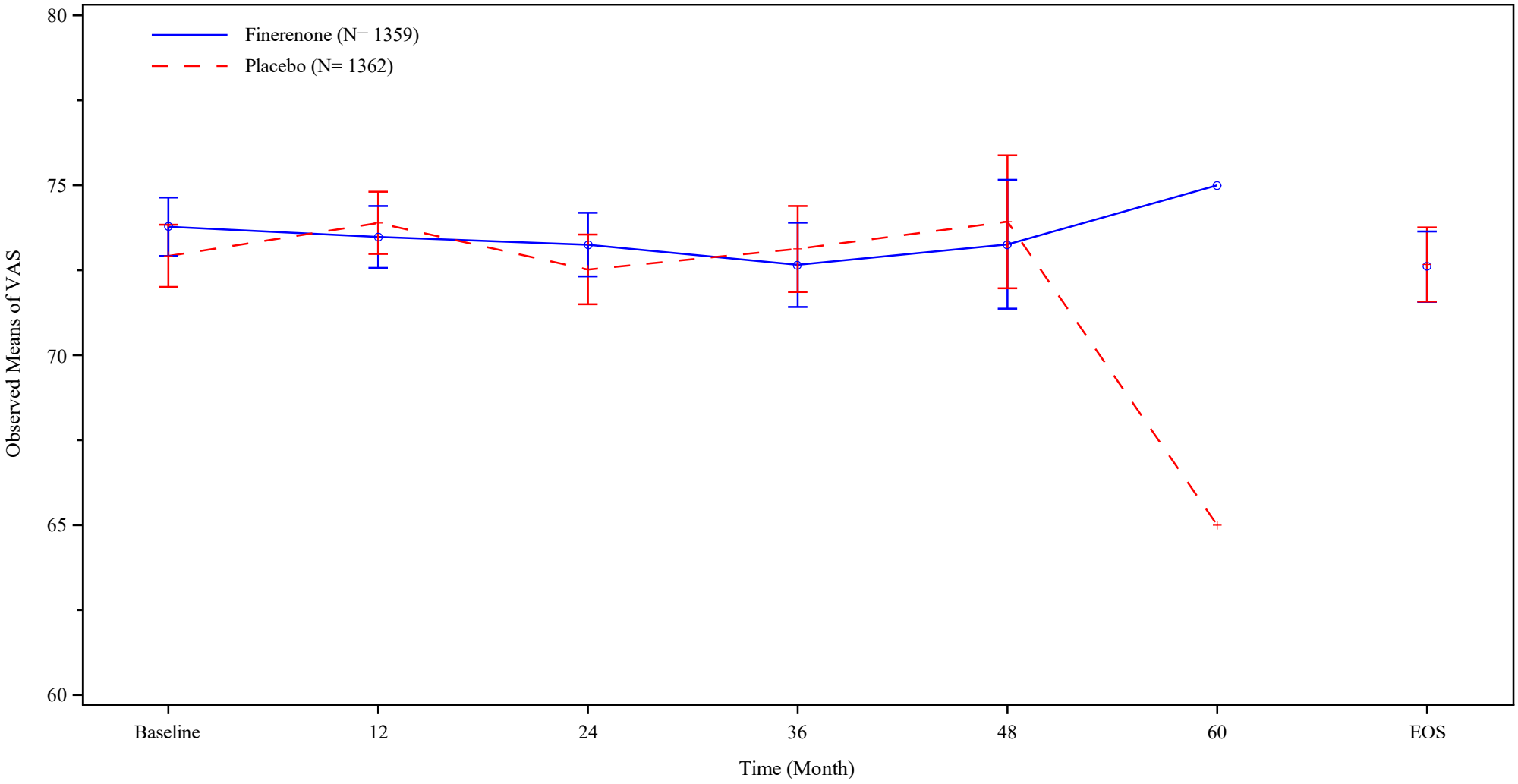
Abbreviations: eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life.
Note: Effects of Kidney Disease on Daily Life uses items 29 to 36 of the KDQoL-36.
Note: Only planned visits - no derived visits such as "Baseline" - are included in this table.

Table A3.2.1: EQ-5D VAS - Observed Means and Change from Baseline - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1326	73.78(15.96)	(72.92, 74.64)	75.00	(0.0, 100.0)	1330	72.92(17.07)	(72.01, 73.84)	75.00	(8.0, 100.0)
Baseline	1326	73.78(15.96)	(72.92, 74.64)	75.00	(0.0, 100.0)	1330	72.92(17.07)	(72.01, 73.84)	75.00	(8.0, 100.0)
Visit 5	1234	73.48(16.32)	(72.57, 74.39)	75.00	(5.0, 100.0)	1235	73.89(16.41)	(72.98, 74.81)	75.00	(0.0, 100.0)
Visit 8	1112	73.25(15.94)	(72.32, 74.19)	75.00	(20.0, 100.0)	1107	72.52(17.44)	(71.50, 73.55)	75.00	(0.0, 100.0)
Visit 11	732	72.66(17.04)	(71.42, 73.90)	75.00	(10.0, 100.0)	732	73.13(17.44)	(71.86, 74.39)	75.00	(0.0, 100.0)
Visit 14	320	73.26(17.22)	(71.37, 75.16)	75.00	(15.0, 100.0)	308	73.93(17.43)	(71.97, 75.88)	80.00	(5.0, 100.0)
Visit 17	1	75.00(-)	(- , -)	75.00	(75.0, 75.0)	2	65.00(21.21)	(-125.59, 255.59)	65.00	(50.0, 80.0)
Last On-Treatment	1185	72.69(16.84)	(71.73, 73.65)	75.00	(5.0, 100.0)	1212	72.07(17.64)	(71.07, 73.06)	75.00	(0.0, 100.0)
Premature Discontinuation	52	68.46(17.92)	(63.47, 73.45)	70.00	(0.0, 95.0)	70	65.60(17.87)	(61.34, 69.86)	70.00	(10.0, 95.0)
End Of Study Visit	1006	72.61(16.79)	(71.57, 73.64)	75.00	(10.0, 100.0)	986	72.67(17.51)	(71.58, 73.76)	75.00	(2.0, 100.0)
Change from Baseline										
Visit 5	1223	-0.51(15.43)	(-1.38, 0.35)	0.00	(-75.0, 70.0)	1216	0.59(16.22)	(-0.32, 1.50)	0.00	(-95.0, 92.0)
Visit 8	1097	-0.98(15.79)	(-1.92, -0.05)	0.00	(-60.0, 80.0)	1088	-0.71(16.68)	(-1.70, 0.28)	0.00	(-90.0, 62.0)
Visit 11	721	-1.86(16.78)	(-3.08, -0.63)	0.00	(-70.0, 81.0)	717	-1.25(16.71)	(-2.47, -0.02)	0.00	(-80.0, 52.0)
Visit 14	316	-1.90(17.26)	(-3.81, 0.01)	0.00	(-75.0, 45.0)	301	-0.97(18.01)	(-3.02, 1.07)	0.00	(-80.0, 72.0)
Visit 17	1	0.00(-)	(- , -)	0.00	(0.0, 0.0)	2	-5.00(21.21)	(-195.59, 185.59)	-5.00	(-20.0, 10.0)
Last On-Treatment	1170	-1.61(16.97)	(-2.58, -0.64)	0.00	(-80.0, 81.0)	1192	-1.16(16.83)	(-2.11, -0.20)	0.00	(-95.0, 72.0)
Premature Discontinuation	52	-6.38(18.03)	(-11.40, -1.37)	-5.00	(-50.0, 25.0)	70	-10.50(19.76)	(-15.21, -5.79)	-10.00	(-70.0, 40.0)
End Of Study Visit	992	-1.92(16.76)	(-2.97, -0.88)	0.00	(-80.0, 75.0)	968	-1.35(16.85)	(-2.42, -0.29)	0.00	(-60.0, 72.0)

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

Figure A3.2.1: EQ-5D VAS - Time Profile Curve
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



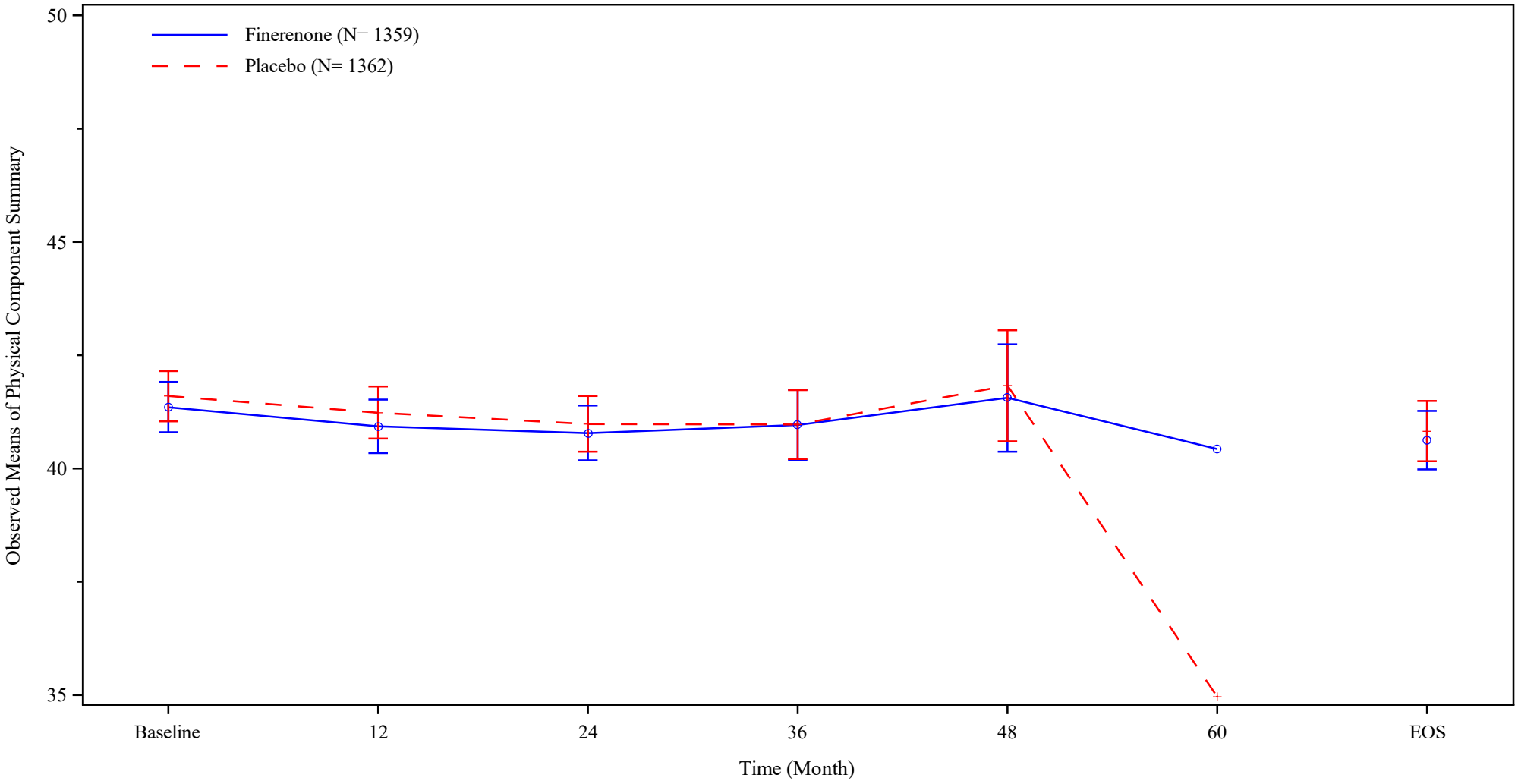
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, EQ-5D=EuroQOL group 5-dimension, N=number of patients, VAS=Visual analog scale.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.2: KDQoL-36 - Observed Means and Change from Baseline of Physical Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1316	41.35(10.22)	(40.80, 41.91)	42.25	(12.6, 64.0)	1322	41.60(10.30)	(41.04, 42.15)	42.73	(14.5, 60.4)
Baseline	1316	41.35(10.22)	(40.80, 41.91)	42.25	(12.6, 64.0)	1322	41.60(10.30)	(41.04, 42.15)	42.73	(14.5, 60.4)
Visit 5	1228	40.93(10.55)	(40.34, 41.52)	41.74	(11.0, 61.9)	1225	41.23(10.27)	(40.66, 41.81)	41.71	(14.2, 63.5)
Visit 8	1110	40.78(10.29)	(40.18, 41.39)	41.24	(14.7, 61.0)	1103	40.98(10.41)	(40.37, 41.60)	41.26	(14.6, 61.2)
Visit 11	729	40.96(10.65)	(40.19, 41.74)	42.19	(14.3, 59.0)	729	40.97(10.42)	(40.21, 41.73)	41.26	(14.6, 62.6)
Visit 14	316	41.56(10.68)	(40.37, 42.74)	42.86	(17.8, 64.2)	304	41.83(10.85)	(40.60, 43.05)	42.01	(13.4, 61.8)
Visit 17	1	40.43(-)	(- , -)	40.43	(40.4, 40.4)	2	34.96(19.11)	(-136.72, 206.63)	34.96	(21.4, 48.5)
Last On-Treatment	1185	40.65(10.23)	(40.06, 41.23)	40.99	(14.4, 61.2)	1211	40.50(10.65)	(39.90, 41.10)	41.12	(13.4, 63.5)
Premature Discontinuation	51	39.69(10.45)	(36.75, 42.63)	40.89	(20.1, 57.1)	70	38.83(10.08)	(36.42, 41.23)	39.68	(19.2, 61.3)
End Of Study Visit	1000	40.63(10.39)	(39.98, 41.27)	40.74	(14.0, 61.2)	977	40.82(10.65)	(40.16, 41.49)	41.62	(16.1, 61.4)
Change from Baseline										
Visit 5	1212	-0.63(8.85)	(-1.13, -0.14)	-0.31	(-30.5, 32.5)	1200	-0.60(8.49)	(-1.08, -0.12)	-0.06	(-34.2, 31.5)
Visit 8	1089	-1.06(9.12)	(-1.60, -0.51)	-0.47	(-30.5, 33.1)	1076	-1.20(9.10)	(-1.74, -0.65)	-0.42	(-36.5, 33.2)
Visit 11	713	-1.42(9.41)	(-2.11, -0.73)	-0.70	(-38.5, 32.2)	708	-2.16(9.18)	(-2.83, -1.48)	-1.25	(-40.1, 36.3)
Visit 14	310	-1.65(9.40)	(-2.70, -0.60)	-1.05	(-35.3, 27.0)	294	-2.01(8.99)	(-3.04, -0.98)	-0.99	(-33.1, 23.4)
Visit 17	1	-3.38(-)	(- , -)	-3.38	(-3.4, -3.4)	2	1.06(14.75)	(-131.49, 133.61)	1.06	(-9.4, 11.5)
Last On-Treatment	1163	-1.19(9.16)	(-1.72, -0.66)	-0.41	(-30.1, 32.5)	1181	-1.31(9.34)	(-1.84, -0.77)	-0.58	(-35.3, 28.5)
Premature Discontinuation	50	-0.09(9.62)	(-2.82, 2.65)	0.46	(-24.5, 23.1)	70	-3.48(9.72)	(-5.80, -1.17)	-1.45	(-26.5, 21.5)
End Of Study Visit	983	-1.61(9.18)	(-2.18, -1.03)	-0.78	(-31.4, 27.4)	955	-1.55(9.75)	(-2.16, -0.93)	-0.63	(-35.9, 26.3)

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

Figure A3.2.2: KDQoL-36 - Time Profile Curve of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



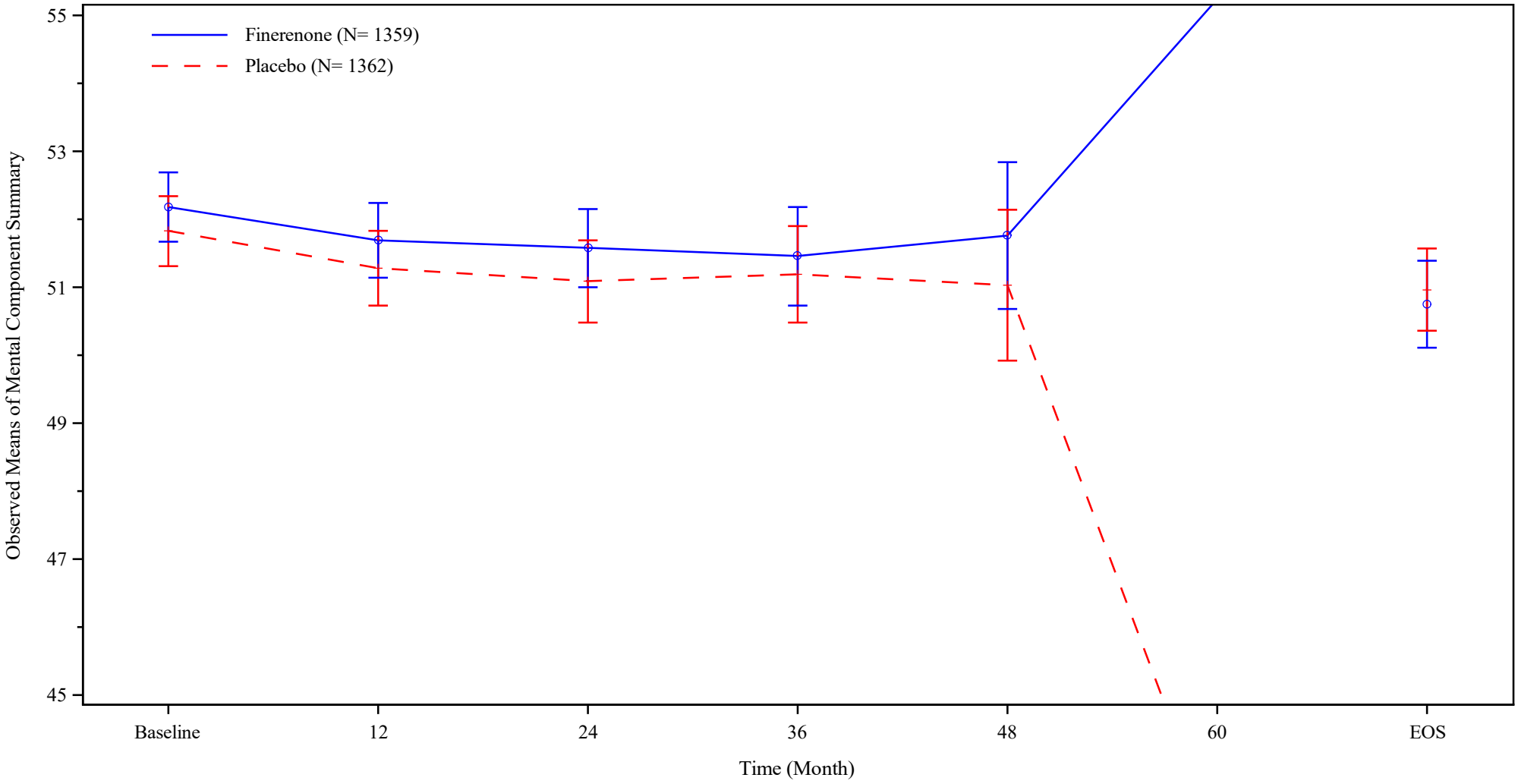
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.3: KDQoL-36 - Observed Means and Change from Baseline of Mental Component Summary - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1316	52.18(9.39)	(51.67, 52.69)	55.04	(20.4, 71.8)	1322	51.83(9.59)	(51.31, 52.34)	54.29	(13.6, 70.4)
Baseline	1316	52.18(9.39)	(51.67, 52.69)	55.04	(20.4, 71.8)	1322	51.83(9.59)	(51.31, 52.34)	54.29	(13.6, 70.4)
Visit 5	1228	51.69(9.83)	(51.14, 52.24)	54.27	(15.5, 70.9)	1225	51.28(9.88)	(50.73, 51.83)	53.77	(16.1, 70.1)
Visit 8	1110	51.58(9.76)	(51.00, 52.15)	54.51	(15.7, 70.9)	1103	51.09(10.31)	(50.48, 51.69)	53.74	(12.5, 71.0)
Visit 11	729	51.46(9.95)	(50.73, 52.18)	54.08	(15.0, 71.2)	729	51.19(9.81)	(50.48, 51.90)	53.34	(16.5, 68.8)
Visit 14	316	51.76(9.74)	(50.68, 52.84)	54.34	(19.7, 67.7)	304	51.03(9.81)	(49.92, 52.14)	53.59	(10.1, 65.8)
Visit 17	1	55.24(-)	(- , -)	55.24	(55.2, 55.2)	2	42.81(1.57)	(28.70, 56.93)	42.81	(41.7, 43.9)
Last On-Treatment	1185	51.15(10.10)	(50.58, 51.73)	53.65	(15.7, 71.2)	1211	50.57(9.99)	(50.01, 51.13)	52.56	(15.0, 69.2)
Premature Discontinuation	51	48.38(11.61)	(45.11, 51.64)	50.71	(19.3, 64.5)	70	48.15(10.85)	(45.56, 50.74)	49.99	(16.7, 65.3)
End Of Study Visit	1000	50.75(10.33)	(50.11, 51.39)	53.38	(21.6, 70.3)	977	50.96(9.63)	(50.36, 51.57)	52.58	(16.6, 69.2)
Change from Baseline										
Visit 5	1212	-0.61(10.07)	(-1.18, -0.04)	-0.03	(-37.1, 37.9)	1200	-0.66(9.73)	(-1.22, -0.11)	-0.45	(-43.1, 40.3)
Visit 8	1089	-0.73(10.04)	(-1.33, -0.13)	-0.10	(-39.3, 37.2)	1076	-0.95(9.94)	(-1.54, -0.36)	-0.48	(-37.8, 39.5)
Visit 11	713	-1.11(10.68)	(-1.89, -0.32)	0.00	(-45.8, 28.7)	708	-1.34(10.12)	(-2.08, -0.59)	-0.37	(-33.2, 34.9)
Visit 14	310	-1.64(10.69)	(-2.83, -0.45)	-0.87	(-38.1, 26.3)	294	-2.46(9.63)	(-3.56, -1.35)	-1.09	(-45.9, 28.2)
Visit 17	1	-6.89(-)	(- , -)	-6.89	(-6.9, -6.9)	2	-3.63(2.80)	(-28.83, 21.56)	-3.63	(-5.6, -1.7)
Last On-Treatment	1163	-1.22(10.53)	(-1.83, -0.61)	-0.46	(-39.0, 41.1)	1181	-1.39(10.09)	(-1.97, -0.82)	-0.82	(-40.2, 36.7)
Premature Discontinuation	50	-3.96(12.37)	(-7.48, -0.45)	-1.05	(-33.0, 23.3)	70	-3.63(10.39)	(-6.11, -1.16)	-2.69	(-29.9, 17.4)
End Of Study Visit	983	-1.39(10.79)	(-2.07, -0.72)	-0.51	(-41.1, 41.1)	955	-1.15(10.06)	(-1.79, -0.52)	-0.68	(-40.2, 35.7)

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

Figure A3.2.3: KDQoL-36 - Time Profile Curve of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



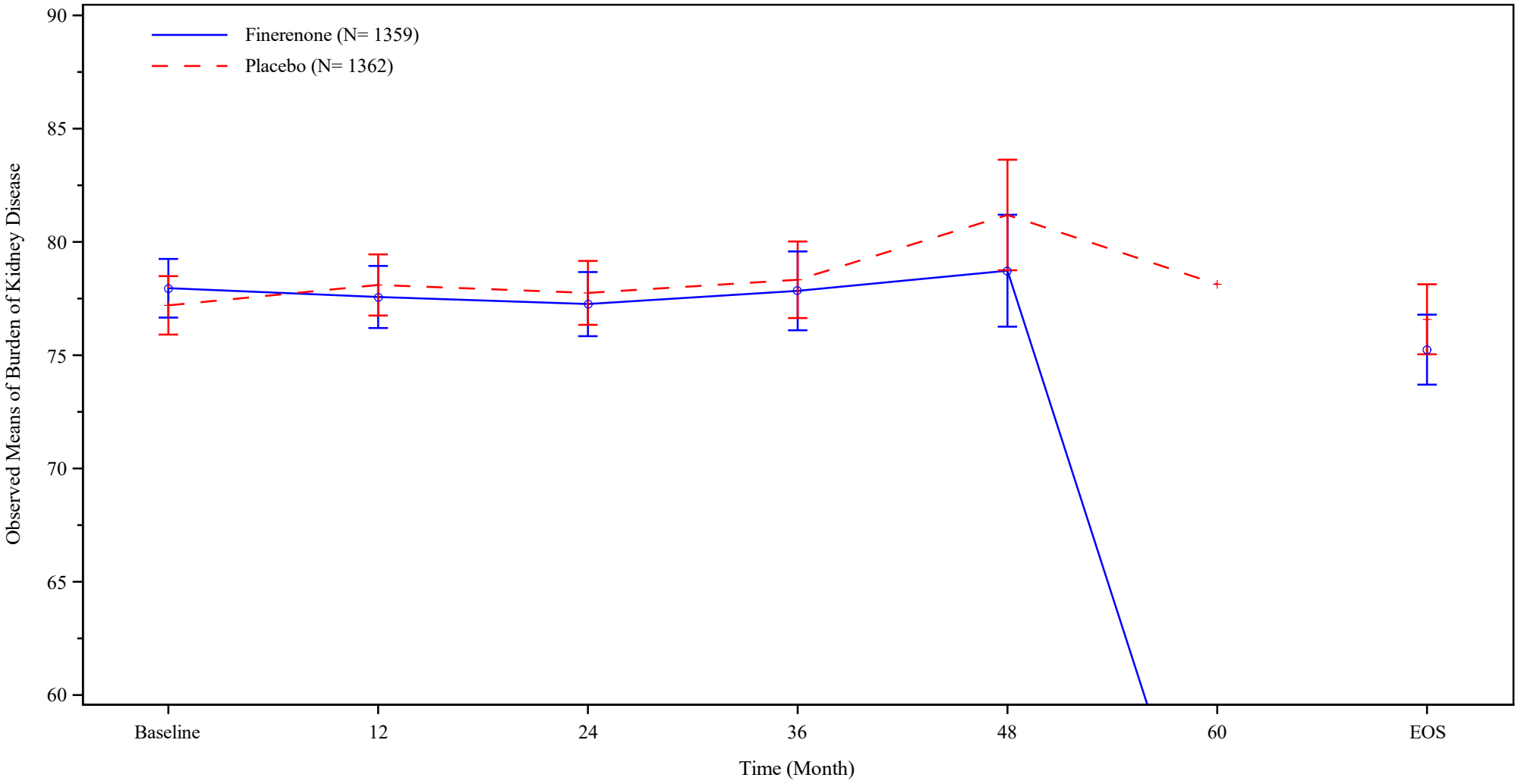
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.4: KDQoL-36 - Observed Means and Change from Baseline of Burden of Kidney Disease - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1327	77.96(24.02)	(76.66, 79.25)	87.50	(0.0, 100.0)	1333	77.20(24.07)	(75.91, 78.49)	81.25	(0.0, 100.0)
Baseline	1327	77.96(24.02)	(76.66, 79.25)	87.50	(0.0, 100.0)	1333	77.20(24.07)	(75.91, 78.49)	81.25	(0.0, 100.0)
Visit 5	1235	77.57(24.48)	(76.20, 78.94)	87.50	(0.0, 100.0)	1231	78.10(24.12)	(76.75, 79.45)	87.50	(0.0, 100.0)
Visit 8	1115	77.26(24.08)	(75.84, 78.67)	81.25	(0.0, 100.0)	1110	77.75(23.93)	(76.34, 79.16)	81.25	(0.0, 100.0)
Visit 11	732	77.84(23.98)	(76.10, 79.58)	87.50	(0.0, 100.0)	732	78.33(23.31)	(76.64, 80.02)	81.25	(0.0, 100.0)
Visit 14	320	78.73(22.45)	(76.26, 81.20)	84.38	(12.5, 100.0)	308	81.19(21.79)	(78.75, 83.63)	87.50	(0.0, 100.0)
Visit 17	1	50.00(-)	(- , -)	50.00	(50.0, 50.0)	2	78.13(30.94)	(-199.82, 356.07)	78.13	(56.3, 100.0)
Last On-Treatment	1185	76.48(24.34)	(75.09, 77.87)	81.25	(0.0, 100.0)	1211	76.14(24.83)	(74.74, 77.54)	81.25	(0.0, 100.0)
Premature Discontinuation	51	68.26(26.69)	(60.75, 75.77)	75.00	(0.0, 100.0)	71	76.50(26.00)	(70.34, 82.65)	81.25	(0.0, 100.0)
End Of Study Visit	1007	75.24(24.97)	(73.70, 76.79)	81.25	(0.0, 100.0)	987	76.58(24.72)	(75.04, 78.13)	81.25	(0.0, 100.0)
Change from Baseline										
Visit 5	1225	-0.20(23.76)	(-1.54, 1.13)	0.00	(-100.0, 100.0)	1215	0.62(23.22)	(-0.68, 1.93)	0.00	(-100.0, 100.0)
Visit 8	1102	-0.64(24.42)	(-2.09, 0.80)	0.00	(-87.5, 100.0)	1092	-0.19(24.43)	(-1.64, 1.27)	0.00	(-100.0, 100.0)
Visit 11	721	-0.73(24.85)	(-2.55, 1.09)	0.00	(-100.0, 100.0)	717	-0.94(23.95)	(-2.70, 0.81)	0.00	(-100.0, 100.0)
Visit 14	315	-3.06(23.46)	(-5.66, -0.45)	0.00	(-75.0, 100.0)	301	-0.66(24.48)	(-3.44, 2.11)	0.00	(-75.0, 100.0)
Visit 17	1	0.00(-)	(- , -)	0.00	(0.0, 0.0)	2	-15.63(22.10)	(-214.16, 182.91)	-15.63	(-31.3, 0.0)
Last On-Treatment	1171	-1.62(25.68)	(-3.09, -0.14)	0.00	(-100.0, 100.0)	1192	-1.16(25.42)	(-2.61, 0.28)	0.00	(-100.0, 100.0)
Premature Discontinuation	51	-7.60(24.82)	(-14.58, -0.62)	0.00	(-75.0, 56.3)	71	-4.84(23.75)	(-10.46, 0.78)	0.00	(-81.3, 43.8)
End Of Study Visit	995	-2.93(26.05)	(-4.55, -1.31)	0.00	(-100.0, 100.0)	970	-0.90(25.61)	(-2.51, 0.72)	0.00	(-100.0, 93.8)

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

Figure A3.2.4: KDQoL-36 - Time Profile Curve of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



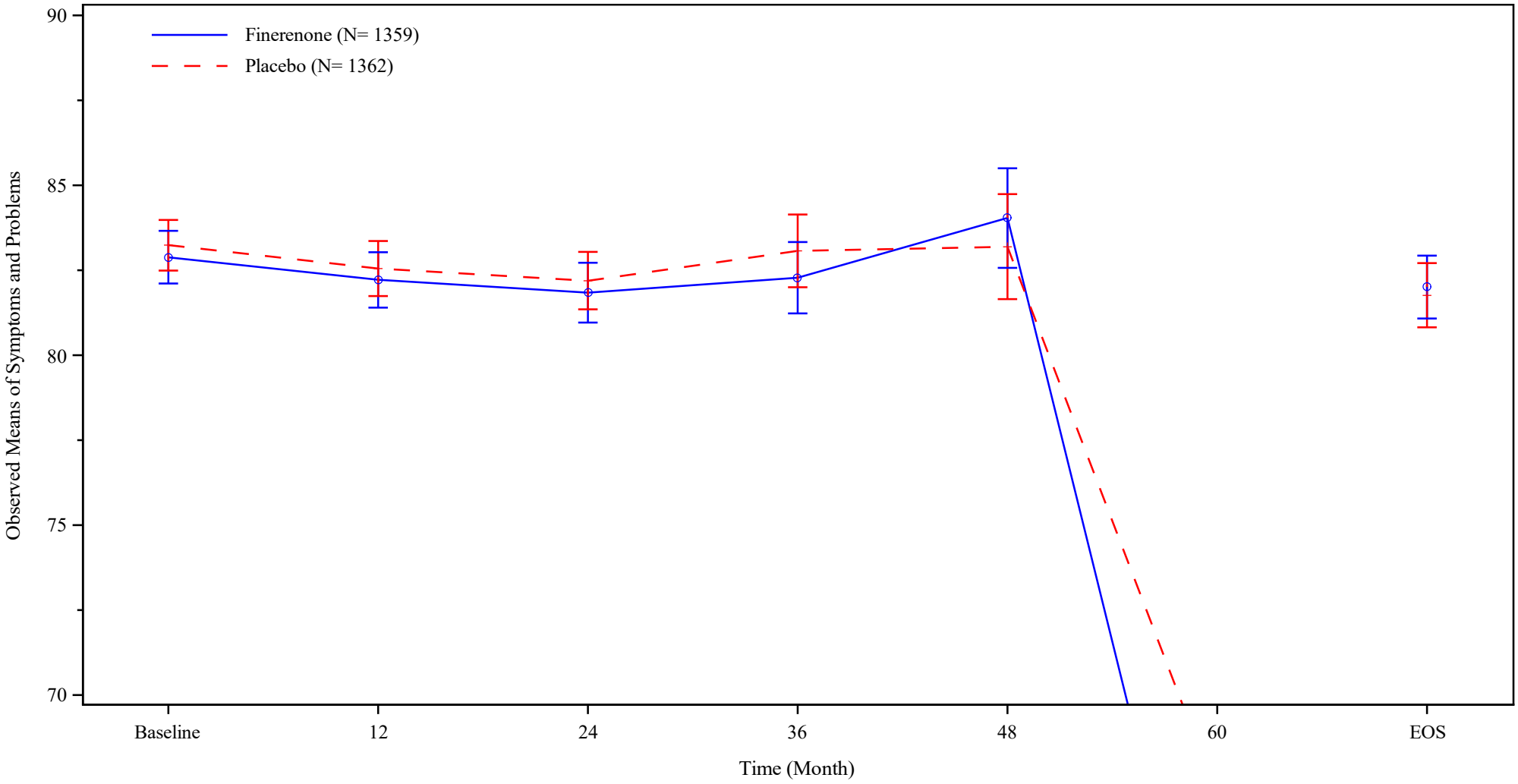
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.5: KDQoL-36 - Observed Means and Change from Baseline of Symptoms and Problems - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1329	82.88(14.36)	(82.11, 83.66)	86.36	(15.9, 100.0)	1335	83.24(13.95)	(82.49, 83.98)	86.36	(2.3, 100.0)
Baseline	1329	82.88(14.36)	(82.11, 83.66)	86.36	(15.9, 100.0)	1335	83.24(13.95)	(82.49, 83.98)	86.36	(2.3, 100.0)
Visit 5	1235	82.22(14.59)	(81.40, 83.03)	86.36	(2.3, 100.0)	1236	82.55(14.54)	(81.74, 83.36)	86.36	(25.0, 100.0)
Visit 8	1113	81.84(14.93)	(80.96, 82.72)	86.36	(4.5, 100.0)	1111	82.19(14.34)	(81.35, 83.04)	86.36	(18.2, 100.0)
Visit 11	733	82.28(14.46)	(81.23, 83.33)	86.36	(15.9, 100.0)	732	83.07(14.73)	(82.00, 84.14)	86.36	(0.0, 100.0)
Visit 14	320	84.04(13.35)	(82.57, 85.50)	86.36	(25.0, 100.0)	308	83.19(13.79)	(81.65, 84.74)	86.36	(22.7, 100.0)
Visit 17	1	59.09(-)	(- , -)	59.09	(59.1, 59.1)	2	67.05(36.96)	(-265.05, 399.14)	67.05	(40.9, 93.2)
Last On-Treatment	1185	82.06(14.53)	(81.24, 82.89)	84.09	(20.5, 100.0)	1212	82.08(15.06)	(81.23, 82.93)	86.36	(0.0, 100.0)
Premature Discontinuation	52	82.51(13.94)	(78.63, 86.39)	85.23	(10.4, 100.0)	71	79.99(16.00)	(76.20, 83.77)	81.82	(27.3, 100.0)
End Of Study Visit	1006	82.01(14.98)	(81.08, 82.93)	86.36	(25.0, 100.0)	989	81.76(15.11)	(80.82, 82.71)	84.09	(0.0, 100.0)
Change from Baseline										
Visit 5	1226	-0.82(11.60)	(-1.47, -0.17)	0.00	(-54.5, 52.3)	1221	-1.00(11.75)	(-1.66, -0.34)	0.00	(-61.4, 61.4)
Visit 8	1101	-1.54(12.20)	(-2.26, -0.82)	0.00	(-65.9, 54.5)	1095	-1.57(12.17)	(-2.29, -0.85)	0.00	(-68.2, 72.7)
Visit 11	722	-1.85(11.73)	(-2.71, -0.99)	-2.27	(-45.5, 38.6)	719	-1.63(12.99)	(-2.59, -0.68)	0.00	(-90.9, 43.2)
Visit 14	315	-1.60(11.37)	(-2.86, -0.34)	0.00	(-31.8, 40.9)	302	-2.59(12.03)	(-3.96, -1.23)	-2.27	(-70.5, 40.9)
Visit 17	1	-27.27(-)	(- , -)	-27.27	(-27.3, -27.3)	2	-13.64(22.50)	(-215.78, 188.51)	-13.64	(-29.5, 2.3)
Last On-Treatment	1172	-1.35(12.96)	(-2.10, -0.61)	0.00	(-54.5, 75.0)	1195	-1.39(13.09)	(-2.14, -0.65)	0.00	(-95.5, 61.4)
Premature Discontinuation	52	-3.75(13.80)	(-7.59, 0.09)	0.00	(-62.3, 43.2)	71	-4.48(13.61)	(-7.71, -1.26)	-2.27	(-61.4, 25.4)
End Of Study Visit	995	-1.39(13.41)	(-2.22, -0.55)	0.00	(-52.3, 75.0)	975	-1.77(13.45)	(-2.62, -0.93)	0.00	(-95.5, 52.3)

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

Figure A3.2.5: KDQoL-36 - Time Profile Curve of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



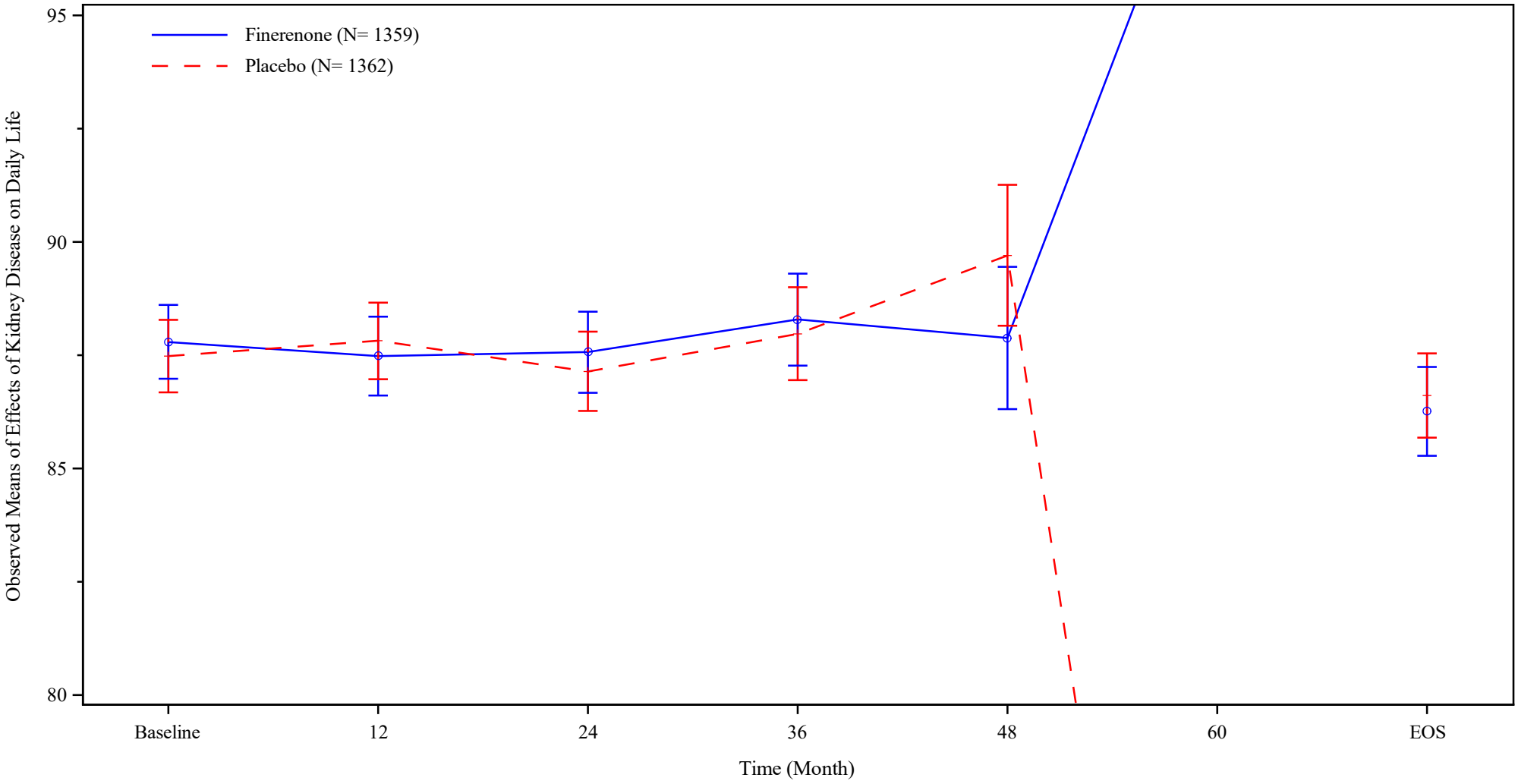
Abbreviations: eGFR=estimated glomerular filtration rate, EOS=End of Study, KDQoL=Kidney Disease Quality of Life, N=number of patients.
Note: Mean and 95% confidence interval limits are shown. Confidence limits are only shown for timepoints with n>10 per treatment group.

Table A3.2.6: KDQoL-36 - Observed Means and Change from Baseline of Effects of Kidney Disease on Daily Life - Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)					Placebo (N=1362)				
Analysis Visit	n	Mean(SD)	95% CI	Median	(Min, Max)	n	Mean(SD)	95% CI	Median	(Min, Max)
Observed Value										
Visit 1	1328	87.79(15.15)	(86.98, 88.61)	93.75	(0.0, 100.0)	1333	87.48(14.87)	(86.68, 88.28)	93.75	(12.5, 100.0)
Baseline	1328	87.79(15.15)	(86.98, 88.61)	93.75	(0.0, 100.0)	1333	87.48(14.87)	(86.68, 88.28)	93.75	(12.5, 100.0)
Visit 5	1236	87.48(15.55)	(86.61, 88.35)	93.75	(0.0, 100.0)	1227	87.82(15.14)	(86.97, 88.66)	93.75	(0.0, 100.0)
Visit 8	1112	87.57(15.20)	(86.67, 88.46)	93.75	(9.4, 100.0)	1111	87.14(14.83)	(86.27, 88.02)	93.75	(9.4, 100.0)
Visit 11	730	88.29(13.98)	(87.27, 89.30)	93.75	(18.8, 100.0)	732	87.97(14.17)	(86.95, 89.00)	93.75	(25.0, 100.0)
Visit 14	320	87.88(14.29)	(86.31, 89.45)	93.75	(28.1, 100.0)	307	89.70(13.81)	(88.15, 91.26)	95.00	(25.0, 100.0)
Visit 17	1	100.00(-)	(- , -)	100.00	(100.0, 100.0)	2	59.38(30.94)	(-218.57, 337.32)	59.38	(37.5, 81.3)
Last On-Treatment	1184	87.03(15.38)	(86.15, 87.91)	92.86	(0.0, 100.0)	1212	86.47(15.49)	(85.60, 87.34)	90.63	(21.9, 100.0)
Premature Discontinuation	52	83.13(16.99)	(78.40, 87.86)	85.94	(31.3, 100.0)	70	88.07(16.35)	(84.18, 91.97)	93.75	(15.6, 100.0)
End Of Study Visit	1006	86.26(15.92)	(85.28, 87.24)	90.63	(0.0, 100.0)	985	86.61(14.91)	(85.68, 87.54)	90.63	(20.8, 100.0)
Change from Baseline										
Visit 5	1226	-0.35(13.97)	(-1.13, 0.44)	0.00	(-93.8, 75.0)	1212	0.15(13.88)	(-0.63, 0.93)	0.00	(-100.0, 75.0)
Visit 8	1100	-0.61(14.37)	(-1.46, 0.24)	0.00	(-75.0, 68.8)	1093	-0.78(14.74)	(-1.65, 0.10)	0.00	(-68.8, 68.8)
Visit 11	720	-0.63(13.82)	(-1.64, 0.38)	0.00	(-71.9, 68.8)	717	-0.67(13.69)	(-1.68, 0.33)	0.00	(-65.6, 65.6)
Visit 14	315	-3.09(14.29)	(-4.68, -1.51)	0.00	(-59.4, 50.0)	301	-0.87(11.53)	(-2.17, 0.44)	0.00	(-50.0, 37.5)
Visit 17	1	0.00(-)	(- , -)	0.00	(0.0, 0.0)	2	-32.81(37.57)	(-370.32, 304.70)	-32.81	(-59.4, -6.3)
Last On-Treatment	1170	-0.88(15.34)	(-1.76, 0.00)	0.00	(-93.8, 81.3)	1193	-1.09(14.63)	(-1.92, -0.26)	0.00	(-75.0, 65.6)
Premature Discontinuation	52	-2.23(15.95)	(-6.67, 2.21)	0.00	(-37.5, 56.3)	70	-1.33(13.31)	(-4.50, 1.85)	0.00	(-59.4, 37.5)
End Of Study Visit	994	-1.84(16.07)	(-2.84, -0.84)	0.00	(-93.8, 90.6)	969	-1.03(14.20)	(-1.92, -0.13)	0.00	(-53.1, 65.6)

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

Figure A3.2.6: KDQoL-36 - Time Profile Curve of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2



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

Table A3.3.1: EQ-5D VAS - Summary and MMRM of Change from Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1223	-0.50	[-1.26 , 0.26]	1216	0.59	[-0.19 , 1.37]	-1.09	[-2.17 , 0.00]	0.0507
Visit 8	1097	-1.02	[-1.81 , -0.23]	1088	-0.88	[-1.74 , -0.01]	-0.14	[-1.31 , 1.03]	0.8103
Visit 11	721	-2.05	[-3.06 , -1.03]	717	-1.34	[-2.36 , -0.31]	-0.71	[-2.14 , 0.73]	0.3337
Visit 14	316	-2.10	[-3.63 , -0.57]	301	-1.86	[-3.47 , -0.26]	-0.24	[-2.44 , 1.96]	0.8309
Overall	1245	-0.58	[-1.42 , 0.26]	1234	-0.42	[-1.29 , 0.46]	-0.16	[-1.18 , 0.86]	0.7582
Hedges' g							-0.01	[-0.09 , 0.07]	0.7952

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.2: KDQoL-36 - Summary and MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1212	-0.65	[-1.10 , -0.20]	1200	-0.62	[-1.06 , -0.19]	-0.03	[-0.66 , 0.60]	0.9362
Visit 8	1089	-1.13	[-1.60 , -0.65]	1076	-1.19	[-1.67 , -0.70]	0.06	[-0.62 , 0.74]	0.8605
Visit 11	713	-1.42	[-2.01 , -0.84]	708	-2.23	[-2.81 , -1.66]	0.81	[0.00 , 1.63]	0.0511
Visit 14	310	-2.02	[-2.85 , -1.18]	294	-2.38	[-3.21 , -1.56]	0.37	[-0.80 , 1.53]	0.5367
Overall	1237	-1.30	[-1.79 , -0.80]	1223	-1.39	[-1.89 , -0.90]	0.10	[-0.49 , 0.68]	0.7476
Hedges' g							0.01	[-0.07 , 0.09]	0.7887

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.3: KDQoL-36 - Summary and MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1212	-0.61	[-1.11 , -0.12]	1200	-0.70	[-1.18 , -0.21]	0.09	[-0.60 , 0.78]	0.8050
Visit 8	1089	-0.81	[-1.32 , -0.29]	1076	-1.05	[-1.58 , -0.52]	0.24	[-0.50 , 0.98]	0.5234
Visit 11	713	-1.31	[-1.95 , -0.66]	708	-1.46	[-2.09 , -0.83]	0.16	[-0.74 , 1.06]	0.7333
Visit 14	310	-1.80	[-2.76 , -0.84]	294	-3.19	[-4.11 , -2.26]	1.39	[0.06 , 2.71]	0.0400
Overall	1237	-0.98	[-1.51 , -0.45]	1223	-1.50	[-2.03 , -0.98]	0.53	[-0.10 , 1.15]	0.1001
Hedges' g							0.06	[-0.02 , 0.13]	0.1686

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.4: KDQoL-36 - Summary and MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1225	-0.24	[-1.41 , 0.92]	1215	0.58	[-0.58 , 1.74]	-0.83	[-2.47 , 0.82]	0.3243
Visit 8	1102	-0.93	[-2.15 , 0.28]	1092	-0.35	[-1.56 , 0.86]	-0.58	[-2.30 , 1.13]	0.5064
Visit 11	721	-0.90	[-2.35 , 0.55]	717	-1.23	[-2.68 , 0.21]	0.33	[-1.71 , 2.37]	0.7489
Visit 14	315	-3.62	[-5.71 , -1.53]	301	-2.74	[-4.84 , -0.63]	-0.89	[-3.83 , 2.06]	0.5562
Overall	1247	-0.68	[-1.92 , 0.56]	1236	-0.30	[-1.52 , 0.91]	-0.37	[-1.81 , 1.07]	0.6126
Hedges' g							-0.02	[-0.10 , 0.06]	0.6748

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.5: KDQoL-36 - Summary and MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1226	-0.81	[-1.41 , -0.21]	1221	-1.00	[-1.61 , -0.39]	0.19	[-0.67 , 1.05]	0.6659
Visit 8	1101	-1.53	[-2.20 , -0.86]	1095	-1.66	[-2.32 , -1.00]	0.13	[-0.81 , 1.07]	0.7827
Visit 11	722	-1.85	[-2.62 , -1.09]	719	-1.65	[-2.50 , -0.80]	-0.21	[-1.34 , 0.93]	0.7229
Visit 14	315	-1.65	[-2.71 , -0.60]	302	-2.70	[-3.78 , -1.61]	1.04	[-0.45 , 2.54]	0.1715
Overall	1248	-1.54	[-2.20 , -0.88]	1238	-1.68	[-2.36 , -1.00]	0.14	[-0.65 , 0.93]	0.7218
Hedges' g							0.01	[-0.07 , 0.09]	0.7672

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.3.6: KDQoL-36 - Summary and MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1359)			Placebo (N=1362)			Finerenone-Placebo		
Visit	N	LS-Means	95% CI for LS-Means	N	LS-Means	95% CI for LS-Means	Difference of LS-Means	95% CI for Difference	p-value
Visit 5	1226	-0.36	[-1.06 , 0.34]	1212	0.16	[-0.54 , 0.86]	-0.52	[-1.51 , 0.47]	0.3048
Visit 8	1100	-0.73	[-1.48 , 0.03]	1093	-0.93	[-1.69 , -0.17]	0.20	[-0.87 , 1.27]	0.7077
Visit 11	720	-0.83	[-1.68 , 0.01]	717	-0.95	[-1.79 , -0.12]	0.12	[-1.06 , 1.30]	0.8407
Visit 14	315	-3.05	[-4.30 , -1.80]	301	-2.01	[-3.13 , -0.90]	-1.04	[-2.69 , 0.61]	0.2179
Overall	1246	-0.92	[-1.69 , -0.15]	1236	-0.74	[-1.49 , 0.00]	-0.18	[-1.07 , 0.71]	0.6937
Hedges' g							-0.01	[-0.09 , 0.07]	0.7435

Convergence Status of MMRM:
Convergence criteria met.

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

Table A3.4.1: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		480 (35.3%)	439 (32.2%)	919 (33.8%)
Number of subjects without events		879 (64.7%)	923 (67.8%)	1802 (66.2%)
Odds Ratio [a]				
OR, 95% CI	1.150 [0.980, 1.348]			
p-value	0.0861			
Relative Risk [b]				
RR, 95% CI	1.096 [0.986, 1.218]			
p-value	0.0890			
Risk Difference [c]				
RD, 95% CI	0.031 [-0.004, 0.067]			
p-value	0.0833			

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

Table A3.4.2: EQ-5D VAS - Effect Measures of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		337 (24.8%)	354 (26.0%)	691 (25.4%)
Number of subjects without events		1022 (75.2%)	1008 (74.0%)	2030 (74.6%)
Odds Ratio [a]				
OR, 95% CI	0.940 [0.791, 1.118]			
p-value	0.4833			
Relative Risk [b]				
RR, 95% CI	0.948 [0.834, 1.079]			
p-value	0.4205			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.041, 0.024]			
p-value	0.6145			

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

Table A3.4.3: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		482 (35.5%)	482 (35.4%)	964 (35.4%)
Number of subjects without events		877 (64.5%)	880 (64.6%)	1757 (64.6%)
Odds Ratio [a]				
OR, 95% CI	1.005 [0.859, 1.176]			
p-value	0.9495			
Relative Risk [b]				
RR, 95% CI	1.000 [0.904, 1.107]			
p-value	0.9962			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.034, 0.038]			
p-value	0.9088			

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

Table A3.4.4: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		486 (35.8%)	453 (33.3%)	939 (34.5%)
Number of subjects without events		873 (64.2%)	909 (66.7%)	1782 (65.5%)
Odds Ratio [a]				
OR, 95% CI	1.120 [0.956, 1.312]			
p-value	0.1614			
Relative Risk [b]				
RR, 95% CI	1.077 [0.971, 1.194]			
p-value	0.1600			
Risk Difference [c]				
RD, 95% CI	0.026 [-0.010, 0.061]			
p-value	0.1579			

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

Table A3.4.5: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		543 (40.0%)	504 (37.0%)	1047 (38.5%)
Number of subjects without events		816 (60.0%)	858 (63.0%)	1674 (61.5%)
Odds Ratio [a]				
OR, 95% CI	1.138 [0.975, 1.329]			
p-value	0.1018			
Relative Risk [b]				
RR, 95% CI	1.079 [0.982, 1.186]			
p-value	0.1153			
Risk Difference [c]				
RD, 95% CI	0.031 [-0.006, 0.067]			
p-value	0.0969			

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

Table A3.4.6: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		306 (22.5%)	317 (23.3%)	623 (22.9%)
Number of subjects without events		1053 (77.5%)	1045 (76.7%)	2098 (77.1%)
Odds Ratio [a]				
OR, 95% CI	0.958 [0.800, 1.146]			
p-value	0.6364			
Relative Risk [b]				
RR, 95% CI	0.964 [0.840, 1.106]			
p-value	0.6020			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.038, 0.025]			
p-value	0.6876			

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

Table A3.4.7: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		355 (26.1%)	319 (23.4%)	674 (24.8%)
Number of subjects without events		1004 (73.9%)	1043 (76.6%)	2047 (75.2%)
Odds Ratio [a]				
OR, 95% CI	1.155 [0.970, 1.376]			
p-value	0.1050			
Relative Risk [b]				
RR, 95% CI	1.116 [0.979, 1.272]			
p-value	0.1000			
Risk Difference [c]				
RD, 95% CI	0.026 [-0.007, 0.058]			
p-value	0.1190			

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

Table A3.4.8: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		307 (22.6%)	318 (23.3%)	625 (23.0%)
Number of subjects without events		1052 (77.4%)	1044 (76.7%)	2096 (77.0%)
Odds Ratio [a]				
OR, 95% CI	0.957 [0.801, 1.145]			
p-value	0.6339			
Relative Risk [b]				
RR, 95% CI	0.968 [0.843, 1.110]			
p-value	0.6389			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.040, 0.024]			
p-value	0.6200			

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

Table A3.4.9: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		299 (22.0%)	287 (21.1%)	586 (21.5%)
Number of subjects without events		1060 (78.0%)	1075 (78.9%)	2135 (78.5%)
Odds Ratio [a]				
OR, 95% CI	1.058 [0.881, 1.270]			
p-value	0.5483			
Relative Risk [b]				
RR, 95% CI	1.045 [0.906, 1.207]			
p-value	0.5440			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.022, 0.040]			
p-value	0.5575			

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

Table A3.4.10: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		361 (26.6%)	399 (29.3%)	760 (27.9%)
Number of subjects without events		998 (73.4%)	963 (70.7%)	1961 (72.1%)
Odds Ratio [a]				
OR, 95% CI	0.873 [0.738, 1.033]			
p-value	0.1132			
Relative Risk [b]				
RR, 95% CI	0.906 [0.802, 1.022]			
p-value	0.1072			
Risk Difference [c]				
RD, 95% CI	-0.026 [-0.060, 0.007]			
p-value	0.1258			

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

Table A3.4.11: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		177 (13.0%)	171 (12.6%)	348 (12.8%)
Number of subjects without events		1182 (87.0%)	1191 (87.4%)	2373 (87.2%)
Odds Ratio [a]				
OR, 95% CI	1.042 [0.832, 1.305]			
p-value	0.7199			
Relative Risk [b]				
RR, 95% CI	1.034 [0.850, 1.258]			
p-value	0.7381			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.018, 0.032]			
p-value	0.6021			

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

Table A3.4.12: KDQoL-36 - Effect Measures of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1359)	Placebo (N=1362)	Total (N=2721)
Number of subjects at risk		1359 (100.0%)	1362 (100.0%)	2721 (100.0%)
Number of subjects with events		208 (15.3%)	226 (16.6%)	434 (16.0%)
Number of subjects without events		1151 (84.7%)	1136 (83.4%)	2287 (84.0%)
Odds Ratio [a]				
OR, 95% CI	0.906 [0.738, 1.113]			
p-value	0.3478			
Relative Risk [b]				
RR, 95% CI	0.919 [0.774, 1.092]			
p-value	0.3396			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.039, 0.016]			
p-value	0.4211			

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Any TEAE	1195(88.1%)	1192(87.9%)
Infections And Infestations	664(48.9%)	651(48.0%)
Nasopharyngitis	139(10.2%)	126(9.3%)
Urinary tract infection	109(8.0%)	109(8.0%)
Upper respiratory tract infection	93(6.9%)	73(5.4%)
Bronchitis	77(5.7%)	62(4.6%)
Pneumonia	58(4.3%)	77(5.7%)
Influenza	53(3.9%)	58(4.3%)
Cellulitis	41(3.0%)	33(2.4%)
Conjunctivitis	30(2.2%)	16(1.2%)
Gastroenteritis	29(2.1%)	26(1.9%)
Respiratory tract infection	27(2.0%)	26(1.9%)
Herpes zoster	26(1.9%)	26(1.9%)
Pharyngitis	21(1.5%)	22(1.6%)
Cystitis	20(1.5%)	24(1.8%)
COVID-19	19(1.4%)	22(1.6%)
Sinusitis	17(1.3%)	19(1.4%)
Lower respiratory tract infection	17(1.3%)	14(1.0%)
Onychomycosis	15(1.1%)	13(1.0%)
Localised infection	13(1.0%)	10(0.7%)
Rhinitis	13(1.0%)	9(0.7%)
Viral infection	11(0.8%)	8(0.6%)
Wound infection	11(0.8%)	5(0.4%)
Erysipelas	10(0.7%)	14(1.0%)
Periodontitis	10(0.7%)	12(0.9%)
Sepsis	9(0.7%)	11(0.8%)
Otitis externa	9(0.7%)	8(0.6%)
Osteomyelitis	9(0.7%)	7(0.5%)
Gingivitis	9(0.7%)	6(0.4%)
Acute sinusitis	8(0.6%)	7(0.5%)
Gastroenteritis viral	8(0.6%)	7(0.5%)
Tinea pedis	8(0.6%)	7(0.5%)
Tonsillitis	7(0.5%)	8(0.6%)
Respiratory tract infection viral	7(0.5%)	6(0.4%)
Tooth abscess	7(0.5%)	5(0.4%)
Paronychia	7(0.5%)	2(0.1%)
Tooth infection	6(0.4%)	11(0.8%)
Diverticulitis	6(0.4%)	6(0.4%)
Pyelonephritis	6(0.4%)	6(0.4%)
Postoperative wound infection	6(0.4%)	4(0.3%)
Urosepsis	6(0.4%)	4(0.3%)
Dermatophytosis of nail	6(0.4%)	0
Ear infection	5(0.4%)	6(0.4%)
Otitis media	5(0.4%)	5(0.4%)
Skin infection	5(0.4%)	5(0.4%)
Abscess limb	5(0.4%)	4(0.3%)
Folliculitis	5(0.4%)	3(0.2%)
COVID-19 pneumonia	4(0.3%)	2(0.1%)
Gangrene	4(0.3%)	1(0.1%)
Fungal skin infection	3(0.2%)	7(0.5%)
Escherichia urinary tract infection	3(0.2%)	4(0.3%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Helicobacter infection	3(0.2%)	4(0.3%)
Urinary tract infection bacterial	3(0.2%)	4(0.3%)
Infected dermal cyst	3(0.2%)	3(0.2%)
Infected skin ulcer	3(0.2%)	2(0.1%)
Laryngitis	3(0.2%)	2(0.1%)
Oesophageal candidiasis	3(0.2%)	2(0.1%)
Pyelonephritis chronic	3(0.2%)	2(0.1%)
Bacteraemia	3(0.2%)	1(0.1%)
Fungal infection	3(0.2%)	1(0.1%)
Tracheobronchitis	3(0.2%)	1(0.1%)
Soft tissue infection	3(0.2%)	0
Infection	2(0.1%)	7(0.5%)
Tracheitis	2(0.1%)	3(0.2%)
Abscess	2(0.1%)	2(0.1%)
Chronic sinusitis	2(0.1%)	2(0.1%)
Tinea cruris	2(0.1%)	2(0.1%)
Tuberculosis	2(0.1%)	2(0.1%)
Vulvovaginal candidiasis	2(0.1%)	2(0.1%)
Abscess neck	2(0.1%)	1(0.1%)
Herpes dermatitis	2(0.1%)	1(0.1%)
Labyrinthitis	2(0.1%)	1(0.1%)
Parotitis	2(0.1%)	1(0.1%)
Pulpitis dental	2(0.1%)	1(0.1%)
Pyelonephritis acute	2(0.1%)	1(0.1%)
Tinea infection	2(0.1%)	1(0.1%)
Vaginal infection	2(0.1%)	1(0.1%)
Aspergilloma	2(0.1%)	0
Emphysematous pyelonephritis	2(0.1%)	0
Groin infection	2(0.1%)	0
Hepatitis C	2(0.1%)	0
Infected bite	2(0.1%)	0
Oral fungal infection	2(0.1%)	0
Pyoderma	2(0.1%)	0
Urinary tract infection fungal	2(0.1%)	0
Vulvovaginal mycotic infection	2(0.1%)	0
Wound infection bacterial	2(0.1%)	0
Viral upper respiratory tract infection	1(0.1%)	5(0.4%)
Septic shock	1(0.1%)	4(0.3%)
Diabetic foot infection	1(0.1%)	3(0.2%)
Furuncle	1(0.1%)	3(0.2%)
Oral candidiasis	1(0.1%)	3(0.2%)
Asymptomatic bacteriuria	1(0.1%)	2(0.1%)
Candida infection	1(0.1%)	2(0.1%)
Ear infection fungal	1(0.1%)	2(0.1%)
Gingival abscess	1(0.1%)	2(0.1%)
Pneumonia viral	1(0.1%)	2(0.1%)
Acarodermatitis	1(0.1%)	1(0.1%)
Anal abscess	1(0.1%)	1(0.1%)
Atypical pneumonia	1(0.1%)	1(0.1%)
Body tinea	1(0.1%)	1(0.1%)
Bronchitis viral	1(0.1%)	1(0.1%)
Enteritis infectious	1(0.1%)	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Epididymitis	1(0.1%)	1(0.1%)
Eyelid infection	1(0.1%)	1(0.1%)
Gastroenteritis norovirus	1(0.1%)	1(0.1%)
Gastroenteritis salmonella	1(0.1%)	1(0.1%)
Hordeolum	1(0.1%)	1(0.1%)
Injection site infection	1(0.1%)	1(0.1%)
Myringitis	1(0.1%)	1(0.1%)
Otitis media acute	1(0.1%)	1(0.1%)
Otitis media chronic	1(0.1%)	1(0.1%)
Pulmonary tuberculosis	1(0.1%)	1(0.1%)
Sialoadenitis	1(0.1%)	1(0.1%)
Staphylococcal infection	1(0.1%)	1(0.1%)
Subcutaneous abscess	1(0.1%)	1(0.1%)
Urethritis	1(0.1%)	1(0.1%)
Abdominal infection	1(0.1%)	0
Abdominal wall abscess	1(0.1%)	0
Arthritis bacterial	1(0.1%)	0
Bacterial sepsis	1(0.1%)	0
Bacteriuria	1(0.1%)	0
Bone abscess	1(0.1%)	0
Cellulitis staphylococcal	1(0.1%)	0
Conjunctivitis viral	1(0.1%)	0
Diabetic gangrene	1(0.1%)	0
Endophthalmitis	1(0.1%)	0
External ear cellulitis	1(0.1%)	0
Febrile infection	1(0.1%)	0
Fungal oesophagitis	1(0.1%)	0
Genital infection	1(0.1%)	0
Genital infection fungal	1(0.1%)	0
Genitourinary tract infection	1(0.1%)	0
Impetigo	1(0.1%)	0
Infected cyst	1(0.1%)	0
Infectious mononucleosis	1(0.1%)	0
Infectious pleural effusion	1(0.1%)	0
Infective myositis	1(0.1%)	0
Infective tenosynovitis	1(0.1%)	0
Latent tuberculosis	1(0.1%)	0
Ludwig angina	1(0.1%)	0
Lyme disease	1(0.1%)	0
Mastitis bacterial	1(0.1%)	0
Medical device site infection	1(0.1%)	0
Ophthalmic herpes simplex	1(0.1%)	0
Oral herpes	1(0.1%)	0
Oropharyngitis fungal	1(0.1%)	0
Osteomyelitis chronic	1(0.1%)	0
Perineal abscess	1(0.1%)	0
Pilonidal cyst	1(0.1%)	0
Pneumonia klebsiella	1(0.1%)	0
Prostatic abscess	1(0.1%)	0
Sinusitis bacterial	1(0.1%)	0
Sputum purulent	1(0.1%)	0
Stitch abscess	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Suspected COVID-19	1(0.1%)	0
Tracheobronchitis bacterial	1(0.1%)	0
Varicella zoster virus infection	1(0.1%)	0
Pneumonia bacterial	0	4(0.3%)
Appendicitis	0	3(0.2%)
Nail infection	0	3(0.2%)
Bronchitis bacterial	0	2(0.1%)
Erythema migrans	0	2(0.1%)
Eye infection	0	2(0.1%)
Groin abscess	0	2(0.1%)
Nail bed infection	0	2(0.1%)
Pharyngotonsillitis	0	2(0.1%)
Pyuria	0	2(0.1%)
Scrotal abscess	0	2(0.1%)
Abdominal abscess	0	1(0.1%)
Acute hepatitis B	0	1(0.1%)
Alveolar osteitis	0	1(0.1%)
Anorectal infection bacterial	0	1(0.1%)
Arteriosclerotic gangrene	0	1(0.1%)
Arthritis infective	0	1(0.1%)
Bacterial disease carrier	0	1(0.1%)
Bacterial rhinitis	0	1(0.1%)
Bacterial tracheitis	0	1(0.1%)
Bacterial vulvovaginitis	0	1(0.1%)
Bartholinitis	0	1(0.1%)
Breast abscess	0	1(0.1%)
Campylobacter gastroenteritis	0	1(0.1%)
Clostridium difficile infection	0	1(0.1%)
Conjunctivitis bacterial	0	1(0.1%)
Coronavirus infection	0	1(0.1%)
Cryptococcosis	0	1(0.1%)
Cystitis bacterial	0	1(0.1%)
Dengue fever	0	1(0.1%)
Dysentery	0	1(0.1%)
Eczema herpeticum	0	1(0.1%)
Eczema infected	0	1(0.1%)
Endocarditis	0	1(0.1%)
Enterococcal bacteraemia	0	1(0.1%)
Enterococcal infection	0	1(0.1%)
Escherichia sepsis	0	1(0.1%)
Fournier's gangrene	0	1(0.1%)
Fungal balanitis	0	1(0.1%)
Gastritis viral	0	1(0.1%)
Gastrointestinal infection	0	1(0.1%)
Gastrointestinal viral infection	0	1(0.1%)
Genital candidiasis	0	1(0.1%)
Genital infection female	0	1(0.1%)
Helicobacter gastritis	0	1(0.1%)
Herpes ophthalmic	0	1(0.1%)
Herpes virus infection	0	1(0.1%)
Herpes zoster reactivation	0	1(0.1%)
Incision site abscess	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Infected seroma	0	1(0.1%)
Infective exacerbation of bronchiectasis	0	1(0.1%)
Infective exacerbation of chronic obstructive airways disease	0	1(0.1%)
Infective spondylitis	0	1(0.1%)
Intervertebral discitis	0	1(0.1%)
Klebsiella infection	0	1(0.1%)
Large intestine infection	0	1(0.1%)
Lymphangitis	0	1(0.1%)
Mastoiditis	0	1(0.1%)
Medical device site joint infection	0	1(0.1%)
Necrotising fasciitis	0	1(0.1%)
Ophthalmic herpes zoster	0	1(0.1%)
Oral infection	0	1(0.1%)
Orchitis	0	1(0.1%)
Periorbital cellulitis	0	1(0.1%)
Pharyngitis bacterial	0	1(0.1%)
Post procedural infection	0	1(0.1%)
Prostatitis Escherichia coli	0	1(0.1%)
Pulmonary sepsis	0	1(0.1%)
Retinitis	0	1(0.1%)
Staphylococcal sepsis	0	1(0.1%)
Subacute endocarditis	0	1(0.1%)
Sweat gland infection	0	1(0.1%)
Urinary tract infection enterococcal	0	1(0.1%)
Viral pericarditis	0	1(0.1%)
Metabolism And Nutrition Disorders	532(39.2%)	437(32.2%)
Hyperkalaemia	186(13.7%)	84(6.2%)
Hypoglycaemia	89(6.6%)	90(6.6%)
Gout	63(4.6%)	57(4.2%)
Hyperuricaemia	63(4.6%)	35(2.6%)
Hyperglycaemia	46(3.4%)	32(2.4%)
Diabetes mellitus	38(2.8%)	38(2.8%)
Diabetes mellitus inadequate control	36(2.7%)	31(2.3%)
Type 2 diabetes mellitus	21(1.5%)	18(1.3%)
Dehydration	20(1.5%)	20(1.5%)
Vitamin D deficiency	20(1.5%)	17(1.3%)
Decreased appetite	20(1.5%)	11(0.8%)
Hypokalaemia	17(1.3%)	37(2.7%)
Hyponatraemia	12(0.9%)	17(1.3%)
Hypertriglyceridaemia	11(0.8%)	15(1.1%)
Hyperlipidaemia	11(0.8%)	8(0.6%)
Vitamin B12 deficiency	11(0.8%)	8(0.6%)
Metabolic acidosis	10(0.7%)	3(0.2%)
Diabetic metabolic decompensation	7(0.5%)	12(0.9%)
Iron deficiency	7(0.5%)	10(0.7%)
Hypovolaemia	7(0.5%)	1(0.1%)
Dyslipidaemia	6(0.4%)	12(0.9%)
Hypomagnesaemia	6(0.4%)	5(0.4%)
Obesity	6(0.4%)	4(0.3%)
Folate deficiency	4(0.3%)	4(0.3%)
Hypercalcaemia	4(0.3%)	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Diabetic ketoacidosis	3(0.2%)	7(0.5%)
Hypocalcaemia	3(0.2%)	4(0.3%)
Hyperphosphataemia	3(0.2%)	3(0.2%)
Metabolic disorder	3(0.2%)	3(0.2%)
Fluid overload	2(0.1%)	8(0.6%)
Hypercholesterolaemia	2(0.1%)	3(0.2%)
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.1%)	3(0.2%)
Hypernatraemia	2(0.1%)	2(0.1%)
Abnormal loss of weight	1(0.1%)	3(0.2%)
Malnutrition	1(0.1%)	2(0.1%)
Hypoalbuminaemia	1(0.1%)	1(0.1%)
Overweight	1(0.1%)	1(0.1%)
Acidosis	1(0.1%)	0
Acidosis hyperchloraemic	1(0.1%)	0
Cachexia	1(0.1%)	0
Diabetic complication	1(0.1%)	0
Hyperchloraemia	1(0.1%)	0
Hypovitaminosis	1(0.1%)	0
Mineral deficiency	1(0.1%)	0
Vitamin B complex deficiency	1(0.1%)	0
Hypervolaemia	0	2(0.1%)
Metabolic syndrome	0	2(0.1%)
Acid-base balance disorder mixed	0	1(0.1%)
Diabetic ketosis	0	1(0.1%)
Hypervitaminosis B12	0	1(0.1%)
Hypochloraemia	0	1(0.1%)
Hypophosphataemia	0	1(0.1%)
Hypoproteinaemia	0	1(0.1%)
Increased appetite	0	1(0.1%)
Lactic acidosis	0	1(0.1%)
Lipid metabolism disorder	0	1(0.1%)
Periarthritis calcarea	0	1(0.1%)
Protein deficiency	0	1(0.1%)
Weight loss poor	0	1(0.1%)
Musculoskeletal And Connective Tissue Disorders	450(33.2%)	461(34.0%)
Arthralgia	124(9.1%)	108(8.0%)
Back pain	114(8.4%)	118(8.7%)
Pain in extremity	62(4.6%)	66(4.9%)
Muscle spasms	60(4.4%)	41(3.0%)
Osteoarthritis	54(4.0%)	60(4.4%)
Myalgia	31(2.3%)	22(1.6%)
Neck pain	19(1.4%)	19(1.4%)
Spinal osteoarthritis	18(1.3%)	21(1.5%)
Arthritis	15(1.1%)	15(1.1%)
Rotator cuff syndrome	12(0.9%)	11(0.8%)
Muscular weakness	11(0.8%)	13(1.0%)
Tendonitis	11(0.8%)	12(0.9%)
Bursitis	10(0.7%)	11(0.8%)
Periarthritis	9(0.7%)	10(0.7%)
Osteoporosis	9(0.7%)	7(0.5%)
Flank pain	8(0.6%)	10(0.7%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Lumbar spinal stenosis	8(0.6%)	7(0.5%)
Tenosynovitis	8(0.6%)	2(0.1%)
Gouty arthritis	7(0.5%)	15(1.1%)
Trigger finger	7(0.5%)	9(0.7%)
Intervertebral disc disorder	7(0.5%)	4(0.3%)
Musculoskeletal chest pain	6(0.4%)	3(0.2%)
Musculoskeletal pain	5(0.4%)	8(0.6%)
Intervertebral disc protrusion	5(0.4%)	6(0.4%)
Joint swelling	4(0.3%)	13(1.0%)
Tendon disorder	4(0.3%)	4(0.3%)
Synovial cyst	4(0.3%)	3(0.2%)
Osteopenia	4(0.3%)	1(0.1%)
Spondylolisthesis	4(0.3%)	0
Spinal stenosis	3(0.2%)	9(0.7%)
Plantar fasciitis	3(0.2%)	6(0.4%)
Spinal pain	3(0.2%)	6(0.4%)
Exostosis	3(0.2%)	3(0.2%)
Intervertebral disc degeneration	3(0.2%)	2(0.1%)
Cervical spinal stenosis	3(0.2%)	1(0.1%)
Polyarthritis	3(0.2%)	0
Rheumatoid arthritis	3(0.2%)	0
Costochondritis	2(0.1%)	4(0.3%)
Tenosynovitis stenosans	2(0.1%)	4(0.3%)
Musculoskeletal stiffness	2(0.1%)	3(0.2%)
Polymyalgia rheumatica	2(0.1%)	3(0.2%)
Chondrocalcinosis pyrophosphate	2(0.1%)	2(0.1%)
Coccydynia	2(0.1%)	2(0.1%)
Foot deformity	2(0.1%)	2(0.1%)
Rhabdomyolysis	2(0.1%)	2(0.1%)
Kyphosis	2(0.1%)	1(0.1%)
Meniscal degeneration	2(0.1%)	1(0.1%)
Muscle fatigue	2(0.1%)	1(0.1%)
Joint effusion	2(0.1%)	0
Pain in jaw	2(0.1%)	0
Scoliosis	2(0.1%)	0
Osteitis	1(0.1%)	5(0.4%)
Dupuytren's contracture	1(0.1%)	4(0.3%)
Groin pain	1(0.1%)	3(0.2%)
Vertebral foraminal stenosis	1(0.1%)	3(0.2%)
Joint stiffness	1(0.1%)	2(0.1%)
Musculoskeletal discomfort	1(0.1%)	2(0.1%)
Arthropathy	1(0.1%)	1(0.1%)
Bone pain	1(0.1%)	1(0.1%)
Fibromyalgia	1(0.1%)	1(0.1%)
Immobilisation syndrome	1(0.1%)	1(0.1%)
Joint range of motion decreased	1(0.1%)	1(0.1%)
Limb mass	1(0.1%)	1(0.1%)
Mobility decreased	1(0.1%)	1(0.1%)
Myofascial pain syndrome	1(0.1%)	1(0.1%)
Myopathy	1(0.1%)	1(0.1%)
Neuropathic arthropathy	1(0.1%)	1(0.1%)
Osteochondritis	1(0.1%)	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Tendon pain	1(0.1%)	1(0.1%)
Arthritis reactive	1(0.1%)	0
Back disorder	1(0.1%)	0
Clubbing	1(0.1%)	0
Enthesopathy	1(0.1%)	0
Facet joint syndrome	1(0.1%)	0
Fracture pain	1(0.1%)	0
Gouty tophus	1(0.1%)	0
Haemarthrosis	1(0.1%)	0
Intervertebral disc compression	1(0.1%)	0
Joint noise	1(0.1%)	0
Limb discomfort	1(0.1%)	0
Mandibular mass	1(0.1%)	0
Muscle discomfort	1(0.1%)	0
Muscle rigidity	1(0.1%)	0
Osteonecrosis	1(0.1%)	0
Palindromic rheumatism	1(0.1%)	0
Sacroiliitis	1(0.1%)	0
Soft tissue swelling	1(0.1%)	0
Vertebral lateral recess stenosis	1(0.1%)	0
Chondrocalcinosis	0	2(0.1%)
Muscle haemorrhage	0	2(0.1%)
Osteochondrosis	0	2(0.1%)
Spinal ligament ossification	0	2(0.1%)
Amyotrophy	0	1(0.1%)
Bone formation increased	0	1(0.1%)
Bursa disorder	0	1(0.1%)
Chondritis	0	1(0.1%)
Crystal arthropathy	0	1(0.1%)
Fasciitis	0	1(0.1%)
Intervertebral disc calcification	0	1(0.1%)
Ligament calcification	0	1(0.1%)
Muscle contracture	0	1(0.1%)
Muscle disorder	0	1(0.1%)
Muscle swelling	0	1(0.1%)
Osteolysis	0	1(0.1%)
Rheumatoid nodule	0	1(0.1%)
Sjogren's syndrome	0	1(0.1%)
Spinal disorder	0	1(0.1%)
Spondylitis	0	1(0.1%)
Systemic lupus erythematosus	0	1(0.1%)
Systemic scleroderma	0	1(0.1%)
Torticollis	0	1(0.1%)
Vertebral lesion	0	1(0.1%)
Gastrointestinal Disorders	423(31.2%)	399(29.4%)
Diarrhoea	98(7.2%)	97(7.2%)
Constipation	88(6.5%)	78(5.8%)
Nausea	50(3.7%)	50(3.7%)
Gastrooesophageal reflux disease	42(3.1%)	29(2.1%)
Vomiting	34(2.5%)	36(2.7%)
Haemorrhoids	31(2.3%)	16(1.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Gastritis	29(2.1%)	20(1.5%)
Large intestine polyp	25(1.8%)	29(2.1%)
Abdominal pain	22(1.6%)	36(2.7%)
Abdominal pain upper	18(1.3%)	22(1.6%)
Dyspepsia	18(1.3%)	17(1.3%)
Toothache	13(1.0%)	11(0.8%)
Hiatus hernia	10(0.7%)	14(1.0%)
Chronic gastritis	9(0.7%)	9(0.7%)
Abdominal distension	8(0.6%)	6(0.4%)
Gastric ulcer	8(0.6%)	3(0.2%)
Abdominal discomfort	7(0.5%)	7(0.5%)
Gastrointestinal haemorrhage	7(0.5%)	7(0.5%)
Abdominal pain lower	7(0.5%)	6(0.4%)
Diverticulum intestinal	7(0.5%)	5(0.4%)
Gastric polyps	6(0.4%)	7(0.5%)
Gastritis erosive	6(0.4%)	7(0.5%)
Dysphagia	6(0.4%)	6(0.4%)
Diverticulum	6(0.4%)	5(0.4%)
Inguinal hernia	5(0.4%)	8(0.6%)
Periodontal disease	5(0.4%)	5(0.4%)
Haematochezia	5(0.4%)	4(0.3%)
Dry mouth	5(0.4%)	3(0.2%)
Colitis	5(0.4%)	2(0.1%)
Ascites	5(0.4%)	0
Dental caries	4(0.3%)	6(0.4%)
Peptic ulcer	4(0.3%)	4(0.3%)
Rectal haemorrhage	4(0.3%)	4(0.3%)
Duodenitis	4(0.3%)	3(0.2%)
Duodenal ulcer	4(0.3%)	2(0.1%)
Tooth disorder	4(0.3%)	2(0.1%)
Haematemesis	4(0.3%)	1(0.1%)
Lower gastrointestinal haemorrhage	4(0.3%)	1(0.1%)
Pancreatic cyst	3(0.2%)	4(0.3%)
Irritable bowel syndrome	3(0.2%)	3(0.2%)
Upper gastrointestinal haemorrhage	3(0.2%)	3(0.2%)
Mouth ulceration	3(0.2%)	2(0.1%)
Pancreatitis acute	3(0.2%)	2(0.1%)
Anal incontinence	3(0.2%)	1(0.1%)
Enterocolitis	3(0.2%)	1(0.1%)
Pancreatitis	3(0.2%)	1(0.1%)
Umbilical hernia	2(0.1%)	6(0.4%)
Flatulence	2(0.1%)	5(0.4%)
Pancreatitis chronic	2(0.1%)	3(0.2%)
Epigastric discomfort	2(0.1%)	2(0.1%)
Gastrointestinal angiodysplasia	2(0.1%)	1(0.1%)
Gingival swelling	2(0.1%)	1(0.1%)
Abdominal symptom	2(0.1%)	0
Anal fistula	2(0.1%)	0
Aphthous ulcer	2(0.1%)	0
Eructation	2(0.1%)	0
Gastric haemorrhage	2(0.1%)	0
Gastroduodenal ulcer	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Incarcerated umbilical hernia	2(0.1%)	0
Intestinal haemorrhage	2(0.1%)	0
Proctalgia	2(0.1%)	0
Varices oesophageal	2(0.1%)	0
Abdominal hernia	1(0.1%)	3(0.2%)
Barrett's oesophagus	1(0.1%)	3(0.2%)
Gingival pain	1(0.1%)	3(0.2%)
Intestinal obstruction	1(0.1%)	3(0.2%)
Rectal polyp	1(0.1%)	3(0.2%)
Colon dysplasia	1(0.1%)	2(0.1%)
Faecaloma	1(0.1%)	2(0.1%)
Food poisoning	1(0.1%)	2(0.1%)
Gastrointestinal disorder	1(0.1%)	2(0.1%)
Lumbar hernia	1(0.1%)	2(0.1%)
Melaena	1(0.1%)	2(0.1%)
Oesophagitis	1(0.1%)	2(0.1%)
Oral pain	1(0.1%)	2(0.1%)
Abdominal mass	1(0.1%)	1(0.1%)
Abnormal faeces	1(0.1%)	1(0.1%)
Acquired oesophageal web	1(0.1%)	1(0.1%)
Anal fissure	1(0.1%)	1(0.1%)
Angular cheilitis	1(0.1%)	1(0.1%)
Enteritis	1(0.1%)	1(0.1%)
Gastric disorder	1(0.1%)	1(0.1%)
Haemorrhoidal haemorrhage	1(0.1%)	1(0.1%)
Ileus	1(0.1%)	1(0.1%)
Oesophageal obstruction	1(0.1%)	1(0.1%)
Small intestinal obstruction	1(0.1%)	1(0.1%)
Abdominal adhesions	1(0.1%)	0
Apical granuloma	1(0.1%)	0
Coeliac artery stenosis	1(0.1%)	0
Colitis ischaemic	1(0.1%)	0
Defaecation disorder	1(0.1%)	0
Dental alveolar anomaly	1(0.1%)	0
Dental attrition	1(0.1%)	0
Dental cyst	1(0.1%)	0
Diabetic gastroparesis	1(0.1%)	0
Diarrhoea haemorrhagic	1(0.1%)	0
Duodenal perforation	1(0.1%)	0
Faeces soft	1(0.1%)	0
Gastric xanthoma	1(0.1%)	0
Gastrointestinal polyp	1(0.1%)	0
Gastrointestinal ulcer	1(0.1%)	0
Glossitis	1(0.1%)	0
Infrequent bowel movements	1(0.1%)	0
Intestinal ischaemia	1(0.1%)	0
Intestinal mass	1(0.1%)	0
Lip disorder	1(0.1%)	0
Mechanical ileus	1(0.1%)	0
Mouth cyst	1(0.1%)	0
Odynophagia	1(0.1%)	0
Oesophageal ulcer	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Oesophagitis ulcerative	1(0.1%)	0
Pancreatic disorder	1(0.1%)	0
Pancreatic duct stenosis	1(0.1%)	0
Pancreatic steatosis	1(0.1%)	0
Parotid gland enlargement	1(0.1%)	0
Peritoneal adhesions	1(0.1%)	0
Portal hypertensive gastropathy	1(0.1%)	0
Precancerous lesion of digestive tract	1(0.1%)	0
Proctitis	1(0.1%)	0
Reflux gastritis	1(0.1%)	0
Small intestinal haemorrhage	1(0.1%)	0
Swollen tongue	1(0.1%)	0
Tongue ulceration	1(0.1%)	0
Stomatitis	0	5(0.4%)
Anal haemorrhage	0	3(0.2%)
Abdominal wall haematoma	0	2(0.1%)
Colitis ulcerative	0	2(0.1%)
Duodenal ulcer haemorrhage	0	2(0.1%)
Hernial eventration	0	2(0.1%)
Lip swelling	0	2(0.1%)
Bowel movement irregularity	0	1(0.1%)
Change of bowel habit	0	1(0.1%)
Chapped lips	0	1(0.1%)
Colitis microscopic	0	1(0.1%)
Diabetic gastroenteropathy	0	1(0.1%)
Diverticulum intestinal haemorrhagic	0	1(0.1%)
Enterovesical fistula	0	1(0.1%)
Erosive duodenitis	0	1(0.1%)
Erosive oesophagitis	0	1(0.1%)
Faeces discoloured	0	1(0.1%)
Faeces hard	0	1(0.1%)
Frequent bowel movements	0	1(0.1%)
Gastric antral vascular ectasia	0	1(0.1%)
Gastric dysplasia	0	1(0.1%)
Gastric mucosa erythema	0	1(0.1%)
Gastric mucosal hypertrophy	0	1(0.1%)
Gastrointestinal motility disorder	0	1(0.1%)
Gastrointestinal obstruction	0	1(0.1%)
Gastrointestinal pain	0	1(0.1%)
Gastrointestinal tract mucosal pigmentation	0	1(0.1%)
Ileal ulcer	0	1(0.1%)
Impaired gastric emptying	0	1(0.1%)
Intestinal polyp	0	1(0.1%)
Lip ulceration	0	1(0.1%)
Noninfective gingivitis	0	1(0.1%)
Oesophageal disorder	0	1(0.1%)
Oesophageal dysplasia	0	1(0.1%)
Oesophageal mass	0	1(0.1%)
Oesophageal polyp	0	1(0.1%)
Oral discomfort	0	1(0.1%)
Pancreatic failure	0	1(0.1%)
Pancreatic mass	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Pancreatolithiasis	0	1(0.1%)
Small intestinal perforation	0	1(0.1%)
Terminal ileitis	0	1(0.1%)
Uvulitis	0	1(0.1%)
Investigations	341(25.1%)	311(22.9%)
Glomerular filtration rate decreased	66(4.9%)	49(3.6%)
Blood potassium increased	43(3.2%)	21(1.5%)
Blood creatinine increased	38(2.8%)	33(2.4%)
Blood creatine phosphokinase increased	36(2.7%)	28(2.1%)
C-reactive protein increased	35(2.6%)	38(2.8%)
Blood pressure increased	21(1.5%)	26(1.9%)
Glycosylated haemoglobin increased	18(1.3%)	14(1.0%)
Weight decreased	14(1.0%)	17(1.3%)
Gamma-glutamyltransferase increased	14(1.0%)	15(1.1%)
Blood glucose increased	14(1.0%)	12(0.9%)
Blood uric acid increased	10(0.7%)	9(0.7%)
Blood urea increased	9(0.7%)	5(0.4%)
Weight increased	8(0.6%)	6(0.4%)
Prostatic specific antigen increased	8(0.6%)	4(0.3%)
Haemoglobin decreased	7(0.5%)	5(0.4%)
Heart rate increased	7(0.5%)	4(0.3%)
Aspartate aminotransferase increased	7(0.5%)	3(0.2%)
Blood triglycerides increased	6(0.4%)	9(0.7%)
Alanine aminotransferase increased	6(0.4%)	7(0.5%)
Blood pressure decreased	6(0.4%)	6(0.4%)
Electrocardiogram QT prolonged	6(0.4%)	3(0.2%)
Liver function test increased	5(0.4%)	5(0.4%)
Occult blood positive	5(0.4%)	4(0.3%)
Blood alkaline phosphatase increased	5(0.4%)	2(0.1%)
Blood bicarbonate decreased	4(0.3%)	2(0.1%)
Blood potassium decreased	4(0.3%)	2(0.1%)
Blood urine present	4(0.3%)	1(0.1%)
Cardiac murmur	3(0.2%)	4(0.3%)
Blood lactate dehydrogenase increased	3(0.2%)	2(0.1%)
Troponin T increased	3(0.2%)	2(0.1%)
White blood cell count increased	3(0.2%)	2(0.1%)
Blood sodium decreased	3(0.2%)	1(0.1%)
Helicobacter test positive	3(0.2%)	1(0.1%)
Platelet count decreased	3(0.2%)	0
Blood magnesium decreased	2(0.1%)	4(0.3%)
Haematocrit decreased	2(0.1%)	2(0.1%)
Influenza A virus test positive	2(0.1%)	2(0.1%)
Blood glucose decreased	2(0.1%)	1(0.1%)
Blood glucose fluctuation	2(0.1%)	1(0.1%)
Colonoscopy	2(0.1%)	1(0.1%)
International normalised ratio increased	2(0.1%)	1(0.1%)
Red blood cell count decreased	2(0.1%)	1(0.1%)
Scan myocardial perfusion abnormal	2(0.1%)	1(0.1%)
Angiocardiogram	2(0.1%)	0
Biopsy prostate	2(0.1%)	0
Blood cholesterol increased	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Electrocardiogram repolarisation abnormality	2(0.1%)	0
Endoscopy	2(0.1%)	0
Pulmonary arterial pressure increased	2(0.1%)	0
Hepatic enzyme increased	1(0.1%)	10(0.7%)
Arthroscopy	1(0.1%)	2(0.1%)
Blood folate decreased	1(0.1%)	2(0.1%)
Blood thyroid stimulating hormone increased	1(0.1%)	2(0.1%)
Ejection fraction decreased	1(0.1%)	2(0.1%)
Electrocardiogram T wave inversion	1(0.1%)	2(0.1%)
Heart rate decreased	1(0.1%)	2(0.1%)
Low density lipoprotein decreased	1(0.1%)	2(0.1%)
Vitamin D decreased	1(0.1%)	2(0.1%)
Amylase increased	1(0.1%)	1(0.1%)
Bacterial test positive	1(0.1%)	1(0.1%)
Blood calcium increased	1(0.1%)	1(0.1%)
Lipids increased	1(0.1%)	1(0.1%)
Liver function test abnormal	1(0.1%)	1(0.1%)
Albumin urine present	1(0.1%)	0
Biopsy artery	1(0.1%)	0
Biopsy bladder	1(0.1%)	0
Blood albumin increased	1(0.1%)	0
Blood alkaline phosphatase abnormal	1(0.1%)	0
Blood creatine phosphokinase MB increased	1(0.1%)	0
Blood growth hormone decreased	1(0.1%)	0
Blood iron decreased	1(0.1%)	0
Blood parathyroid hormone increased	1(0.1%)	0
Blood phosphorus decreased	1(0.1%)	0
Blood pressure diastolic decreased	1(0.1%)	0
Blood pressure orthostatic decreased	1(0.1%)	0
Blood testosterone decreased	1(0.1%)	0
Cancer staging	1(0.1%)	0
Carbohydrate antigen 125 increased	1(0.1%)	0
Cardiac function test abnormal	1(0.1%)	0
Catheterisation cardiac	1(0.1%)	0
Colonoscopy normal	1(0.1%)	0
Cystoscopy	1(0.1%)	0
Electrocardiogram Q wave abnormal	1(0.1%)	0
Electrocardiogram QRS complex abnormal	1(0.1%)	0
Electrocardiogram ST-T segment depression	1(0.1%)	0
Electrocardiogram abnormal	1(0.1%)	0
Haematocrit increased	1(0.1%)	0
Haematology test abnormal	1(0.1%)	0
Lipids abnormal	1(0.1%)	0
Low density lipoprotein increased	1(0.1%)	0
Optic nerve cup/disc ratio increased	1(0.1%)	0
Protein S decreased	1(0.1%)	0
Protein total increased	1(0.1%)	0
Protein urine present	1(0.1%)	0
Pulmonary imaging procedure abnormal	1(0.1%)	0
Pulse abnormal	1(0.1%)	0
Red blood cell sedimentation rate decreased	1(0.1%)	0
Serratia test positive	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
White blood cell count decreased	1(0.1%)	0
N-terminal prohormone brain natriuretic peptide increased	0	8(0.6%)
Troponin increased	0	6(0.4%)
Urine albumin/creatinine ratio increased	0	5(0.4%)
Serum ferritin decreased	0	3(0.2%)
Transaminases increased	0	3(0.2%)
Anticoagulation drug level above therapeutic	0	2(0.1%)
Intraocular pressure increased	0	2(0.1%)
SARS-CoV-2 test positive	0	2(0.1%)
Vitamin B12 decreased	0	2(0.1%)
Anticoagulation drug level below therapeutic	0	1(0.1%)
Biopsy kidney	0	1(0.1%)
Blood albumin decreased	0	1(0.1%)
Blood calcium decreased	0	1(0.1%)
Blood lactic acid increased	0	1(0.1%)
Blood magnesium increased	0	1(0.1%)
Blood pressure systolic increased	0	1(0.1%)
Brain natriuretic peptide increased	0	1(0.1%)
Carbohydrate antigen 19-9 increased	0	1(0.1%)
Carbohydrate antigen 50 increased	0	1(0.1%)
Carcinoembryonic antigen increased	0	1(0.1%)
Carotid bruit	0	1(0.1%)
Chest X-ray abnormal	0	1(0.1%)
Coagulation time prolonged	0	1(0.1%)
Cytogenetic analysis abnormal	0	1(0.1%)
ECG signs of myocardial ischaemia	0	1(0.1%)
Electrocardiogram ST segment abnormal	0	1(0.1%)
Electrocardiogram ST segment elevation	0	1(0.1%)
Electroencephalogram abnormal	0	1(0.1%)
Eosinophil count increased	0	1(0.1%)
Fibrin D dimer increased	0	1(0.1%)
Gastric pH decreased	0	1(0.1%)
Glomerular filtration rate increased	0	1(0.1%)
Glycosylated haemoglobin abnormal	0	1(0.1%)
Herpes simplex test positive	0	1(0.1%)
Imaging procedure abnormal	0	1(0.1%)
Left ventricular end-diastolic pressure increased	0	1(0.1%)
Mean cell volume decreased	0	1(0.1%)
Oral soft tissue biopsy	0	1(0.1%)
Polymerase chain reaction positive	0	1(0.1%)
Proteus test positive	0	1(0.1%)
Red blood cell sedimentation rate increased	0	1(0.1%)
Red blood cells urine positive	0	1(0.1%)
Renal function test abnormal	0	1(0.1%)
Scan adrenal gland abnormal	0	1(0.1%)
Thyroid hormones increased	0	1(0.1%)
Urine analysis abnormal	0	1(0.1%)
Nervous System Disorders	325(23.9%)	331(24.4%)
Dizziness	95(7.0%)	90(6.6%)
Headache	42(3.1%)	44(3.2%)
Diabetic neuropathy	31(2.3%)	28(2.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Syncope	24(1.8%)	32(2.4%)
Sciatica	16(1.2%)	19(1.4%)
Hypoaesthesia	16(1.2%)	14(1.0%)
Carotid artery stenosis	15(1.1%)	10(0.7%)
Neuropathy peripheral	15(1.1%)	10(0.7%)
Carpal tunnel syndrome	12(0.9%)	12(0.9%)
Cognitive disorder	8(0.6%)	8(0.6%)
Polyneuropathy	8(0.6%)	7(0.5%)
Carotid arteriosclerosis	8(0.6%)	6(0.4%)
Presyncope	8(0.6%)	6(0.4%)
Loss of consciousness	8(0.6%)	0
Dementia	7(0.5%)	5(0.4%)
Memory impairment	6(0.4%)	8(0.6%)
Restless legs syndrome	6(0.4%)	3(0.2%)
Tremor	5(0.4%)	10(0.7%)
Paraesthesia	5(0.4%)	9(0.7%)
Dizziness postural	5(0.4%)	8(0.6%)
Lethargy	5(0.4%)	0
Neuralgia	4(0.3%)	8(0.6%)
Cerebral atrophy	4(0.3%)	2(0.1%)
Somnolence	3(0.2%)	7(0.5%)
Transient ischaemic attack	3(0.2%)	7(0.5%)
Parkinson's disease	3(0.2%)	5(0.4%)
Seizure	3(0.2%)	4(0.3%)
Cerebral infarction	3(0.2%)	2(0.1%)
Hemiparesis	3(0.2%)	2(0.1%)
Cervicobrachial syndrome	3(0.2%)	1(0.1%)
Autonomic neuropathy	3(0.2%)	0
Cerebral microangiopathy	3(0.2%)	0
Cervical radiculopathy	3(0.2%)	0
Tension headache	3(0.2%)	0
Amnesia	2(0.1%)	7(0.5%)
Balance disorder	2(0.1%)	7(0.5%)
Facial paralysis	2(0.1%)	6(0.4%)
Vascular encephalopathy	2(0.1%)	4(0.3%)
Dementia Alzheimer's type	2(0.1%)	2(0.1%)
Migraine	2(0.1%)	2(0.1%)
Lumbar radiculopathy	2(0.1%)	1(0.1%)
Parkinsonism	2(0.1%)	1(0.1%)
Cerebral haemorrhage	2(0.1%)	0
Cerebral small vessel ischaemic disease	2(0.1%)	0
IVth nerve paralysis	2(0.1%)	0
Normal pressure hydrocephalus	2(0.1%)	0
Vascular headache	2(0.1%)	0
Cerebrovascular disorder	1(0.1%)	3(0.2%)
Lacunar infarction	1(0.1%)	3(0.2%)
Sensory disturbance	1(0.1%)	3(0.2%)
Aphasia	1(0.1%)	2(0.1%)
Cerebral arteriosclerosis	1(0.1%)	2(0.1%)
Dysarthria	1(0.1%)	2(0.1%)
Dysgeusia	1(0.1%)	2(0.1%)
Metabolic encephalopathy	1(0.1%)	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Nerve compression	1(0.1%)	2(0.1%)
Radiculopathy	1(0.1%)	2(0.1%)
Subarachnoid haemorrhage	1(0.1%)	2(0.1%)
Anosmia	1(0.1%)	1(0.1%)
Cerebrovascular accident	1(0.1%)	1(0.1%)
Decreased vibratory sense	1(0.1%)	1(0.1%)
Encephalopathy	1(0.1%)	1(0.1%)
Facial paresis	1(0.1%)	1(0.1%)
Hypersomnia	1(0.1%)	1(0.1%)
Myoclonus	1(0.1%)	1(0.1%)
Partial seizures	1(0.1%)	1(0.1%)
Post herpetic neuralgia	1(0.1%)	1(0.1%)
Vertebral artery stenosis	1(0.1%)	1(0.1%)
Ageusia	1(0.1%)	0
Altered state of consciousness	1(0.1%)	0
Basilar artery occlusion	1(0.1%)	0
Basilar artery stenosis	1(0.1%)	0
Cerebral artery occlusion	1(0.1%)	0
Cerebral microhaemorrhage	1(0.1%)	0
Cerebrospinal fluid leakage	1(0.1%)	0
Cerebrovascular insufficiency	1(0.1%)	0
Cerebrovascular stenosis	1(0.1%)	0
Cervicogenic headache	1(0.1%)	0
Dyskinesia	1(0.1%)	0
Generalised tonic-clonic seizure	1(0.1%)	0
Guillain-Barre syndrome	1(0.1%)	0
Hemianaesthesia	1(0.1%)	0
Hepatic encephalopathy	1(0.1%)	0
Hypogeusia	1(0.1%)	0
Ischaemic stroke	1(0.1%)	0
Meralgia paraesthetica	1(0.1%)	0
Muscle contractions involuntary	1(0.1%)	0
Orthostatic intolerance	1(0.1%)	0
Parosmia	1(0.1%)	0
Peripheral motor neuropathy	1(0.1%)	0
Sinus headache	1(0.1%)	0
Slow speech	1(0.1%)	0
Speech disorder	1(0.1%)	0
Toxic encephalopathy	1(0.1%)	0
Unresponsive to stimuli	1(0.1%)	0
Vocal cord paralysis	1(0.1%)	0
White matter lesion	1(0.1%)	0
Essential tremor	0	4(0.3%)
Cerebral artery stenosis	0	3(0.2%)
Axonal neuropathy	0	2(0.1%)
Burning sensation	0	2(0.1%)
Cerebral ischaemia	0	2(0.1%)
Intracranial aneurysm	0	2(0.1%)
Lumbosacral radiculopathy	0	2(0.1%)
Peripheral sensory neuropathy	0	2(0.1%)
Amnestic disorder	0	1(0.1%)
Brain stem infarction	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Carotid artery disease	0	1(0.1%)
Carotid artery occlusion	0	1(0.1%)
Central nervous system lesion	0	1(0.1%)
Cerebellar atrophy	0	1(0.1%)
Cerebellar stroke	0	1(0.1%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.1%)
Cubital tunnel syndrome	0	1(0.1%)
Dementia with Lewy bodies	0	1(0.1%)
Disturbance in attention	0	1(0.1%)
Epidural lipomatosis	0	1(0.1%)
Epilepsy	0	1(0.1%)
Facial nerve disorder	0	1(0.1%)
Hemiparaesthesia	0	1(0.1%)
Hyperglycaemic unconsciousness	0	1(0.1%)
Hypertensive encephalopathy	0	1(0.1%)
Hypoglycaemic unconsciousness	0	1(0.1%)
IIIrd nerve paralysis	0	1(0.1%)
Intraventricular haemorrhage	0	1(0.1%)
Mental impairment	0	1(0.1%)
Mixed dementia	0	1(0.1%)
Mononeuropathy multiplex	0	1(0.1%)
Multiple system atrophy	0	1(0.1%)
Muscle tone disorder	0	1(0.1%)
Myelomalacia	0	1(0.1%)
Myelopathy	0	1(0.1%)
Nervous system disorder	0	1(0.1%)
Neuritis	0	1(0.1%)
Neurological symptom	0	1(0.1%)
Paraplegia	0	1(0.1%)
Peripheral nerve paresis	0	1(0.1%)
Peripheral sensorimotor neuropathy	0	1(0.1%)
Piriformis syndrome	0	1(0.1%)
Posthaemorrhagic hydrocephalus	0	1(0.1%)
Precerebral arteriosclerosis	0	1(0.1%)
Pronator teres syndrome	0	1(0.1%)
Radicular pain	0	1(0.1%)
Senile dementia	0	1(0.1%)
Spinal cord compression	0	1(0.1%)
Spinal cord haematoma	0	1(0.1%)
Spondylitic myelopathy	0	1(0.1%)
Subdural effusion	0	1(0.1%)
Subdural hygroma	0	1(0.1%)
Thalamic infarction	0	1(0.1%)
Thalamus haemorrhage	0	1(0.1%)
Trigeminal neuralgia	0	1(0.1%)
Vascular dementia	0	1(0.1%)
Vertebral artery occlusion	0	1(0.1%)
Visual field defect	0	1(0.1%)
Respiratory, Thoracic And Mediastinal Disorders	286(21.1%)	267(19.7%)
Cough	76(5.6%)	71(5.2%)
Dyspnoea	60(4.4%)	48(3.5%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Chronic obstructive pulmonary disease	24(1.8%)	12(0.9%)
Sleep apnoea syndrome	17(1.3%)	19(1.4%)
Dyspnoea exertional	17(1.3%)	17(1.3%)
Pleural effusion	13(1.0%)	2(0.1%)
Oropharyngeal pain	12(0.9%)	12(0.9%)
Rhinitis allergic	12(0.9%)	9(0.7%)
Epistaxis	10(0.7%)	9(0.7%)
Pulmonary mass	9(0.7%)	8(0.6%)
Productive cough	8(0.6%)	6(0.4%)
Upper respiratory tract inflammation	8(0.6%)	3(0.2%)
Interstitial lung disease	8(0.6%)	2(0.1%)
Asthma	7(0.5%)	10(0.7%)
Pulmonary hypertension	6(0.4%)	9(0.7%)
Respiratory failure	6(0.4%)	4(0.3%)
Bronchitis chronic	5(0.4%)	7(0.5%)
Acute respiratory failure	4(0.3%)	5(0.4%)
Respiratory disorder	4(0.3%)	4(0.3%)
Catarrh	4(0.3%)	3(0.2%)
Obstructive airways disorder	4(0.3%)	0
Rhinorrhoea	3(0.2%)	7(0.5%)
Pulmonary embolism	3(0.2%)	5(0.4%)
Emphysema	3(0.2%)	2(0.1%)
Pulmonary congestion	2(0.1%)	6(0.4%)
Dysphonia	2(0.1%)	4(0.3%)
Nasal congestion	2(0.1%)	3(0.2%)
Pulmonary fibrosis	2(0.1%)	3(0.2%)
Rales	2(0.1%)	3(0.2%)
Wheezing	2(0.1%)	3(0.2%)
Atelectasis	2(0.1%)	1(0.1%)
Bronchiectasis	2(0.1%)	1(0.1%)
Bronchospasm	2(0.1%)	1(0.1%)
Hypoxia	2(0.1%)	1(0.1%)
Sinus congestion	2(0.1%)	1(0.1%)
Laryngeal oedema	2(0.1%)	0
Pneumonia aspiration	2(0.1%)	0
Sneezing	2(0.1%)	0
Pulmonary oedema	1(0.1%)	6(0.4%)
Bronchial hyperreactivity	1(0.1%)	3(0.2%)
Haemoptysis	1(0.1%)	3(0.2%)
Nasal obstruction	1(0.1%)	3(0.2%)
Acute pulmonary oedema	1(0.1%)	2(0.1%)
Dry throat	1(0.1%)	1(0.1%)
Hiccups	1(0.1%)	1(0.1%)
Lung disorder	1(0.1%)	1(0.1%)
Alveolar lung disease	1(0.1%)	0
Asthmatic crisis	1(0.1%)	0
Bronchial disorder	1(0.1%)	0
Chronic respiratory failure	1(0.1%)	0
Combined pulmonary fibrosis and emphysema	1(0.1%)	0
Dyspnoea paroxysmal nocturnal	1(0.1%)	0
Hydrothorax	1(0.1%)	0
Lower respiratory tract inflammation	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Lung consolidation	1(0.1%)	0
Lung opacity	1(0.1%)	0
Nasal crusting	1(0.1%)	0
Nasal disorder	1(0.1%)	0
Nasal mucosal disorder	1(0.1%)	0
Nasal septum deviation	1(0.1%)	0
Oropharyngeal discomfort	1(0.1%)	0
Oropharyngeal dysplasia	1(0.1%)	0
Paranasal cyst	1(0.1%)	0
Paranasal sinus hypersecretion	1(0.1%)	0
Pharyngeal inflammation	1(0.1%)	0
Pharyngeal paraesthesia	1(0.1%)	0
Pleural fibrosis	1(0.1%)	0
Pleuritic pain	1(0.1%)	0
Pneumonitis	1(0.1%)	0
Respiratory tract congestion	1(0.1%)	0
Reversible airways obstruction	1(0.1%)	0
Vocal cord polyp	1(0.1%)	0
Hypercapnia	0	2(0.1%)
Idiopathic pulmonary fibrosis	0	2(0.1%)
Lung cyst	0	2(0.1%)
Pleurisy	0	2(0.1%)
Pneumothorax	0	2(0.1%)
Throat irritation	0	2(0.1%)
Allergic cough	0	1(0.1%)
Allergic sinusitis	0	1(0.1%)
Aspiration	0	1(0.1%)
Atopic cough	0	1(0.1%)
Cough variant asthma	0	1(0.1%)
Hepatic hydrothorax	0	1(0.1%)
Hypersensitivity pneumonitis	0	1(0.1%)
Laryngeal disorder	0	1(0.1%)
Laryngeal inflammation	0	1(0.1%)
Lung perforation	0	1(0.1%)
Orthopnoea	0	1(0.1%)
Paranasal sinus discomfort	0	1(0.1%)
Rhinitis perennial	0	1(0.1%)
Rhonchi	0	1(0.1%)
Small airways disease	0	1(0.1%)
Snoring	0	1(0.1%)
Throat tightness	0	1(0.1%)
Upper respiratory tract congestion	0	1(0.1%)
Vasomotor rhinitis	0	1(0.1%)
Vocal cord disorder	0	1(0.1%)
Vocal cord leukoplakia	0	1(0.1%)
Vascular Disorders	269(19.8%)	248(18.3%)
Hypotension	87(6.4%)	54(4.0%)
Hypertension	66(4.9%)	106(7.8%)
Peripheral arterial occlusive disease	28(2.1%)	19(1.4%)
Orthostatic hypotension	17(1.3%)	9(0.7%)
Hypertensive crisis	12(0.9%)	9(0.7%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Intermittent claudication	11(0.8%)	6(0.4%)
Peripheral venous disease	11(0.8%)	6(0.4%)
Aortic stenosis	9(0.7%)	7(0.5%)
Varicose vein	9(0.7%)	5(0.4%)
Aortic arteriosclerosis	6(0.4%)	8(0.6%)
Deep vein thrombosis	5(0.4%)	6(0.4%)
Peripheral vascular disorder	5(0.4%)	6(0.4%)
Aortic aneurysm	4(0.3%)	8(0.6%)
Haematoma	4(0.3%)	7(0.5%)
Arteriosclerosis	4(0.3%)	3(0.2%)
Peripheral artery occlusion	4(0.3%)	3(0.2%)
Peripheral artery stenosis	4(0.3%)	3(0.2%)
Extremity necrosis	4(0.3%)	1(0.1%)
Hypertensive urgency	3(0.2%)	3(0.2%)
Peripheral ischaemia	2(0.1%)	5(0.4%)
Aortic dilatation	2(0.1%)	3(0.2%)
Blood pressure fluctuation	2(0.1%)	2(0.1%)
Thrombophlebitis	2(0.1%)	1(0.1%)
Aortic dissection	2(0.1%)	0
Cyanosis	2(0.1%)	0
Post thrombotic syndrome	2(0.1%)	0
Hot flush	1(0.1%)	4(0.3%)
Hypertensive emergency	1(0.1%)	2(0.1%)
Phlebitis	1(0.1%)	2(0.1%)
Thrombosis	1(0.1%)	2(0.1%)
Aortic occlusion	1(0.1%)	1(0.1%)
Blood pressure inadequately controlled	1(0.1%)	1(0.1%)
Circulatory collapse	1(0.1%)	1(0.1%)
Diabetic vascular disorder	1(0.1%)	1(0.1%)
Iliac artery stenosis	1(0.1%)	1(0.1%)
Lymphoedema	1(0.1%)	1(0.1%)
Microangiopathy	1(0.1%)	1(0.1%)
Peripheral coldness	1(0.1%)	1(0.1%)
Subclavian artery stenosis	1(0.1%)	1(0.1%)
Venous thrombosis limb	1(0.1%)	1(0.1%)
Arterial occlusive disease	1(0.1%)	0
Artery dissection	1(0.1%)	0
Brachiocephalic arteriosclerosis	1(0.1%)	0
Macroangiopathy	1(0.1%)	0
Penetrating aortic ulcer	1(0.1%)	0
Peripheral artery aneurysm	1(0.1%)	0
Peripheral embolism	1(0.1%)	0
Subclavian artery dissection	1(0.1%)	0
Thrombophlebitis superficial	1(0.1%)	0
Varicose ulceration	1(0.1%)	0
Vasculitis	1(0.1%)	0
Essential hypertension	0	3(0.2%)
Accelerated hypertension	0	2(0.1%)
Hyperaemia	0	2(0.1%)
Aortic thrombosis	0	1(0.1%)
Arterial disorder	0	1(0.1%)
Arterial stenosis	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Arterial thrombosis	0	1(0.1%)
Arteriosclerosis Moenckeberg-type	0	1(0.1%)
Inferior vena cava syndrome	0	1(0.1%)
Internal haemorrhage	0	1(0.1%)
Labile hypertension	0	1(0.1%)
Peripheral artery aneurysm rupture	0	1(0.1%)
Systolic hypertension	0	1(0.1%)
Vein disorder	0	1(0.1%)
General Disorders And Administration Site Conditions	258(19.0%)	297(21.9%)
Oedema peripheral	88(6.5%)	112(8.3%)
Fatigue	45(3.3%)	33(2.4%)
Chest pain	41(3.0%)	52(3.8%)
Peripheral swelling	19(1.4%)	23(1.7%)
Asthenia	18(1.3%)	28(2.1%)
Pyrexia	17(1.3%)	17(1.3%)
Chest discomfort	10(0.7%)	9(0.7%)
Oedema	9(0.7%)	21(1.5%)
Pain	8(0.6%)	6(0.4%)
Inflammation	8(0.6%)	5(0.4%)
Influenza like illness	6(0.4%)	10(0.7%)
Gait disturbance	5(0.4%)	5(0.4%)
Chills	4(0.3%)	1(0.1%)
Generalised oedema	4(0.3%)	1(0.1%)
Malaise	3(0.2%)	8(0.6%)
Feeling cold	3(0.2%)	5(0.4%)
General physical health deterioration	3(0.2%)	5(0.4%)
Drug intolerance	3(0.2%)	2(0.1%)
Death	2(0.1%)	4(0.3%)
Cyst	2(0.1%)	3(0.2%)
Impaired healing	2(0.1%)	2(0.1%)
Nodule	2(0.1%)	2(0.1%)
Face oedema	2(0.1%)	0
Gravitational oedema	2(0.1%)	0
Unevaluable event	2(0.1%)	0
Mass	1(0.1%)	2(0.1%)
Adverse drug reaction	1(0.1%)	1(0.1%)
Hunger	1(0.1%)	1(0.1%)
Polyp	1(0.1%)	1(0.1%)
Systemic inflammatory response syndrome	1(0.1%)	1(0.1%)
Application site reaction	1(0.1%)	0
Catheter site inflammation	1(0.1%)	0
Complication associated with device	1(0.1%)	0
Exercise tolerance decreased	1(0.1%)	0
Hernia	1(0.1%)	0
Hernia pain	1(0.1%)	0
Illness	1(0.1%)	0
Injection site erosion	1(0.1%)	0
Injection site pain	1(0.1%)	0
Injection site pruritus	1(0.1%)	0
Oedema due to cardiac disease	1(0.1%)	0
Precancerous condition	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Pseudopolyp	1(0.1%)	0
Sensation of foreign body	1(0.1%)	0
Stent-graft endoleak	1(0.1%)	0
Swelling face	1(0.1%)	0
Non-cardiac chest pain	0	6(0.4%)
Localised oedema	0	3(0.2%)
Adhesion	0	1(0.1%)
Calcinosis	0	1(0.1%)
Discomfort	0	1(0.1%)
Facial pain	0	1(0.1%)
Hyperpyrexia	0	1(0.1%)
Hyperthermia	0	1(0.1%)
Injection site atrophy	0	1(0.1%)
Medical device site nerve damage	0	1(0.1%)
Multiple organ dysfunction syndrome	0	1(0.1%)
Non-pitting oedema	0	1(0.1%)
Sense of oppression	0	1(0.1%)
Suprapubic pain	0	1(0.1%)
Swelling	0	1(0.1%)
Vascular stent stenosis	0	1(0.1%)
Vessel puncture site bruise	0	1(0.1%)
Vessel puncture site haemorrhage	0	1(0.1%)
Injury, Poisoning And Procedural Complications	258(19.0%)	264(19.5%)
Fall	48(3.5%)	42(3.1%)
Limb injury	41(3.0%)	28(2.1%)
Contusion	40(2.9%)	36(2.7%)
Ligament sprain	20(1.5%)	19(1.4%)
Skin laceration	16(1.2%)	9(0.7%)
Skin abrasion	15(1.1%)	13(1.0%)
Rib fracture	10(0.7%)	13(1.0%)
Foot fracture	10(0.7%)	10(0.7%)
Head injury	9(0.7%)	12(0.9%)
Post-traumatic pain	9(0.7%)	1(0.1%)
Thermal burn	8(0.6%)	5(0.4%)
Accident	7(0.5%)	6(0.4%)
Spinal compression fracture	7(0.5%)	4(0.3%)
Procedural pain	6(0.4%)	6(0.4%)
Wound	6(0.4%)	6(0.4%)
Subcutaneous haematoma	6(0.4%)	4(0.3%)
Joint injury	5(0.4%)	4(0.3%)
Muscle strain	5(0.4%)	4(0.3%)
Joint dislocation	5(0.4%)	3(0.2%)
Tooth fracture	5(0.4%)	3(0.2%)
Bone contusion	5(0.4%)	1(0.1%)
Femur fracture	4(0.3%)	4(0.3%)
Muscle rupture	4(0.3%)	2(0.1%)
Tibia fracture	4(0.3%)	0
Humerus fracture	3(0.2%)	9(0.7%)
Radius fracture	3(0.2%)	6(0.4%)
Ankle fracture	3(0.2%)	4(0.3%)
Hand fracture	3(0.2%)	3(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Soft tissue injury	3(0.2%)	3(0.2%)
Upper limb fracture	3(0.2%)	3(0.2%)
Wrist fracture	3(0.2%)	3(0.2%)
Chest injury	3(0.2%)	2(0.1%)
Hip fracture	3(0.2%)	2(0.1%)
Arthropod sting	3(0.2%)	1(0.1%)
Clavicle fracture	3(0.2%)	0
Traumatic haematoma	3(0.2%)	0
Tendon rupture	2(0.1%)	4(0.3%)
Overdose	2(0.1%)	3(0.2%)
Concussion	2(0.1%)	2(0.1%)
Animal bite	2(0.1%)	1(0.1%)
Heat illness	2(0.1%)	1(0.1%)
Ligament rupture	2(0.1%)	1(0.1%)
Muscle injury	2(0.1%)	1(0.1%)
Patella fracture	2(0.1%)	1(0.1%)
Post procedural haemorrhage	2(0.1%)	1(0.1%)
Procedural haemorrhage	2(0.1%)	1(0.1%)
Scratch	2(0.1%)	1(0.1%)
Chillblains	2(0.1%)	0
Craniocerebral injury	2(0.1%)	0
Femoral neck fracture	2(0.1%)	0
Foreign body	2(0.1%)	0
Incision site pain	2(0.1%)	0
Scapula fracture	2(0.1%)	0
Scar	2(0.1%)	0
Spinal column injury	2(0.1%)	0
Wound secretion	2(0.1%)	0
Meniscus injury	1(0.1%)	5(0.4%)
Road traffic accident	1(0.1%)	5(0.4%)
Subdural haematoma	1(0.1%)	4(0.3%)
Lumbar vertebral fracture	1(0.1%)	3(0.2%)
Skin wound	1(0.1%)	3(0.2%)
Fractured coccyx	1(0.1%)	2(0.1%)
Skin injury	1(0.1%)	2(0.1%)
Ulna fracture	1(0.1%)	2(0.1%)
Accidental overdose	1(0.1%)	1(0.1%)
Anaemia postoperative	1(0.1%)	1(0.1%)
Arthropod bite	1(0.1%)	1(0.1%)
Brain contusion	1(0.1%)	1(0.1%)
Ear injury	1(0.1%)	1(0.1%)
Fibula fracture	1(0.1%)	1(0.1%)
Post procedural haematoma	1(0.1%)	1(0.1%)
Post procedural inflammation	1(0.1%)	1(0.1%)
Subdural haemorrhage	1(0.1%)	1(0.1%)
Acetabulum fracture	1(0.1%)	0
Barotitis media	1(0.1%)	0
Bladder injury	1(0.1%)	0
Cervical vertebral fracture	1(0.1%)	0
Closed globe injury	1(0.1%)	0
Dental restoration failure	1(0.1%)	0
Eye injury	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Foreign body aspiration	1(0.1%)	0
Foreign body in ear	1(0.1%)	0
Gun shot wound	1(0.1%)	0
Heat stroke	1(0.1%)	0
Hyphaema	1(0.1%)	0
Incisional hernia	1(0.1%)	0
Inflammation of wound	1(0.1%)	0
Injury of conjunctiva	1(0.1%)	0
Lower limb fracture	1(0.1%)	0
Mouth injury	1(0.1%)	0
Nail avulsion	1(0.1%)	0
Periorbital haematoma	1(0.1%)	0
Post procedural hypothyroidism	1(0.1%)	0
Post-traumatic neck syndrome	1(0.1%)	0
Postoperative delirium	1(0.1%)	0
Postoperative wound complication	1(0.1%)	0
Radiation proctopathy	1(0.1%)	0
Radiation skin injury	1(0.1%)	0
Skull fracture	1(0.1%)	0
Skull fractured base	1(0.1%)	0
Splenic injury	1(0.1%)	0
Splenic rupture	1(0.1%)	0
Tendon injury	1(0.1%)	0
Testicular injury	1(0.1%)	0
Tooth injury	1(0.1%)	0
Traumatic fracture	1(0.1%)	0
Facial bones fracture	0	5(0.4%)
Epicondylitis	0	3(0.2%)
Injury	0	3(0.2%)
Spinal fracture	0	3(0.2%)
Back injury	0	2(0.1%)
Burns second degree	0	2(0.1%)
Seroma	0	2(0.1%)
Vascular pseudoaneurysm	0	2(0.1%)
Animal scratch	0	1(0.1%)
Brachial plexus injury	0	1(0.1%)
Cardiac procedure complication	0	1(0.1%)
Cartilage injury	0	1(0.1%)
Cataract operation complication	0	1(0.1%)
Eschar	0	1(0.1%)
Exposure to SARS-CoV-2	0	1(0.1%)
Fractured sacrum	0	1(0.1%)
Incision site haematoma	0	1(0.1%)
Injury corneal	0	1(0.1%)
Limb fracture	0	1(0.1%)
Multiple injuries	0	1(0.1%)
Nail injury	0	1(0.1%)
Nasal injury	0	1(0.1%)
Pelvic fracture	0	1(0.1%)
Periprosthetic fracture	0	1(0.1%)
Post procedural complication	0	1(0.1%)
Post procedural oedema	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Procedural complication	0	1(0.1%)
Procedural intestinal perforation	0	1(0.1%)
Reproductive tract procedural complication	0	1(0.1%)
Spinal cord injury cervical	0	1(0.1%)
Stomal hernia	0	1(0.1%)
Stress fracture	0	1(0.1%)
Tooth dislocation	0	1(0.1%)
Toxicity to various agents	0	1(0.1%)
Tracheal deviation	0	1(0.1%)
Transfusion reaction	0	1(0.1%)
Traumatic ulcer	0	1(0.1%)
Urinary retention postoperative	0	1(0.1%)
VIIIth nerve injury	0	1(0.1%)
Vascular anastomosis aneurysm	0	1(0.1%)
Wound complication	0	1(0.1%)
Wound dehiscence	0	1(0.1%)
Wound haemorrhage	0	1(0.1%)
Renal And Urinary Disorders	254(18.7%)	240(17.7%)
Acute kidney injury	58(4.3%)	65(4.8%)
Renal impairment	44(3.2%)	32(2.4%)
Renal cyst	28(2.1%)	21(1.5%)
Haematuria	25(1.8%)	21(1.5%)
Nephrolithiasis	19(1.4%)	21(1.5%)
Urinary incontinence	18(1.3%)	11(0.8%)
Chronic kidney disease	15(1.1%)	17(1.3%)
Renal failure	15(1.1%)	5(0.4%)
Urinary retention	10(0.7%)	14(1.0%)
Dysuria	9(0.7%)	11(0.8%)
Diabetic nephropathy	6(0.4%)	4(0.3%)
Pollakiuria	5(0.4%)	13(1.0%)
Micturition urgency	5(0.4%)	1(0.1%)
Ureterolithiasis	4(0.3%)	6(0.4%)
Renal colic	4(0.3%)	4(0.3%)
Nephropathy	4(0.3%)	3(0.2%)
Hydronephrosis	3(0.2%)	8(0.6%)
Calculus urinary	3(0.2%)	3(0.2%)
Lower urinary tract symptoms	3(0.2%)	2(0.1%)
Urinary tract obstruction	3(0.2%)	2(0.1%)
Calculus bladder	3(0.2%)	1(0.1%)
Urine flow decreased	3(0.2%)	0
Hypertonic bladder	2(0.1%)	5(0.4%)
Proteinuria	2(0.1%)	4(0.3%)
Renal disorder	2(0.1%)	1(0.1%)
Urge incontinence	2(0.1%)	1(0.1%)
Bladder disorder	2(0.1%)	0
Stress urinary incontinence	2(0.1%)	0
Urinary hesitation	2(0.1%)	0
Nocturia	1(0.1%)	8(0.6%)
Urethral stenosis	1(0.1%)	4(0.3%)
Bladder hypertrophy	1(0.1%)	2(0.1%)
End stage renal disease	1(0.1%)	2(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Neurogenic bladder	1(0.1%)	2(0.1%)
Polyuria	1(0.1%)	2(0.1%)
Renal artery stenosis	1(0.1%)	2(0.1%)
Acquired cystic kidney disease	1(0.1%)	1(0.1%)
Albuminuria	1(0.1%)	1(0.1%)
Bladder diverticulum	1(0.1%)	1(0.1%)
Urinary tract disorder	1(0.1%)	1(0.1%)
Azotaemia	1(0.1%)	0
Bladder irritation	1(0.1%)	0
Nephroangiosclerosis	1(0.1%)	0
Nephropathy toxic	1(0.1%)	0
Oliguria	1(0.1%)	0
Renal vessel disorder	1(0.1%)	0
Tubulointerstitial nephritis	1(0.1%)	0
Urate nephropathy	1(0.1%)	0
Ureteric obstruction	1(0.1%)	0
Renal mass	0	3(0.2%)
Incontinence	0	2(0.1%)
Renal atrophy	0	2(0.1%)
Ureteric stenosis	0	2(0.1%)
Bladder mass	0	1(0.1%)
Bladder neck obstruction	0	1(0.1%)
Bladder outlet obstruction	0	1(0.1%)
Glycosuria	0	1(0.1%)
Microalbuminuria	0	1(0.1%)
Pelvi-ureteric obstruction	0	1(0.1%)
Renal artery arteriosclerosis	0	1(0.1%)
Renal hypertension	0	1(0.1%)
Renal hypertrophy	0	1(0.1%)
Renal pain	0	1(0.1%)
Urinary tract inflammation	0	1(0.1%)
Urine abnormality	0	1(0.1%)
Urine odour abnormal	0	1(0.1%)
Skin And Subcutaneous Tissue Disorders	244(18.0%)	231(17.0%)
Pruritus	46(3.4%)	33(2.4%)
Skin ulcer	33(2.4%)	30(2.2%)
Eczema	30(2.2%)	21(1.5%)
Rash	21(1.5%)	12(0.9%)
Dry skin	15(1.1%)	16(1.2%)
Diabetic foot	14(1.0%)	13(1.0%)
Dermatitis	14(1.0%)	10(0.7%)
Skin lesion	11(0.8%)	15(1.1%)
Actinic keratosis	11(0.8%)	11(0.8%)
Urticaria	9(0.7%)	5(0.4%)
Hyperkeratosis	7(0.5%)	9(0.7%)
Dermatitis contact	7(0.5%)	6(0.4%)
Decubitus ulcer	6(0.4%)	3(0.2%)
Eczema asteatotic	6(0.4%)	1(0.1%)
Erythema	5(0.4%)	9(0.7%)
Dermal cyst	4(0.3%)	4(0.3%)
Alopecia	4(0.3%)	3(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Psoriasis	4(0.3%)	3(0.2%)
Palmoplantar keratoderma	4(0.3%)	2(0.1%)
Skin exfoliation	4(0.3%)	1(0.1%)
Blister	3(0.2%)	7(0.5%)
Dermatitis allergic	3(0.2%)	5(0.4%)
Hyperhidrosis	3(0.2%)	5(0.4%)
Ingrowing nail	3(0.2%)	5(0.4%)
Acne	3(0.2%)	2(0.1%)
Stasis dermatitis	3(0.2%)	2(0.1%)
Xeroderma	3(0.2%)	0
Rash papular	2(0.1%)	2(0.1%)
Seborrhoeic dermatitis	2(0.1%)	2(0.1%)
Skin fissures	2(0.1%)	1(0.1%)
Diabetic ulcer	2(0.1%)	0
Night sweats	2(0.1%)	0
Petechiae	2(0.1%)	0
Rash maculo-papular	2(0.1%)	0
Skin discolouration	2(0.1%)	0
Skin disorder	2(0.1%)	0
Skin hypertrophy	2(0.1%)	0
Rosacea	1(0.1%)	5(0.4%)
Angioedema	1(0.1%)	3(0.2%)
Ecchymosis	1(0.1%)	3(0.2%)
Dermatitis atopic	1(0.1%)	1(0.1%)
Lipodystrophy acquired	1(0.1%)	1(0.1%)
Pruritus allergic	1(0.1%)	1(0.1%)
Acanthosis nigricans	1(0.1%)	0
Androgenetic alopecia	1(0.1%)	0
Asteatosis	1(0.1%)	0
Chronic pigmented purpura	1(0.1%)	0
Chronic spontaneous urticaria	1(0.1%)	0
Erythematotelangiectatic rosacea	1(0.1%)	0
Granuloma annulare	1(0.1%)	0
Hand dermatitis	1(0.1%)	0
Lichen planopilaris	1(0.1%)	0
Macule	1(0.1%)	0
Nail disorder	1(0.1%)	0
Necrobiosis lipoidica diabeticorum	1(0.1%)	0
Neurodermatitis	1(0.1%)	0
Onychomadesis	1(0.1%)	0
Pain of skin	1(0.1%)	0
Pemphigus	1(0.1%)	0
Post inflammatory pigmentation change	1(0.1%)	0
Scab	1(0.1%)	0
Skin dystrophy	1(0.1%)	0
Skin fibrosis	1(0.1%)	0
Skin necrosis	1(0.1%)	0
Solar lentigo	1(0.1%)	0
Toxic skin eruption	1(0.1%)	0
Vitiligo	1(0.1%)	0
Drug eruption	0	3(0.2%)
Intertrigo	0	3(0.2%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Pemphigoid	0	3(0.2%)
Skin irritation	0	3(0.2%)
Lipohypertrophy	0	2(0.1%)
Skin hyperpigmentation	0	2(0.1%)
Angiokeratoma	0	1(0.1%)
Circumoral oedema	0	1(0.1%)
Dermatitis bullous	0	1(0.1%)
Diabetic cheiroarthropathy	0	1(0.1%)
Diabetic dermopathy	0	1(0.1%)
Granuloma skin	0	1(0.1%)
Hidradenitis	0	1(0.1%)
Ischaemic skin ulcer	0	1(0.1%)
Penile ulceration	0	1(0.1%)
Rash macular	0	1(0.1%)
Rash pruritic	0	1(0.1%)
Reactive perforating collagenosis	0	1(0.1%)
Skin haemorrhage	0	1(0.1%)
Skin mass	0	1(0.1%)
Trichorrhexis	0	1(0.1%)
Cardiac Disorders	217(16.0%)	212(15.6%)
Angina pectoris	26(1.9%)	20(1.5%)
Cardiac failure	24(1.8%)	37(2.7%)
Bradycardia	24(1.8%)	13(1.0%)
Atrial fibrillation	17(1.3%)	11(0.8%)
Mitral valve incompetence	16(1.2%)	8(0.6%)
Coronary artery disease	13(1.0%)	17(1.3%)
Bundle branch block right	12(0.9%)	4(0.3%)
Cardiac failure chronic	11(0.8%)	14(1.0%)
Ventricular extrasystoles	11(0.8%)	13(1.0%)
Sinus bradycardia	11(0.8%)	5(0.4%)
Atrioventricular block first degree	8(0.6%)	8(0.6%)
Palpitations	8(0.6%)	7(0.5%)
Angina unstable	8(0.6%)	2(0.1%)
Myocardial ischaemia	7(0.5%)	11(0.8%)
Tricuspid valve incompetence	7(0.5%)	6(0.4%)
Coronary artery stenosis	6(0.4%)	7(0.5%)
Supraventricular extrasystoles	6(0.4%)	5(0.4%)
Cardiac failure congestive	6(0.4%)	3(0.2%)
Bundle branch block left	5(0.4%)	10(0.7%)
Aortic valve stenosis	5(0.4%)	4(0.3%)
Diastolic dysfunction	5(0.4%)	2(0.1%)
Tachycardia	4(0.3%)	6(0.4%)
Left ventricular hypertrophy	4(0.3%)	4(0.3%)
Hypertensive heart disease	4(0.3%)	0
Myocardial infarction	4(0.3%)	0
Aortic valve incompetence	3(0.2%)	7(0.5%)
Sinus tachycardia	3(0.2%)	4(0.3%)
Arteriosclerosis coronary artery	3(0.2%)	3(0.2%)
Left ventricular dysfunction	3(0.2%)	2(0.1%)
Cardiac failure acute	3(0.2%)	0
Congestive cardiomyopathy	3(0.2%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Atrioventricular block second degree	2(0.1%)	10(0.7%)
Arrhythmia	2(0.1%)	2(0.1%)
Atrial flutter	2(0.1%)	2(0.1%)
Cardiomegaly	2(0.1%)	2(0.1%)
Cardiac valve disease	2(0.1%)	1(0.1%)
Left ventricular failure	2(0.1%)	1(0.1%)
Pericarditis	2(0.1%)	1(0.1%)
Ventricular hypokinesia	2(0.1%)	1(0.1%)
Degenerative aortic valve disease	2(0.1%)	0
Left atrial enlargement	2(0.1%)	0
Sinus node dysfunction	1(0.1%)	4(0.3%)
Supraventricular tachycardia	1(0.1%)	4(0.3%)
Atrioventricular block complete	1(0.1%)	2(0.1%)
Cardiac arrest	1(0.1%)	2(0.1%)
Extrasystoles	1(0.1%)	2(0.1%)
Mitral valve stenosis	1(0.1%)	2(0.1%)
Pericardial effusion	1(0.1%)	2(0.1%)
Acute left ventricular failure	1(0.1%)	1(0.1%)
Aortic valve sclerosis	1(0.1%)	1(0.1%)
Cardiomyopathy	1(0.1%)	1(0.1%)
Metabolic cardiomyopathy	1(0.1%)	1(0.1%)
Aortic valve calcification	1(0.1%)	0
Arrhythmia supraventricular	1(0.1%)	0
Atrial tachycardia	1(0.1%)	0
Atrial thrombosis	1(0.1%)	0
Atrioventricular block	1(0.1%)	0
Bundle branch block bilateral	1(0.1%)	0
Cardiac aneurysm	1(0.1%)	0
Cardiac discomfort	1(0.1%)	0
Cardiac hypertrophy	1(0.1%)	0
Cardiac septal hypertrophy	1(0.1%)	0
Chronic left ventricular failure	1(0.1%)	0
Cor pulmonale	1(0.1%)	0
Degenerative mitral valve disease	1(0.1%)	0
Intracardiac mass	1(0.1%)	0
Left atrial dilatation	1(0.1%)	0
Left ventricular dilatation	1(0.1%)	0
Mitral valve calcification	1(0.1%)	0
Mitral valve disease	1(0.1%)	0
Mitral valve sclerosis	1(0.1%)	0
Myocardial fibrosis	1(0.1%)	0
Pulseless electrical activity	1(0.1%)	0
Right atrial dilatation	1(0.1%)	0
Systolic dysfunction	1(0.1%)	0
Tachycardia paroxysmal	1(0.1%)	0
Ventricular hypertrophy	1(0.1%)	0
Ventricular tachyarrhythmia	1(0.1%)	0
Ischaemic cardiomyopathy	0	3(0.2%)
Cardiac dysfunction	0	2(0.1%)
Cardiovascular disorder	0	2(0.1%)
Aortic valve disease	0	1(0.1%)
Aortic valve disease mixed	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Bifascicular block	0	1(0.1%)
Cardiac tamponade	0	1(0.1%)
Cardiac valve sclerosis	0	1(0.1%)
Cardio-respiratory arrest	0	1(0.1%)
Cardiomyopathy acute	0	1(0.1%)
Cardiovascular insufficiency	0	1(0.1%)
Coronary artery insufficiency	0	1(0.1%)
Coronary artery occlusion	0	1(0.1%)
Coronary artery perforation	0	1(0.1%)
Hypertensive cardiomyopathy	0	1(0.1%)
Mitral valve prolapse	0	1(0.1%)
Sinoatrial block	0	1(0.1%)
Sinus arrhythmia	0	1(0.1%)
Tachyarrhythmia	0	1(0.1%)
Ventricular tachycardia	0	1(0.1%)
Eye Disorders	176(13.0%)	171(12.6%)
Cataract	60(4.4%)	73(5.4%)
Diabetic retinopathy	29(2.1%)	22(1.6%)
Dry eye	12(0.9%)	8(0.6%)
Visual impairment	8(0.6%)	6(0.4%)
Glaucoma	7(0.5%)	12(0.9%)
Vitreous haemorrhage	7(0.5%)	9(0.7%)
Vision blurred	7(0.5%)	7(0.5%)
Blepharitis	6(0.4%)	4(0.3%)
Macular oedema	5(0.4%)	6(0.4%)
Macular degeneration	5(0.4%)	4(0.3%)
Asthenopia	5(0.4%)	0
Conjunctivitis allergic	4(0.3%)	3(0.2%)
Macular fibrosis	4(0.3%)	2(0.1%)
Diabetic retinal oedema	4(0.3%)	1(0.1%)
Retinal haemorrhage	3(0.2%)	4(0.3%)
Eye inflammation	3(0.2%)	2(0.1%)
Eye haemorrhage	3(0.2%)	1(0.1%)
Periorbital oedema	3(0.2%)	1(0.1%)
Retinal vascular disorder	3(0.2%)	1(0.1%)
Retinopathy	3(0.2%)	1(0.1%)
Vitreous opacities	3(0.2%)	1(0.1%)
Astigmatism	3(0.2%)	0
Strabismus	3(0.2%)	0
Eye pruritus	2(0.1%)	2(0.1%)
Ocular hypertension	2(0.1%)	2(0.1%)
Presbyopia	2(0.1%)	2(0.1%)
Conjunctival haemorrhage	2(0.1%)	1(0.1%)
Eyelid ptosis	2(0.1%)	1(0.1%)
Ocular discomfort	2(0.1%)	1(0.1%)
Pterygium	2(0.1%)	1(0.1%)
Age-related macular degeneration	2(0.1%)	0
Conjunctival deposit	2(0.1%)	0
Keratitis	2(0.1%)	0
Vitreous detachment	2(0.1%)	0
Retinal detachment	1(0.1%)	4(0.3%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Macular hole	1(0.1%)	3(0.2%)
Posterior capsule opacification	1(0.1%)	2(0.1%)
Vitreous degeneration	1(0.1%)	2(0.1%)
Chalazion	1(0.1%)	1(0.1%)
Dry age-related macular degeneration	1(0.1%)	1(0.1%)
Eye irritation	1(0.1%)	1(0.1%)
Eye pain	1(0.1%)	1(0.1%)
Lacrimation increased	1(0.1%)	1(0.1%)
Meibomian gland dysfunction	1(0.1%)	1(0.1%)
Open angle glaucoma	1(0.1%)	1(0.1%)
Retinal aneurysm	1(0.1%)	1(0.1%)
Retinal artery occlusion	1(0.1%)	1(0.1%)
Retinopathy hypertensive	1(0.1%)	1(0.1%)
Retinopathy proliferative	1(0.1%)	1(0.1%)
Visual acuity reduced	1(0.1%)	1(0.1%)
Arteriosclerotic retinopathy	1(0.1%)	0
Cataract subcapsular	1(0.1%)	0
Chorioretinopathy	1(0.1%)	0
Conjunctival oedema	1(0.1%)	0
Corneal disorder	1(0.1%)	0
Corneal leukoma	1(0.1%)	0
Diabetic glaucoma	1(0.1%)	0
Diplopia	1(0.1%)	0
Eye haematoma	1(0.1%)	0
Eyelid skin dryness	1(0.1%)	0
Foreign body sensation in eyes	1(0.1%)	0
Hypermetropia	1(0.1%)	0
Iritis	1(0.1%)	0
Lacrimation decreased	1(0.1%)	0
Myopia	1(0.1%)	0
Normal tension glaucoma	1(0.1%)	0
Optic nerve cupping	1(0.1%)	0
Punctate keratitis	1(0.1%)	0
Retinal disorder	1(0.1%)	0
Retinal exudates	1(0.1%)	0
Rhegmatogenous retinal detachment	1(0.1%)	0
Scleritis	1(0.1%)	0
Swelling of eyelid	1(0.1%)	0
Uveitis	1(0.1%)	0
Vernal keratoconjunctivitis	1(0.1%)	0
Corneal erosion	0	2(0.1%)
Optic atrophy	0	2(0.1%)
Photopsia	0	2(0.1%)
Retinal tear	0	2(0.1%)
Retinal vein occlusion	0	2(0.1%)
Tractional retinal detachment	0	2(0.1%)
Vitreous floaters	0	2(0.1%)
Abnormal sensation in eye	0	1(0.1%)
Angle closure glaucoma	0	1(0.1%)
Aphakia	0	1(0.1%)
Blindness	0	1(0.1%)
Cystoid macular oedema	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Dermatochalasis	0	1(0.1%)
Eyelid oedema	0	1(0.1%)
Eyelid retraction	0	1(0.1%)
Iridocyclitis	0	1(0.1%)
Lens disorder	0	1(0.1%)
Maculopathy	0	1(0.1%)
Ocular hyperaemia	0	1(0.1%)
Optic ischaemic neuropathy	0	1(0.1%)
Periorbital swelling	0	1(0.1%)
Photophobia	0	1(0.1%)
Visual acuity reduced transiently	0	1(0.1%)
Blood And Lymphatic System Disorders	149(11.0%)	151(11.1%)
Anaemia	90(6.6%)	97(7.2%)
Iron deficiency anaemia	14(1.0%)	21(1.5%)
Thrombocytopenia	9(0.7%)	10(0.7%)
Nephrogenic anaemia	8(0.6%)	3(0.2%)
Normocytic anaemia	7(0.5%)	1(0.1%)
Lymphadenopathy	4(0.3%)	2(0.1%)
Microcytic anaemia	4(0.3%)	2(0.1%)
Abdominal lymphadenopathy	4(0.3%)	0
Splenomegaly	3(0.2%)	1(0.1%)
Anaemia of chronic disease	3(0.2%)	0
Thrombocytosis	3(0.2%)	0
Leukocytosis	2(0.1%)	6(0.4%)
Eosinophilia	2(0.1%)	2(0.1%)
Lymphadenopathy mediastinal	2(0.1%)	0
Macrocytosis	2(0.1%)	0
Spontaneous haematoma	2(0.1%)	0
Polycythaemia	1(0.1%)	2(0.1%)
Hypocoagulable state	1(0.1%)	1(0.1%)
Lymphadenitis	1(0.1%)	1(0.1%)
Coagulopathy	1(0.1%)	0
Hilar lymphadenopathy	1(0.1%)	0
Hypereosinophilic syndrome	1(0.1%)	0
Lymphocytic infiltration	1(0.1%)	0
Lymphopenia	1(0.1%)	0
Neutrophilia	1(0.1%)	0
Splenic granuloma	1(0.1%)	0
Hypochromic anaemia	0	5(0.4%)
Pancytopenia	0	3(0.2%)
Acquired haemophilia	0	1(0.1%)
Anaemia macrocytic	0	1(0.1%)
Bicytopenia	0	1(0.1%)
Haemoconcentration	0	1(0.1%)
Hyperglobulinaemia	0	1(0.1%)
Normochromic normocytic anaemia	0	1(0.1%)
Splenic embolism	0	1(0.1%)
Spontaneous haemorrhage	0	1(0.1%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	138(10.2%)	141(10.4%)
Basal cell carcinoma	17(1.3%)	18(1.3%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Prostate cancer	8(0.6%)	16(1.2%)
Lung neoplasm malignant	6(0.4%)	5(0.4%)
Colon cancer	6(0.4%)	4(0.3%)
Bladder cancer	5(0.4%)	5(0.4%)
Squamous cell carcinoma of skin	5(0.4%)	5(0.4%)
Colon adenoma	5(0.4%)	4(0.3%)
Lipoma	5(0.4%)	3(0.2%)
Skin papilloma	4(0.3%)	3(0.2%)
Seborrhoeic keratosis	4(0.3%)	2(0.1%)
Melanocytic naevus	3(0.2%)	1(0.1%)
Meningioma	3(0.2%)	1(0.1%)
Pancreatic carcinoma	3(0.2%)	1(0.1%)
Squamous cell carcinoma	3(0.2%)	1(0.1%)
Pancreatic neoplasm	3(0.2%)	0
Renal cell carcinoma	3(0.2%)	0
Lung neoplasm	2(0.1%)	5(0.4%)
Lung adenocarcinoma	2(0.1%)	3(0.2%)
Bladder transitional cell carcinoma	2(0.1%)	2(0.1%)
Hepatic cancer	2(0.1%)	2(0.1%)
Breast cancer	2(0.1%)	1(0.1%)
Metastases to liver	2(0.1%)	1(0.1%)
Plasma cell myeloma	2(0.1%)	1(0.1%)
Prostate cancer recurrent	2(0.1%)	1(0.1%)
Bladder cancer recurrent	2(0.1%)	0
Chronic lymphocytic leukaemia	2(0.1%)	0
Intraductal papillary mucinous neoplasm	2(0.1%)	0
Metastases to central nervous system	2(0.1%)	0
Metastases to lymph nodes	2(0.1%)	0
Myelodysplastic syndrome	2(0.1%)	0
Prostatic adenoma	2(0.1%)	0
Bladder neoplasm	1(0.1%)	3(0.2%)
Blepharal papilloma	1(0.1%)	3(0.2%)
Neoplasm skin	1(0.1%)	3(0.2%)
Colorectal cancer	1(0.1%)	2(0.1%)
Skin cancer	1(0.1%)	2(0.1%)
Uterine leiomyoma	1(0.1%)	2(0.1%)
Adenocarcinoma gastric	1(0.1%)	1(0.1%)
Adenoma benign	1(0.1%)	1(0.1%)
Anogenital warts	1(0.1%)	1(0.1%)
Bladder transitional cell carcinoma recurrent	1(0.1%)	1(0.1%)
Bronchial carcinoma	1(0.1%)	1(0.1%)
Cholangiocarcinoma	1(0.1%)	1(0.1%)
Gastrointestinal tract adenoma	1(0.1%)	1(0.1%)
Hepatocellular carcinoma	1(0.1%)	1(0.1%)
Keratoacanthoma	1(0.1%)	1(0.1%)
Pancreatic carcinoma metastatic	1(0.1%)	1(0.1%)
Renal hamartoma	1(0.1%)	1(0.1%)
Small cell lung cancer	1(0.1%)	1(0.1%)
Thyroid cancer	1(0.1%)	1(0.1%)
Transitional cell carcinoma	1(0.1%)	1(0.1%)
Acute myeloid leukaemia	1(0.1%)	0
Adenocarcinoma	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Adenocarcinoma of colon	1(0.1%)	0
Atypical fibroxanthoma	1(0.1%)	0
Benign neoplasm of conjunctiva	1(0.1%)	0
Benign neoplasm of skin	1(0.1%)	0
Benign renal neoplasm	1(0.1%)	0
Brain neoplasm malignant	1(0.1%)	0
Breast cancer metastatic	1(0.1%)	0
Cancer pain	1(0.1%)	0
Cerebral haemangioma	1(0.1%)	0
Enchondromatosis	1(0.1%)	0
Endometrial adenocarcinoma	1(0.1%)	0
Epithelioid mesothelioma	1(0.1%)	0
Fibroma	1(0.1%)	0
Haemangioma	1(0.1%)	0
Haemangioma of bone	1(0.1%)	0
Invasive ductal breast carcinoma	1(0.1%)	0
Invasive lobular breast carcinoma	1(0.1%)	0
Metastases to bone	1(0.1%)	0
Oesophageal adenocarcinoma	1(0.1%)	0
Oral fibroma	1(0.1%)	0
Oral papilloma	1(0.1%)	0
Oropharyngeal squamous cell carcinoma	1(0.1%)	0
Osteochondroma	1(0.1%)	0
Pancreatic carcinoma stage IV	1(0.1%)	0
Paraneoplastic syndrome	1(0.1%)	0
Pituitary tumour	1(0.1%)	0
Prostate cancer metastatic	1(0.1%)	0
Pyogenic granuloma	1(0.1%)	0
Rectal adenocarcinoma	1(0.1%)	0
Soft tissue neoplasm	1(0.1%)	0
Squamous cell carcinoma of the parotid gland	1(0.1%)	0
Tongue neoplasm benign	1(0.1%)	0
Transitional cell carcinoma recurrent	1(0.1%)	0
Uterine cancer	1(0.1%)	0
Adrenal adenoma	0	5(0.4%)
Oesophageal carcinoma	0	3(0.2%)
Benign neoplasm of bladder	0	2(0.1%)
Bowen's disease	0	2(0.1%)
Colon neoplasm	0	2(0.1%)
Endometrial cancer	0	2(0.1%)
Large intestine benign neoplasm	0	2(0.1%)
Malignant melanoma in situ	0	2(0.1%)
Renal neoplasm	0	2(0.1%)
Benign anorectal neoplasm	0	1(0.1%)
Benign gastrointestinal neoplasm	0	1(0.1%)
Benign neoplasm of prostate	0	1(0.1%)
Benign neoplasm of thyroid gland	0	1(0.1%)
Benign pancreatic neoplasm	0	1(0.1%)
Bladder papilloma	0	1(0.1%)
Bone cancer	0	1(0.1%)
Brain neoplasm	0	1(0.1%)
Cervix carcinoma	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Colorectal adenocarcinoma	0	1(0.1%)
Dysplastic naevus	0	1(0.1%)
Gastric adenoma	0	1(0.1%)
Gastric cancer	0	1(0.1%)
Gastrointestinal cancer metastatic	0	1(0.1%)
Haemangioblastoma	0	1(0.1%)
Hepatic cancer metastatic	0	1(0.1%)
Intraductal papilloma of breast	0	1(0.1%)
Invasive papillary breast carcinoma	0	1(0.1%)
Kaposi's sarcoma	0	1(0.1%)
Lip squamous cell carcinoma	0	1(0.1%)
Lung cancer metastatic	0	1(0.1%)
Lymphoma	0	1(0.1%)
Malignant melanoma	0	1(0.1%)
Malignant pleural effusion	0	1(0.1%)
Metastases to lung	0	1(0.1%)
Metastases to spine	0	1(0.1%)
Metastasis	0	1(0.1%)
Neoplasm	0	1(0.1%)
Neoplasm malignant	0	1(0.1%)
Oesophageal neoplasm	0	1(0.1%)
Ovarian neoplasm	0	1(0.1%)
Papillary renal cell carcinoma	0	1(0.1%)
Pituitary tumour benign	0	1(0.1%)
Prostate cancer stage IV	0	1(0.1%)
Renal cancer	0	1(0.1%)
Retroperitoneal neoplasm	0	1(0.1%)
Sarcoma	0	1(0.1%)
Sarcomatoid carcinoma of the lung	0	1(0.1%)
Squamous cell carcinoma of the oral cavity	0	1(0.1%)
Thymoma	0	1(0.1%)
Thyroid neoplasm	0	1(0.1%)
Surgical And Medical Procedures	109(8.0%)	101(7.4%)
Cataract operation	28(2.1%)	30(2.2%)
Tooth extraction	10(0.7%)	7(0.5%)
Skin neoplasm excision	5(0.4%)	4(0.3%)
Toe amputation	5(0.4%)	1(0.1%)
Knee arthroplasty	4(0.3%)	5(0.4%)
Large intestinal polypectomy	4(0.3%)	1(0.1%)
Carpal tunnel decompression	3(0.2%)	3(0.2%)
Tendon sheath incision	3(0.2%)	2(0.1%)
Peripheral artery angioplasty	3(0.2%)	1(0.1%)
Intraocular lens implant	2(0.1%)	3(0.2%)
Transurethral prostatectomy	2(0.1%)	3(0.2%)
Cardiac pacemaker insertion	2(0.1%)	1(0.1%)
Polypectomy	2(0.1%)	1(0.1%)
Skin lesion removal	2(0.1%)	1(0.1%)
Spinal laminectomy	2(0.1%)	1(0.1%)
Arteriovenous fistula operation	2(0.1%)	0
Colectomy	2(0.1%)	0
Hip arthroplasty	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Shoulder arthroplasty	2(0.1%)	0
Intervertebral disc operation	1(0.1%)	3(0.2%)
Dental implantation	1(0.1%)	2(0.1%)
Inguinal hernia repair	1(0.1%)	2(0.1%)
Aortic aneurysm repair	1(0.1%)	1(0.1%)
Coronary artery bypass	1(0.1%)	1(0.1%)
Coronary revascularisation	1(0.1%)	1(0.1%)
Intestinal polypectomy	1(0.1%)	1(0.1%)
Knee operation	1(0.1%)	1(0.1%)
Transurethral bladder resection	1(0.1%)	1(0.1%)
Aortic valve replacement	1(0.1%)	0
Biliary catheter removal	1(0.1%)	0
Bladder calculus removal	1(0.1%)	0
Brachytherapy	1(0.1%)	0
Breast prosthesis removal	1(0.1%)	0
Cancer surgery	1(0.1%)	0
Canthoplasty	1(0.1%)	0
Carotid endarterectomy	1(0.1%)	0
Chemotherapy	1(0.1%)	0
Circumcision	1(0.1%)	0
Coronary angioplasty	1(0.1%)	0
Debridement	1(0.1%)	0
Dental care	1(0.1%)	0
Dental operation	1(0.1%)	0
Eye operation	1(0.1%)	0
Finger repair operation	1(0.1%)	0
Gastrectomy	1(0.1%)	0
Gingival operation	1(0.1%)	0
Hernia repair	1(0.1%)	0
Infiltration anaesthesia	1(0.1%)	0
Internal fixation of fracture	1(0.1%)	0
Lens capsulotomy	1(0.1%)	0
Lithotripsy	1(0.1%)	0
Metabolic surgery	1(0.1%)	0
Micrographic skin surgery	1(0.1%)	0
Oophorectomy bilateral	1(0.1%)	0
Oral surgery	1(0.1%)	0
Ostectomy	1(0.1%)	0
Pancreatic stent placement	1(0.1%)	0
Parathyroidectomy	1(0.1%)	0
Parotidectomy	1(0.1%)	0
Peripheral artery bypass	1(0.1%)	0
Radical hysterectomy	1(0.1%)	0
Removal of internal fixation	1(0.1%)	0
Renal stone removal	1(0.1%)	0
Retinal operation	1(0.1%)	0
Skin graft	1(0.1%)	0
Suture insertion	1(0.1%)	0
Synovectomy	1(0.1%)	0
Thyroidectomy	1(0.1%)	0
Ureteric calculus removal	1(0.1%)	0
Urethral bulking agent injection	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Vitrectomy	1(0.1%)	0
Cholecystectomy	0	4(0.3%)
Umbilical hernia repair	0	2(0.1%)
Angioplasty	0	1(0.1%)
Appendicectomy	0	1(0.1%)
Bladder neck resection	0	1(0.1%)
Caecum operation	0	1(0.1%)
Central venous catheter removal	0	1(0.1%)
Central venous catheterisation	0	1(0.1%)
Cheilectomy	0	1(0.1%)
Eye laser surgery	0	1(0.1%)
Gastric bypass	0	1(0.1%)
Gastric electrical stimulation	0	1(0.1%)
Hydrocele operation	0	1(0.1%)
Insertion of ambulatory peritoneal catheter	0	1(0.1%)
Intraocular lens repositioning	0	1(0.1%)
Intravitreal implant	0	1(0.1%)
Joint injection	0	1(0.1%)
Leg amputation	0	1(0.1%)
Lens extraction	0	1(0.1%)
Nasal polypectomy	0	1(0.1%)
Neurosurgery	0	1(0.1%)
Papilloma excision	0	1(0.1%)
Percutaneous coronary intervention	0	1(0.1%)
Phlebotomy	0	1(0.1%)
Posterior lens capsulotomy	0	1(0.1%)
Preoperative care	0	1(0.1%)
Prostatectomy	0	1(0.1%)
Radical prostatectomy	0	1(0.1%)
Radioactive iodine therapy	0	1(0.1%)
Rectocele repair	0	1(0.1%)
Removal of foreign body from larynx	0	1(0.1%)
Renal cyst excision	0	1(0.1%)
Renal disorder prophylaxis	0	1(0.1%)
Sebaceous cyst excision	0	1(0.1%)
Skin ulcer excision	0	1(0.1%)
Stent placement	0	1(0.1%)
Varicose vein operation	0	1(0.1%)
Zonulolysis	0	1(0.1%)
Psychiatric Disorders	96(7.1%)	126(9.3%)
Insomnia	33(2.4%)	38(2.8%)
Depression	25(1.8%)	31(2.3%)
Anxiety	12(0.9%)	19(1.4%)
Confusional state	6(0.4%)	7(0.5%)
Sleep disorder	5(0.4%)	6(0.4%)
Mixed anxiety and depressive disorder	3(0.2%)	0
Delirium	2(0.1%)	4(0.3%)
Apathy	2(0.1%)	1(0.1%)
Hallucination	2(0.1%)	1(0.1%)
Stress	2(0.1%)	1(0.1%)
Anxiety disorder	2(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Completed suicide	2(0.1%)	0
Tic	2(0.1%)	0
Adjustment disorder with depressed mood	1(0.1%)	1(0.1%)
Aggression	1(0.1%)	1(0.1%)
Suicidal ideation	1(0.1%)	1(0.1%)
Bipolar disorder	1(0.1%)	0
Depressed mood	1(0.1%)	0
Disorientation	1(0.1%)	0
Enuresis	1(0.1%)	0
Generalised anxiety disorder	1(0.1%)	0
Mental disorder	1(0.1%)	0
Mental disorder due to a general medical condition	1(0.1%)	0
Middle insomnia	1(0.1%)	0
Nightmare	1(0.1%)	0
Schizophrenia	1(0.1%)	0
Mental status changes	0	4(0.3%)
Major depression	0	3(0.2%)
Post-traumatic stress disorder	0	3(0.2%)
Adjustment disorder	0	1(0.1%)
Alcohol abuse	0	1(0.1%)
Claustrophobia	0	1(0.1%)
Daydreaming	0	1(0.1%)
Delusional disorder, unspecified type	0	1(0.1%)
Dysphemia	0	1(0.1%)
Irritability	0	1(0.1%)
Parasomnia	0	1(0.1%)
Personality change	0	1(0.1%)
Restlessness	0	1(0.1%)
Social avoidant behaviour	0	1(0.1%)
Tension	0	1(0.1%)
Reproductive System And Breast Disorders	86(6.3%)	73(5.4%)
Benign prostatic hyperplasia	38(2.8%)	33(2.4%)
Erectile dysfunction	10(0.7%)	10(0.7%)
Prostatomegaly	9(0.7%)	2(0.1%)
Prostatitis	6(0.4%)	7(0.5%)
Prostatism	3(0.2%)	0
Atrophic vulvovaginitis	2(0.1%)	2(0.1%)
Balanoposthitis	2(0.1%)	2(0.1%)
Gynaecomastia	2(0.1%)	2(0.1%)
Pelvic pain	2(0.1%)	2(0.1%)
Breast pain	2(0.1%)	0
Nipple pain	2(0.1%)	0
Scrotal dermatitis	1(0.1%)	1(0.1%)
Testicular pain	1(0.1%)	1(0.1%)
Vaginal haemorrhage	1(0.1%)	1(0.1%)
Breast necrosis	1(0.1%)	0
Endometrial hyperplasia	1(0.1%)	0
Menstruation irregular	1(0.1%)	0
Postmenopausal haemorrhage	1(0.1%)	0
Prostatic dysplasia	1(0.1%)	0
Prostatovesiculitis	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Testicular perforation	1(0.1%)	0
Uterine disorder	1(0.1%)	0
Uterine haemorrhage	1(0.1%)	0
Vulvovaginal dryness	1(0.1%)	0
Vulvovaginal pruritus	1(0.1%)	0
Ovarian cyst	0	2(0.1%)
Prostatic disorder	0	2(0.1%)
Uterine polyp	0	2(0.1%)
Vulvovaginal pain	0	2(0.1%)
Adnexa uteri mass	0	1(0.1%)
Hydrometra	0	1(0.1%)
Penile erythema	0	1(0.1%)
Penile vascular disorder	0	1(0.1%)
Prostatic calcification	0	1(0.1%)
Rectocele	0	1(0.1%)
Vaginal oedema	0	1(0.1%)
Hepatobiliary Disorders	77(5.7%)	69(5.1%)
Cholelithiasis	17(1.3%)	18(1.3%)
Hepatic steatosis	16(1.2%)	18(1.3%)
Cholecystitis acute	8(0.6%)	5(0.4%)
Hepatic cirrhosis	6(0.4%)	6(0.4%)
Hepatic function abnormal	5(0.4%)	5(0.4%)
Cholecystitis chronic	5(0.4%)	1(0.1%)
Cholecystitis	4(0.3%)	7(0.5%)
Gallbladder polyp	4(0.3%)	3(0.2%)
Liver disorder	3(0.2%)	1(0.1%)
Cholestasis	3(0.2%)	0
Bile duct stone	2(0.1%)	2(0.1%)
Non-alcoholic steatohepatitis	2(0.1%)	2(0.1%)
Biliary colic	2(0.1%)	1(0.1%)
Hepatic cyst	2(0.1%)	1(0.1%)
Hepatomegaly	2(0.1%)	0
Portal hypertension	1(0.1%)	2(0.1%)
Alcoholic liver disease	1(0.1%)	1(0.1%)
Cholangitis acute	1(0.1%)	1(0.1%)
Gallbladder disorder	1(0.1%)	1(0.1%)
Gallbladder enlargement	1(0.1%)	1(0.1%)
Hepatic pain	1(0.1%)	1(0.1%)
Hyperplastic cholecystopathy	1(0.1%)	1(0.1%)
Bile duct stenosis	1(0.1%)	0
Chronic hepatitis	1(0.1%)	0
Drug-induced liver injury	1(0.1%)	0
Gallbladder fistula	1(0.1%)	0
Hepatic failure	1(0.1%)	0
Hepatic fibrosis	1(0.1%)	0
Hepatic lesion	1(0.1%)	0
Hyperbilirubinaemia	1(0.1%)	0
Hypertransaminasaemia	1(0.1%)	0
Jaundice	1(0.1%)	0
Jaundice cholestatic	1(0.1%)	0
Ocular icterus	1(0.1%)	0

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Porcelain gallbladder	1(0.1%)	0
Cholangitis	0	2(0.1%)
Cardiac cirrhosis	0	1(0.1%)
Cholecystocholangitis	0	1(0.1%)
Congestive hepatopathy	0	1(0.1%)
Gallbladder cholesterolosis	0	1(0.1%)
Hepatic mass	0	1(0.1%)
Hepatic vascular thrombosis	0	1(0.1%)
Nonalcoholic fatty liver disease	0	1(0.1%)
Ear And Labyrinth Disorders	63(4.6%)	72(5.3%)
Vertigo	31(2.3%)	34(2.5%)
Tinnitus	9(0.7%)	14(1.0%)
Ear pain	4(0.3%)	5(0.4%)
Cerumen impaction	4(0.3%)	2(0.1%)
Ear pruritus	3(0.2%)	0
Presbyacusis	3(0.2%)	0
Vertigo positional	2(0.1%)	3(0.2%)
Tympanic membrane perforation	2(0.1%)	2(0.1%)
Deafness unilateral	2(0.1%)	1(0.1%)
Hypoacusis	2(0.1%)	1(0.1%)
Meniere's disease	2(0.1%)	0
Excessive cerumen production	1(0.1%)	4(0.3%)
Deafness neurosensory	1(0.1%)	3(0.2%)
Vestibular disorder	1(0.1%)	2(0.1%)
Acute vestibular syndrome	1(0.1%)	0
Inner ear disorder	1(0.1%)	0
Motion sickness	0	2(0.1%)
Sudden hearing loss	0	2(0.1%)
Deafness	0	1(0.1%)
Middle ear inflammation	0	1(0.1%)
Vestibular ataxia	0	1(0.1%)
Endocrine Disorders	44(3.2%)	35(2.6%)
Hypothyroidism	14(1.0%)	13(1.0%)
Thyroid mass	6(0.4%)	3(0.2%)
Hyperparathyroidism secondary	5(0.4%)	3(0.2%)
Hyperthyroidism	4(0.3%)	3(0.2%)
Hyperparathyroidism	3(0.2%)	4(0.3%)
Goitre	3(0.2%)	2(0.1%)
Adrenal mass	2(0.1%)	2(0.1%)
Androgen deficiency	1(0.1%)	0
Autoimmune thyroiditis	1(0.1%)	0
Cushing's syndrome	1(0.1%)	0
Hyperparathyroidism primary	1(0.1%)	0
Primary hyperaldosteronism	1(0.1%)	0
Primary hypothyroidism	1(0.1%)	0
Thyroid cyst	1(0.1%)	0
Thyroiditis subacute	1(0.1%)	0
Toxic nodular goitre	1(0.1%)	0
Basedow's disease	0	1(0.1%)
Euthyroid sick syndrome	0	1(0.1%)

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

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Hyperplasia adrenal	0	1(0.1%)
Hypogonadism	0	1(0.1%)
Hypoparathyroidism	0	1(0.1%)
Secondary hyperthyroidism	0	1(0.1%)
Immune System Disorders	24(1.8%)	17(1.3%)
Seasonal allergy	12(0.9%)	7(0.5%)
Drug hypersensitivity	5(0.4%)	2(0.1%)
Allergy to arthropod sting	2(0.1%)	1(0.1%)
Hypersensitivity	1(0.1%)	4(0.3%)
Allergy to animal	1(0.1%)	0
Amyloidosis	1(0.1%)	0
Dust allergy	1(0.1%)	0
Multiple allergies	1(0.1%)	0
Allergy to vaccine	0	1(0.1%)
Anaphylactic reaction	0	1(0.1%)
Mite allergy	0	1(0.1%)
Congenital, Familial And Genetic Disorders	6(0.4%)	11(0.8%)
Phimosis	1(0.1%)	4(0.3%)
Bicuspid aortic valve	1(0.1%)	0
Congenital cystic kidney disease	1(0.1%)	0
Factor XII deficiency	1(0.1%)	0
Limb malformation	1(0.1%)	0
Type V hyperlipidaemia	1(0.1%)	0
Hydrocele	0	3(0.2%)
Atrial septal defect	0	1(0.1%)
Congenital aortic anomaly	0	1(0.1%)
Epidermolysis bullosa	0	1(0.1%)
Hypospadias	0	1(0.1%)
Product Issues	3(0.2%)	2(0.1%)
Device capturing issue	1(0.1%)	0
Device lead damage	1(0.1%)	0
Device leakage	1(0.1%)	0
Lead dislodgement	1(0.1%)	0
Device malfunction	0	1(0.1%)
Patient-device incompatibility	0	1(0.1%)
Social Circumstances	1(0.1%)	2(0.1%)
Substance use	1(0.1%)	0
Walking disability	0	2(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Any TEAE	492(36.3%)	511(37.7%)
Infections And Infestations	154(11.3%)	169(12.5%)
Pneumonia	33(2.4%)	45(3.3%)
Cellulitis	18(1.3%)	11(0.8%)
COVID-19	11(0.8%)	6(0.4%)
Urinary tract infection	9(0.7%)	26(1.9%)
Sepsis	8(0.6%)	11(0.8%)
Urosepsis	6(0.4%)	4(0.3%)
Pyelonephritis	6(0.4%)	3(0.2%)
Gastroenteritis	5(0.4%)	8(0.6%)
Erysipelas	5(0.4%)	6(0.4%)
Osteomyelitis	5(0.4%)	3(0.2%)
Influenza	4(0.3%)	4(0.3%)
Respiratory tract infection	4(0.3%)	3(0.2%)
COVID-19 pneumonia	4(0.3%)	2(0.1%)
Gangrene	3(0.2%)	1(0.1%)
Postoperative wound infection	3(0.2%)	1(0.1%)
Upper respiratory tract infection	2(0.1%)	2(0.1%)
Abscess limb	2(0.1%)	1(0.1%)
Aspergilloma	2(0.1%)	0
Bacteraemia	2(0.1%)	0
Diverticulitis	2(0.1%)	0
Emphysematous pyelonephritis	2(0.1%)	0
Gastroenteritis viral	2(0.1%)	0
Septic shock	1(0.1%)	4(0.3%)
Localised infection	1(0.1%)	3(0.2%)
Bronchitis	1(0.1%)	2(0.1%)
Cystitis	1(0.1%)	2(0.1%)
Anal abscess	1(0.1%)	1(0.1%)
Diabetic foot infection	1(0.1%)	1(0.1%)
Escherichia urinary tract infection	1(0.1%)	1(0.1%)
Gastroenteritis norovirus	1(0.1%)	1(0.1%)
Infection	1(0.1%)	1(0.1%)
Pneumonia viral	1(0.1%)	1(0.1%)
Pulmonary tuberculosis	1(0.1%)	1(0.1%)
Tuberculosis	1(0.1%)	1(0.1%)
Abdominal wall abscess	1(0.1%)	0
Abscess neck	1(0.1%)	0
Acute sinusitis	1(0.1%)	0
Arthritis bacterial	1(0.1%)	0
Bacterial sepsis	1(0.1%)	0
Gastroenteritis salmonella	1(0.1%)	0
Genitourinary tract infection	1(0.1%)	0
Herpes zoster	1(0.1%)	0
Infectious mononucleosis	1(0.1%)	0
Infectious pleural effusion	1(0.1%)	0
Infective myositis	1(0.1%)	0
Infective tenosynovitis	1(0.1%)	0
Medical device site infection	1(0.1%)	0
Osteomyelitis chronic	1(0.1%)	0
Otitis externa	1(0.1%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Pilonidal cyst	1(0.1%)	0
Pneumonia klebsiella	1(0.1%)	0
Prostatic abscess	1(0.1%)	0
Pyelonephritis acute	1(0.1%)	0
Sialoadenitis	1(0.1%)	0
Soft tissue infection	1(0.1%)	0
Subcutaneous abscess	1(0.1%)	0
Urinary tract infection fungal	1(0.1%)	0
Wound infection bacterial	1(0.1%)	0
Pneumonia bacterial	0	4(0.3%)
Appendicitis	0	3(0.2%)
Lower respiratory tract infection	0	3(0.2%)
Pyelonephritis chronic	0	2(0.1%)
Skin infection	0	2(0.1%)
Wound infection	0	2(0.1%)
Acute hepatitis B	0	1(0.1%)
Arteriosclerotic gangrene	0	1(0.1%)
Campylobacter gastroenteritis	0	1(0.1%)
Clostridium difficile infection	0	1(0.1%)
Coronavirus infection	0	1(0.1%)
Cystitis bacterial	0	1(0.1%)
Enterococcal bacteraemia	0	1(0.1%)
Escherichia sepsis	0	1(0.1%)
Eye infection	0	1(0.1%)
Fournier's gangrene	0	1(0.1%)
Gastritis viral	0	1(0.1%)
Gastrointestinal viral infection	0	1(0.1%)
Infective exacerbation of bronchiectasis	0	1(0.1%)
Infective exacerbation of chronic obstructive airways disease	0	1(0.1%)
Intervertebral discitis	0	1(0.1%)
Labyrinthitis	0	1(0.1%)
Large intestine infection	0	1(0.1%)
Necrotising fasciitis	0	1(0.1%)
Orchitis	0	1(0.1%)
Otitis media	0	1(0.1%)
Periorbital cellulitis	0	1(0.1%)
Pulmonary sepsis	0	1(0.1%)
Staphylococcal infection	0	1(0.1%)
Staphylococcal sepsis	0	1(0.1%)
Subacute endocarditis	0	1(0.1%)
Tooth abscess	0	1(0.1%)
Tooth infection	0	1(0.1%)
Urinary tract infection bacterial	0	1(0.1%)
Viral infection	0	1(0.1%)
Metabolism And Nutrition Disorders	74(5.5%)	67(4.9%)
Hyperglycaemia	14(1.0%)	5(0.4%)
Hyperkalaemia	14(1.0%)	2(0.1%)
Hypoglycaemia	10(0.7%)	16(1.2%)
Diabetes mellitus	8(0.6%)	6(0.4%)
Diabetes mellitus inadequate control	7(0.5%)	7(0.5%)
Type 2 diabetes mellitus	6(0.4%)	4(0.3%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Dehydration	5(0.4%)	6(0.4%)
Diabetic metabolic decompensation	3(0.2%)	4(0.3%)
Hyponatraemia	2(0.1%)	5(0.4%)
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.1%)	3(0.2%)
Hypercalcaemia	2(0.1%)	0
Hypovolaemia	2(0.1%)	0
Diabetic ketoacidosis	1(0.1%)	6(0.4%)
Gout	1(0.1%)	1(0.1%)
Obesity	1(0.1%)	1(0.1%)
Diabetic complication	1(0.1%)	0
Metabolic acidosis	1(0.1%)	0
Hypokalaemia	0	4(0.3%)
Fluid overload	0	2(0.1%)
Hypocalcaemia	0	1(0.1%)
Periarthritis calcarea	0	1(0.1%)
Gastrointestinal Disorders	66(4.9%)	56(4.1%)
Large intestine polyp	9(0.7%)	7(0.5%)
Gastrointestinal haemorrhage	5(0.4%)	5(0.4%)
Diarrhoea	5(0.4%)	2(0.1%)
Upper gastrointestinal haemorrhage	3(0.2%)	3(0.2%)
Pancreatitis acute	3(0.2%)	2(0.1%)
Rectal haemorrhage	3(0.2%)	2(0.1%)
Abdominal pain upper	2(0.1%)	2(0.1%)
Gastrooesophageal reflux disease	2(0.1%)	2(0.1%)
Vomiting	2(0.1%)	2(0.1%)
Constipation	2(0.1%)	1(0.1%)
Gastric ulcer	2(0.1%)	1(0.1%)
Gastritis	2(0.1%)	1(0.1%)
Pancreatitis	2(0.1%)	1(0.1%)
Dyspepsia	2(0.1%)	0
Gastroduodenal ulcer	2(0.1%)	0
Lower gastrointestinal haemorrhage	2(0.1%)	0
Peptic ulcer	2(0.1%)	0
Abdominal pain	1(0.1%)	3(0.2%)
Inguinal hernia	1(0.1%)	3(0.2%)
Intestinal obstruction	1(0.1%)	3(0.2%)
Duodenal ulcer	1(0.1%)	1(0.1%)
Haemorrhoids	1(0.1%)	1(0.1%)
Small intestinal obstruction	1(0.1%)	1(0.1%)
Abdominal symptom	1(0.1%)	0
Anal fistula	1(0.1%)	0
Ascites	1(0.1%)	0
Colitis	1(0.1%)	0
Colitis ischaemic	1(0.1%)	0
Dental cyst	1(0.1%)	0
Duodenal perforation	1(0.1%)	0
Enteritis	1(0.1%)	0
Gastric haemorrhage	1(0.1%)	0
Gastritis erosive	1(0.1%)	0
Incarcerated umbilical hernia	1(0.1%)	0
Intestinal ischaemia	1(0.1%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Intestinal mass	1(0.1%)	0
Mechanical ileus	1(0.1%)	0
Nausea	1(0.1%)	0
Oesophageal obstruction	1(0.1%)	0
Pancreatic duct stenosis	1(0.1%)	0
Parotid gland enlargement	1(0.1%)	0
Small intestinal haemorrhage	1(0.1%)	0
Varices oesophageal	1(0.1%)	0
Abdominal wall haematoma	0	2(0.1%)
Duodenal ulcer haemorrhage	0	2(0.1%)
Gastric polyps	0	2(0.1%)
Abdominal mass	0	1(0.1%)
Abdominal pain lower	0	1(0.1%)
Anal haemorrhage	0	1(0.1%)
Colitis ulcerative	0	1(0.1%)
Diverticulum	0	1(0.1%)
Food poisoning	0	1(0.1%)
Gastric dysplasia	0	1(0.1%)
Gastrointestinal pain	0	1(0.1%)
Haematemesis	0	1(0.1%)
Haematochezia	0	1(0.1%)
Impaired gastric emptying	0	1(0.1%)
Oesophageal dysplasia	0	1(0.1%)
Oesophageal polyp	0	1(0.1%)
Pancreatic cyst	0	1(0.1%)
Pancreatic mass	0	1(0.1%)
Pancreatitis chronic	0	1(0.1%)
Rectal polyp	0	1(0.1%)
Small intestinal perforation	0	1(0.1%)
Umbilical hernia	0	1(0.1%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	63(4.6%)	74(5.5%)
Bladder cancer	5(0.4%)	4(0.3%)
Colon cancer	5(0.4%)	4(0.3%)
Prostate cancer	4(0.3%)	9(0.7%)
Lung neoplasm malignant	4(0.3%)	4(0.3%)
Pancreatic carcinoma	3(0.2%)	1(0.1%)
Lung adenocarcinoma	2(0.1%)	3(0.2%)
Bladder transitional cell carcinoma	2(0.1%)	2(0.1%)
Hepatic cancer	2(0.1%)	2(0.1%)
Metastases to liver	2(0.1%)	1(0.1%)
Prostate cancer recurrent	2(0.1%)	1(0.1%)
Metastases to central nervous system	2(0.1%)	0
Pancreatic neoplasm	2(0.1%)	0
Plasma cell myeloma	2(0.1%)	0
Renal cell carcinoma	2(0.1%)	0
Lung neoplasm	1(0.1%)	4(0.3%)
Bladder neoplasm	1(0.1%)	2(0.1%)
Adenocarcinoma gastric	1(0.1%)	1(0.1%)
Basal cell carcinoma	1(0.1%)	1(0.1%)
Bladder transitional cell carcinoma recurrent	1(0.1%)	1(0.1%)
Breast cancer	1(0.1%)	1(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Bronchial carcinoma	1(0.1%)	1(0.1%)
Cholangiocarcinoma	1(0.1%)	1(0.1%)
Colorectal cancer	1(0.1%)	1(0.1%)
Hepatocellular carcinoma	1(0.1%)	1(0.1%)
Pancreatic carcinoma metastatic	1(0.1%)	1(0.1%)
Small cell lung cancer	1(0.1%)	1(0.1%)
Squamous cell carcinoma	1(0.1%)	1(0.1%)
Acute myeloid leukaemia	1(0.1%)	0
Adenocarcinoma	1(0.1%)	0
Adenocarcinoma of colon	1(0.1%)	0
Bladder cancer recurrent	1(0.1%)	0
Breast cancer metastatic	1(0.1%)	0
Colon adenoma	1(0.1%)	0
Enchondromatosis	1(0.1%)	0
Endometrial adenocarcinoma	1(0.1%)	0
Epithelioid mesothelioma	1(0.1%)	0
Invasive lobular breast carcinoma	1(0.1%)	0
Metastases to bone	1(0.1%)	0
Metastases to lymph nodes	1(0.1%)	0
Myelodysplastic syndrome	1(0.1%)	0
Oesophageal adenocarcinoma	1(0.1%)	0
Oropharyngeal squamous cell carcinoma	1(0.1%)	0
Pancreatic carcinoma stage IV	1(0.1%)	0
Prostate cancer metastatic	1(0.1%)	0
Rectal adenocarcinoma	1(0.1%)	0
Skin cancer	1(0.1%)	0
Squamous cell carcinoma of the parotid gland	1(0.1%)	0
Transitional cell carcinoma	1(0.1%)	0
Transitional cell carcinoma recurrent	1(0.1%)	0
Uterine cancer	1(0.1%)	0
Oesophageal carcinoma	0	3(0.2%)
Endometrial cancer	0	2(0.1%)
Adrenal adenoma	0	1(0.1%)
Benign anorectal neoplasm	0	1(0.1%)
Benign gastrointestinal neoplasm	0	1(0.1%)
Benign neoplasm of bladder	0	1(0.1%)
Benign neoplasm of prostate	0	1(0.1%)
Benign pancreatic neoplasm	0	1(0.1%)
Bone cancer	0	1(0.1%)
Brain neoplasm	0	1(0.1%)
Cervix carcinoma	0	1(0.1%)
Colon neoplasm	0	1(0.1%)
Colorectal adenocarcinoma	0	1(0.1%)
Gastrointestinal cancer metastatic	0	1(0.1%)
Haemangioblastoma	0	1(0.1%)
Hepatic cancer metastatic	0	1(0.1%)
Invasive papillary breast carcinoma	0	1(0.1%)
Lung cancer metastatic	0	1(0.1%)
Lymphoma	0	1(0.1%)
Malignant melanoma	0	1(0.1%)
Malignant pleural effusion	0	1(0.1%)
Metastasis	0	1(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Neoplasm malignant	0	1(0.1%)
Neoplasm skin	0	1(0.1%)
Oesophageal neoplasm	0	1(0.1%)
Ovarian neoplasm	0	1(0.1%)
Papillary renal cell carcinoma	0	1(0.1%)
Renal cancer	0	1(0.1%)
Renal neoplasm	0	1(0.1%)
Retroperitoneal neoplasm	0	1(0.1%)
Sarcoma	0	1(0.1%)
Squamous cell carcinoma of the oral cavity	0	1(0.1%)
Thymoma	0	1(0.1%)
Thyroid cancer	0	1(0.1%)
Renal And Urinary Disorders	52(3.8%)	64(4.7%)
Acute kidney injury	24(1.8%)	33(2.4%)
Diabetic nephropathy	3(0.2%)	4(0.3%)
Nephrolithiasis	3(0.2%)	3(0.2%)
Ureterolithiasis	3(0.2%)	3(0.2%)
Urinary retention	3(0.2%)	3(0.2%)
Renal failure	3(0.2%)	0
Chronic kidney disease	2(0.1%)	4(0.3%)
Haematuria	2(0.1%)	3(0.2%)
Calculus urinary	2(0.1%)	1(0.1%)
Renal colic	2(0.1%)	1(0.1%)
Urinary tract obstruction	2(0.1%)	1(0.1%)
Calculus bladder	2(0.1%)	0
Renal impairment	1(0.1%)	3(0.2%)
Tubulointerstitial nephritis	1(0.1%)	0
Ureteric obstruction	1(0.1%)	0
Urinary incontinence	1(0.1%)	0
Hydronephrosis	0	3(0.2%)
Urethral stenosis	0	2(0.1%)
End stage renal disease	0	1(0.1%)
Lower urinary tract symptoms	0	1(0.1%)
Proteinuria	0	1(0.1%)
Renal artery stenosis	0	1(0.1%)
Renal cyst	0	1(0.1%)
Urinary tract disorder	0	1(0.1%)
Injury, Poisoning And Procedural Complications	47(3.5%)	49(3.6%)
Femur fracture	4(0.3%)	4(0.3%)
Fall	4(0.3%)	3(0.2%)
Contusion	3(0.2%)	1(0.1%)
Tibia fracture	3(0.2%)	0
Ankle fracture	2(0.1%)	3(0.2%)
Hip fracture	2(0.1%)	2(0.1%)
Post procedural haemorrhage	2(0.1%)	1(0.1%)
Spinal compression fracture	2(0.1%)	1(0.1%)
Accident	2(0.1%)	0
Clavicle fracture	2(0.1%)	0
Craniocerebral injury	2(0.1%)	0
Femoral neck fracture	2(0.1%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Subdural haematoma	1(0.1%)	3(0.2%)
Radius fracture	1(0.1%)	2(0.1%)
Road traffic accident	1(0.1%)	2(0.1%)
Brain contusion	1(0.1%)	1(0.1%)
Foot fracture	1(0.1%)	1(0.1%)
Head injury	1(0.1%)	1(0.1%)
Subdural haemorrhage	1(0.1%)	1(0.1%)
Accidental overdose	1(0.1%)	0
Acetabulum fracture	1(0.1%)	0
Bone contusion	1(0.1%)	0
Chest injury	1(0.1%)	0
Concussion	1(0.1%)	0
Fibula fracture	1(0.1%)	0
Foreign body aspiration	1(0.1%)	0
Gun shot wound	1(0.1%)	0
Ligament rupture	1(0.1%)	0
Lower limb fracture	1(0.1%)	0
Patella fracture	1(0.1%)	0
Scapula fracture	1(0.1%)	0
Skin laceration	1(0.1%)	0
Skull fractured base	1(0.1%)	0
Splenic injury	1(0.1%)	0
Traumatic fracture	1(0.1%)	0
Upper limb fracture	1(0.1%)	0
Humerus fracture	0	2(0.1%)
Meniscus injury	0	2(0.1%)
Rib fracture	0	2(0.1%)
Facial bones fracture	0	1(0.1%)
Joint dislocation	0	1(0.1%)
Limb injury	0	1(0.1%)
Multiple injuries	0	1(0.1%)
Overdose	0	1(0.1%)
Pelvic fracture	0	1(0.1%)
Periprosthetic fracture	0	1(0.1%)
Post procedural haematoma	0	1(0.1%)
Procedural complication	0	1(0.1%)
Procedural haemorrhage	0	1(0.1%)
Procedural intestinal perforation	0	1(0.1%)
Reproductive tract procedural complication	0	1(0.1%)
Skin injury	0	1(0.1%)
Spinal fracture	0	1(0.1%)
Tendon rupture	0	1(0.1%)
Thermal burn	0	1(0.1%)
Vascular anastomosis aneurysm	0	1(0.1%)
Vascular pseudoaneurysm	0	1(0.1%)
Respiratory, Thoracic And Mediastinal Disorders	47(3.5%)	45(3.3%)
Chronic obstructive pulmonary disease	10(0.7%)	4(0.3%)
Dyspnoea	8(0.6%)	3(0.2%)
Pleural effusion	5(0.4%)	1(0.1%)
Acute respiratory failure	4(0.3%)	5(0.4%)
Respiratory failure	4(0.3%)	2(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Sleep apnoea syndrome	3(0.2%)	2(0.1%)
Pulmonary embolism	2(0.1%)	5(0.4%)
Interstitial lung disease	2(0.1%)	2(0.1%)
Cough	2(0.1%)	1(0.1%)
Pulmonary mass	2(0.1%)	0
Asthma	1(0.1%)	3(0.2%)
Pulmonary oedema	1(0.1%)	2(0.1%)
Alveolar lung disease	1(0.1%)	0
Asthmatic crisis	1(0.1%)	0
Chronic respiratory failure	1(0.1%)	0
Epistaxis	1(0.1%)	0
Hypoxia	1(0.1%)	0
Laryngeal oedema	1(0.1%)	0
Nasal septum deviation	1(0.1%)	0
Obstructive airways disorder	1(0.1%)	0
Pneumonia aspiration	1(0.1%)	0
Pulmonary congestion	0	3(0.2%)
Idiopathic pulmonary fibrosis	0	2(0.1%)
Pneumothorax	0	2(0.1%)
Acute pulmonary oedema	0	1(0.1%)
Aspiration	0	1(0.1%)
Bronchial hyperreactivity	0	1(0.1%)
Bronchiectasis	0	1(0.1%)
Bronchitis chronic	0	1(0.1%)
Dysphonia	0	1(0.1%)
Dyspnoea exertional	0	1(0.1%)
Haemoptysis	0	1(0.1%)
Hepatic hydrothorax	0	1(0.1%)
Hypercapnia	0	1(0.1%)
Laryngeal disorder	0	1(0.1%)
Lung perforation	0	1(0.1%)
Pulmonary hypertension	0	1(0.1%)
Small airways disease	0	1(0.1%)
Nervous System Disorders	43(3.2%)	50(3.7%)
Syncope	10(0.7%)	12(0.9%)
Diabetic neuropathy	3(0.2%)	3(0.2%)
Dizziness	2(0.1%)	4(0.3%)
Sciatica	2(0.1%)	1(0.1%)
Headache	2(0.1%)	0
Normal pressure hydrocephalus	2(0.1%)	0
Vascular headache	2(0.1%)	0
Presyncope	1(0.1%)	2(0.1%)
Subarachnoid haemorrhage	1(0.1%)	2(0.1%)
Aphasia	1(0.1%)	1(0.1%)
Carotid artery stenosis	1(0.1%)	1(0.1%)
Cognitive disorder	1(0.1%)	1(0.1%)
Facial paralysis	1(0.1%)	1(0.1%)
Lumbar radiculopathy	1(0.1%)	1(0.1%)
Polyneuropathy	1(0.1%)	1(0.1%)
Seizure	1(0.1%)	1(0.1%)
Transient ischaemic attack	1(0.1%)	1(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Amnesia	1(0.1%)	0
Cerebral haemorrhage	1(0.1%)	0
Cerebrospinal fluid leakage	1(0.1%)	0
Generalised tonic-clonic seizure	1(0.1%)	0
Guillain-Barre syndrome	1(0.1%)	0
Hemiparesis	1(0.1%)	0
Hepatic encephalopathy	1(0.1%)	0
Ischaemic stroke	1(0.1%)	0
Lethargy	1(0.1%)	0
Loss of consciousness	1(0.1%)	0
Metabolic encephalopathy	1(0.1%)	0
Neuralgia	1(0.1%)	0
Partial seizures	1(0.1%)	0
Toxic encephalopathy	1(0.1%)	0
Vascular encephalopathy	1(0.1%)	0
Balance disorder	0	1(0.1%)
Carpal tunnel syndrome	0	1(0.1%)
Cerebrovascular disorder	0	1(0.1%)
Cervicobrachial syndrome	0	1(0.1%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.1%)
Dementia Alzheimer's type	0	1(0.1%)
Dizziness postural	0	1(0.1%)
Epilepsy	0	1(0.1%)
Facial nerve disorder	0	1(0.1%)
Facial paresis	0	1(0.1%)
Hyperglycaemic unconsciousness	0	1(0.1%)
Hypertensive encephalopathy	0	1(0.1%)
Hypoglycaemic unconsciousness	0	1(0.1%)
Intracranial aneurysm	0	1(0.1%)
Intraventricular haemorrhage	0	1(0.1%)
Lacunar infarction	0	1(0.1%)
Myelopathy	0	1(0.1%)
Neuropathy peripheral	0	1(0.1%)
Paraesthesia	0	1(0.1%)
Peripheral nerve paresis	0	1(0.1%)
Posthaemorrhagic hydrocephalus	0	1(0.1%)
Spinal cord compression	0	1(0.1%)
Spondylitic myelopathy	0	1(0.1%)
Surgical And Medical Procedures	42(3.1%)	41(3.0%)
Knee arthroplasty	4(0.3%)	5(0.4%)
Cataract operation	4(0.3%)	1(0.1%)
Transurethral prostatectomy	2(0.1%)	3(0.2%)
Peripheral artery angioplasty	2(0.1%)	1(0.1%)
Spinal laminectomy	2(0.1%)	1(0.1%)
Arteriovenous fistula operation	2(0.1%)	0
Colectomy	2(0.1%)	0
Aortic aneurysm repair	1(0.1%)	1(0.1%)
Coronary artery bypass	1(0.1%)	1(0.1%)
Skin neoplasm excision	1(0.1%)	1(0.1%)
Toe amputation	1(0.1%)	1(0.1%)
Aortic valve replacement	1(0.1%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Biliary catheter removal	1(0.1%)	0
Bladder calculus removal	1(0.1%)	0
Brachytherapy	1(0.1%)	0
Cardiac pacemaker insertion	1(0.1%)	0
Carotid endarterectomy	1(0.1%)	0
Chemotherapy	1(0.1%)	0
Circumcision	1(0.1%)	0
Gastrectomy	1(0.1%)	0
Hip arthroplasty	1(0.1%)	0
Lithotripsy	1(0.1%)	0
Metabolic surgery	1(0.1%)	0
Pancreatic stent placement	1(0.1%)	0
Parathyroidectomy	1(0.1%)	0
Parotidectomy	1(0.1%)	0
Peripheral artery bypass	1(0.1%)	0
Polypectomy	1(0.1%)	0
Radical hysterectomy	1(0.1%)	0
Renal stone removal	1(0.1%)	0
Retinal operation	1(0.1%)	0
Shoulder arthroplasty	1(0.1%)	0
Skin graft	1(0.1%)	0
Thyroidectomy	1(0.1%)	0
Cholecystectomy	0	3(0.2%)
Intervertebral disc operation	0	3(0.2%)
Inguinal hernia repair	0	2(0.1%)
Appendicectomy	0	1(0.1%)
Bladder neck resection	0	1(0.1%)
Caecum operation	0	1(0.1%)
Cheilectomy	0	1(0.1%)
Coronary revascularisation	0	1(0.1%)
Gastric bypass	0	1(0.1%)
Hydrocele operation	0	1(0.1%)
Insertion of ambulatory peritoneal catheter	0	1(0.1%)
Knee operation	0	1(0.1%)
Leg amputation	0	1(0.1%)
Nasal polypectomy	0	1(0.1%)
Neurosurgery	0	1(0.1%)
Preoperative care	0	1(0.1%)
Prostatectomy	0	1(0.1%)
Radical prostatectomy	0	1(0.1%)
Radioactive iodine therapy	0	1(0.1%)
Rectocele repair	0	1(0.1%)
Removal of foreign body from larynx	0	1(0.1%)
Renal cyst excision	0	1(0.1%)
Renal disorder prophylaxis	0	1(0.1%)
Skin ulcer excision	0	1(0.1%)
Tooth extraction	0	1(0.1%)
Transurethral bladder resection	0	1(0.1%)
Varicose vein operation	0	1(0.1%)
Musculoskeletal And Connective Tissue Disorders	37(2.7%)	38(2.8%)
Osteoarthritis	10(0.7%)	5(0.4%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Arthralgia	5(0.4%)	6(0.4%)
Back pain	4(0.3%)	1(0.1%)
Intervertebral disc disorder	2(0.1%)	1(0.1%)
Muscular weakness	2(0.1%)	1(0.1%)
Myalgia	2(0.1%)	0
Spondylolisthesis	2(0.1%)	0
Intervertebral disc protrusion	1(0.1%)	2(0.1%)
Arthritis	1(0.1%)	1(0.1%)
Lumbar spinal stenosis	1(0.1%)	1(0.1%)
Facet joint syndrome	1(0.1%)	0
Immobilisation syndrome	1(0.1%)	0
Intervertebral disc compression	1(0.1%)	0
Intervertebral disc degeneration	1(0.1%)	0
Neuropathic arthropathy	1(0.1%)	0
Pain in extremity	1(0.1%)	0
Rotator cuff syndrome	1(0.1%)	0
Synovial cyst	1(0.1%)	0
Vertebral lateral recess stenosis	1(0.1%)	0
Neck pain	0	5(0.4%)
Spinal pain	0	3(0.2%)
Gouty arthritis	0	2(0.1%)
Spinal osteoarthritis	0	2(0.1%)
Bursitis	0	1(0.1%)
Costochondritis	0	1(0.1%)
Exostosis	0	1(0.1%)
Foot deformity	0	1(0.1%)
Muscle haemorrhage	0	1(0.1%)
Musculoskeletal chest pain	0	1(0.1%)
Osteolysis	0	1(0.1%)
Spinal ligament ossification	0	1(0.1%)
Spinal stenosis	0	1(0.1%)
Vertebral foraminal stenosis	0	1(0.1%)
Vascular Disorders	24(1.8%)	36(2.7%)
Hypertension	4(0.3%)	11(0.8%)
Aortic stenosis	4(0.3%)	0
Extremity necrosis	3(0.2%)	1(0.1%)
Hypertensive crisis	2(0.1%)	3(0.2%)
Aortic aneurysm	2(0.1%)	1(0.1%)
Hypertensive urgency	1(0.1%)	2(0.1%)
Thrombosis	1(0.1%)	2(0.1%)
Hypertensive emergency	1(0.1%)	1(0.1%)
Hypotension	1(0.1%)	1(0.1%)
Peripheral arterial occlusive disease	1(0.1%)	1(0.1%)
Aortic dissection	1(0.1%)	0
Post thrombotic syndrome	1(0.1%)	0
Thrombophlebitis	1(0.1%)	0
Varicose ulceration	1(0.1%)	0
Varicose vein	1(0.1%)	0
Vasculitis	1(0.1%)	0
Peripheral ischaemia	0	4(0.3%)
Deep vein thrombosis	0	3(0.2%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Arterial thrombosis	0	1(0.1%)
Circulatory collapse	0	1(0.1%)
Labile hypertension	0	1(0.1%)
Orthostatic hypotension	0	1(0.1%)
Peripheral artery aneurysm rupture	0	1(0.1%)
Peripheral artery occlusion	0	1(0.1%)
Peripheral artery stenosis	0	1(0.1%)
Systolic hypertension	0	1(0.1%)
General Disorders And Administration Site Conditions	21(1.5%)	33(2.4%)
Chest pain	10(0.7%)	12(0.9%)
Death	2(0.1%)	4(0.3%)
Asthenia	2(0.1%)	1(0.1%)
Pyrexia	2(0.1%)	0
General physical health deterioration	1(0.1%)	5(0.4%)
Systemic inflammatory response syndrome	1(0.1%)	1(0.1%)
Complication associated with device	1(0.1%)	0
Drug intolerance	1(0.1%)	0
Oedema due to cardiac disease	1(0.1%)	0
Malaise	0	2(0.1%)
Non-cardiac chest pain	0	2(0.1%)
Oedema peripheral	0	2(0.1%)
Pain	0	2(0.1%)
Adhesion	0	1(0.1%)
Multiple organ dysfunction syndrome	0	1(0.1%)
Oedema	0	1(0.1%)
Polyp	0	1(0.1%)
Cardiac Disorders	20(1.5%)	24(1.8%)
Cardiac failure	2(0.1%)	6(0.4%)
Angina unstable	2(0.1%)	0
Bradycardia	2(0.1%)	0
Cardiac failure acute	2(0.1%)	0
Angina pectoris	1(0.1%)	2(0.1%)
Cardiac arrest	1(0.1%)	2(0.1%)
Cardiac failure chronic	1(0.1%)	2(0.1%)
Myocardial ischaemia	1(0.1%)	2(0.1%)
Aortic valve stenosis	1(0.1%)	1(0.1%)
Arteriosclerosis coronary artery	1(0.1%)	1(0.1%)
Atrial fibrillation	1(0.1%)	1(0.1%)
Acute left ventricular failure	1(0.1%)	0
Coronary artery disease	1(0.1%)	0
Coronary artery stenosis	1(0.1%)	0
Pericarditis	1(0.1%)	0
Pulseless electrical activity	1(0.1%)	0
Ventricular hypokinesia	1(0.1%)	0
Sinus node dysfunction	0	2(0.1%)
Aortic valve incompetence	0	1(0.1%)
Atrioventricular block complete	0	1(0.1%)
Bundle branch block left	0	1(0.1%)
Cardio-respiratory arrest	0	1(0.1%)
Coronary artery occlusion	0	1(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Left ventricular hypertrophy	0	1(0.1%)
Sinoatrial block	0	1(0.1%)
Investigations	18(1.3%)	19(1.4%)
Glomerular filtration rate decreased	3(0.2%)	1(0.1%)
Blood glucose increased	3(0.2%)	0
Colonoscopy	2(0.1%)	1(0.1%)
Endoscopy	2(0.1%)	0
Blood creatinine increased	1(0.1%)	2(0.1%)
C-reactive protein increased	1(0.1%)	1(0.1%)
Biopsy bladder	1(0.1%)	0
Blood potassium increased	1(0.1%)	0
Blood pressure orthostatic decreased	1(0.1%)	0
Cancer staging	1(0.1%)	0
Cardiac function test abnormal	1(0.1%)	0
Colonoscopy normal	1(0.1%)	0
Electrocardiogram abnormal	1(0.1%)	0
Haematocrit decreased	1(0.1%)	0
Arthroscopy	0	2(0.1%)
Glycosylated haemoglobin increased	0	2(0.1%)
Influenza A virus test positive	0	2(0.1%)
Anticoagulation drug level below therapeutic	0	1(0.1%)
Biopsy kidney	0	1(0.1%)
Blood creatine phosphokinase increased	0	1(0.1%)
Blood magnesium decreased	0	1(0.1%)
Blood urine present	0	1(0.1%)
Hepatic enzyme increased	0	1(0.1%)
Liver function test increased	0	1(0.1%)
Troponin increased	0	1(0.1%)
Eye Disorders	16(1.2%)	11(0.8%)
Cataract	6(0.4%)	4(0.3%)
Vitreous haemorrhage	3(0.2%)	1(0.1%)
Diabetic retinopathy	2(0.1%)	0
Macular fibrosis	2(0.1%)	0
Age-related macular degeneration	1(0.1%)	0
Eye haemorrhage	1(0.1%)	0
Glaucoma	1(0.1%)	0
Retinopathy	1(0.1%)	0
Retinopathy proliferative	1(0.1%)	0
Rhegmatogenous retinal detachment	1(0.1%)	0
Macular hole	0	2(0.1%)
Retinal detachment	0	2(0.1%)
Macular oedema	0	1(0.1%)
Optic ischaemic neuropathy	0	1(0.1%)
Retinal haemorrhage	0	1(0.1%)
Hepatobiliary Disorders	15(1.1%)	17(1.3%)
Cholecystitis acute	7(0.5%)	4(0.3%)
Cholelithiasis	3(0.2%)	4(0.3%)
Cholecystitis	2(0.1%)	4(0.3%)
Bile duct stone	2(0.1%)	2(0.1%)

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Cholecystitis chronic	2(0.1%)	0
Biliary colic	1(0.1%)	1(0.1%)
Cholangitis acute	1(0.1%)	1(0.1%)
Hepatic function abnormal	1(0.1%)	0
Non-alcoholic steatohepatitis	1(0.1%)	0
Cholangitis	0	1(0.1%)
Cholecystocholangitis	0	1(0.1%)
Hepatic cirrhosis	0	1(0.1%)
Portal hypertension	0	1(0.1%)
Skin And Subcutaneous Tissue Disorders	15(1.1%)	12(0.9%)
Diabetic foot	8(0.6%)	2(0.1%)
Skin ulcer	7(0.5%)	4(0.3%)
Decubitus ulcer	1(0.1%)	0
Diabetic ulcer	1(0.1%)	0
Palmoplantar keratoderma	1(0.1%)	0
Toxic skin eruption	1(0.1%)	0
Pemphigoid	0	2(0.1%)
Dermatitis allergic	0	1(0.1%)
Diabetic cheiroarthropathy	0	1(0.1%)
Ingrowing nail	0	1(0.1%)
Reactive perforating collagenosis	0	1(0.1%)
Blood And Lymphatic System Disorders	14(1.0%)	18(1.3%)
Anaemia	11(0.8%)	13(1.0%)
Hilar lymphadenopathy	1(0.1%)	0
Hypereosinophilic syndrome	1(0.1%)	0
Hypocoagulable state	1(0.1%)	0
Lymphadenopathy mediastinal	1(0.1%)	0
Microcytic anaemia	1(0.1%)	0
Acquired haemophilia	0	1(0.1%)
Bicytopenia	0	1(0.1%)
Iron deficiency anaemia	0	1(0.1%)
Leukocytosis	0	1(0.1%)
Normochromic normocytic anaemia	0	1(0.1%)
Reproductive System And Breast Disorders	9(0.7%)	5(0.4%)
Benign prostatic hyperplasia	5(0.4%)	2(0.1%)
Breast necrosis	1(0.1%)	0
Endometrial hyperplasia	1(0.1%)	0
Prostatism	1(0.1%)	0
Scrotal dermatitis	1(0.1%)	0
Ovarian cyst	0	1(0.1%)
Prostatitis	0	1(0.1%)
Uterine polyp	0	1(0.1%)
Psychiatric Disorders	7(0.5%)	6(0.4%)
Anxiety	2(0.1%)	0
Completed suicide	2(0.1%)	0
Confusional state	1(0.1%)	1(0.1%)
Bipolar disorder	1(0.1%)	0
Mental disorder due to a general medical condition	1(0.1%)	0

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

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Mental status changes	0	2(0.1%)
Delusional disorder, unspecified type	0	1(0.1%)
Depression	0	1(0.1%)
Major depression	0	1(0.1%)
Ear And Labyrinth Disorders	6(0.4%)	10(0.7%)
Vertigo	4(0.3%)	6(0.4%)
Acute vestibular syndrome	1(0.1%)	0
Tympanic membrane perforation	1(0.1%)	0
Sudden hearing loss	0	1(0.1%)
Vertigo positional	0	1(0.1%)
Vestibular ataxia	0	1(0.1%)
Vestibular disorder	0	1(0.1%)
Endocrine Disorders	4(0.3%)	0
Hyperparathyroidism	1(0.1%)	0
Hypothyroidism	1(0.1%)	0
Primary hyperaldosteronism	1(0.1%)	0
Toxic nodular goitre	1(0.1%)	0
Congenital, Familial And Genetic Disorders	1(0.1%)	1(0.1%)
Phimosis	1(0.1%)	0
Hypospadias	0	1(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Any TEAE	290(21.4%)	295(21.8%)
Infections And Infestations	81(6.0%)	86(6.3%)
Pneumonia	14(1.0%)	25(1.8%)
COVID-19	11(0.8%)	5(0.4%)
Cellulitis	6(0.4%)	8(0.6%)
Urosepsis	6(0.4%)	1(0.1%)
Urinary tract infection	5(0.4%)	8(0.6%)
Sepsis	5(0.4%)	6(0.4%)
Gastroenteritis	4(0.3%)	3(0.2%)
COVID-19 pneumonia	4(0.3%)	1(0.1%)
Influenza	3(0.2%)	2(0.1%)
Gangrene	3(0.2%)	1(0.1%)
Erysipelas	3(0.2%)	0
Pyelonephritis	3(0.2%)	0
Osteomyelitis	2(0.1%)	2(0.1%)
Respiratory tract infection	2(0.1%)	1(0.1%)
Emphysematous pyelonephritis	2(0.1%)	0
Viral infection	2(0.1%)	0
Septic shock	1(0.1%)	3(0.2%)
Localised infection	1(0.1%)	2(0.1%)
Abscess limb	1(0.1%)	1(0.1%)
Bronchitis	1(0.1%)	1(0.1%)
Herpes zoster	1(0.1%)	1(0.1%)
Nasopharyngitis	1(0.1%)	1(0.1%)
Postoperative wound infection	1(0.1%)	1(0.1%)
Pulmonary tuberculosis	1(0.1%)	1(0.1%)
Upper respiratory tract infection	1(0.1%)	1(0.1%)
Acute sinusitis	1(0.1%)	0
Anal abscess	1(0.1%)	0
Bacteraemia	1(0.1%)	0
Bacterial sepsis	1(0.1%)	0
Infectious mononucleosis	1(0.1%)	0
Medical device site infection	1(0.1%)	0
Parotitis	1(0.1%)	0
Pneumonia klebsiella	1(0.1%)	0
Subcutaneous abscess	1(0.1%)	0
Wound infection bacterial	1(0.1%)	0
Appendicitis	0	3(0.2%)
Lower respiratory tract infection	0	2(0.1%)
Pneumonia bacterial	0	2(0.1%)
Acute hepatitis B	0	1(0.1%)
Anorectal infection bacterial	0	1(0.1%)
Arteriosclerotic gangrene	0	1(0.1%)
Bacterial rhinitis	0	1(0.1%)
Bacterial tracheitis	0	1(0.1%)
Campylobacter gastroenteritis	0	1(0.1%)
Coronavirus infection	0	1(0.1%)
Cystitis	0	1(0.1%)
Diabetic foot infection	0	1(0.1%)
Diverticulitis	0	1(0.1%)
Endocarditis	0	1(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Enterococcal bacteraemia	0	1(0.1%)
Enterococcal infection	0	1(0.1%)
Escherichia sepsis	0	1(0.1%)
Fournier's gangrene	0	1(0.1%)
Gastritis viral	0	1(0.1%)
Infection	0	1(0.1%)
Infective exacerbation of bronchiectasis	0	1(0.1%)
Medical device site joint infection	0	1(0.1%)
Necrotising fasciitis	0	1(0.1%)
Pharyngitis bacterial	0	1(0.1%)
Skin infection	0	1(0.1%)
Staphylococcal sepsis	0	1(0.1%)
Subacute endocarditis	0	1(0.1%)
Tooth infection	0	1(0.1%)
Urinary tract infection bacterial	0	1(0.1%)
Metabolism And Nutrition Disorders	45(3.3%)	38(2.8%)
Hyperkalaemia	13(1.0%)	1(0.1%)
Hypoglycaemia	11(0.8%)	15(1.1%)
Hyperglycaemia	4(0.3%)	5(0.4%)
Dehydration	4(0.3%)	4(0.3%)
Diabetes mellitus inadequate control	4(0.3%)	3(0.2%)
Gout	3(0.2%)	1(0.1%)
Diabetes mellitus	2(0.1%)	1(0.1%)
Hypovolaemia	2(0.1%)	0
Hyperglycaemic hyperosmolar nonketotic syndrome	1(0.1%)	2(0.1%)
Hypokalaemia	1(0.1%)	1(0.1%)
Decreased appetite	1(0.1%)	0
Hypercalcaemia	1(0.1%)	0
Metabolic acidosis	1(0.1%)	0
Obesity	1(0.1%)	0
Hyponatraemia	0	2(0.1%)
Diabetic ketoacidosis	0	1(0.1%)
Diabetic metabolic decompensation	0	1(0.1%)
Fluid overload	0	1(0.1%)
Hypertriglyceridaemia	0	1(0.1%)
Hypocalcaemia	0	1(0.1%)
Type 2 diabetes mellitus	0	1(0.1%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	40(2.9%)	47(3.5%)
Colon cancer	4(0.3%)	4(0.3%)
Bladder cancer	2(0.1%)	3(0.2%)
Lung adenocarcinoma	2(0.1%)	3(0.2%)
Hepatic cancer	2(0.1%)	1(0.1%)
Lung neoplasm malignant	2(0.1%)	1(0.1%)
Pancreatic carcinoma	2(0.1%)	1(0.1%)
Metastases to central nervous system	2(0.1%)	0
Metastases to liver	2(0.1%)	0
Pancreatic neoplasm	2(0.1%)	0
Renal cell carcinoma	2(0.1%)	0
Prostate cancer	1(0.1%)	6(0.4%)
Lung neoplasm	1(0.1%)	2(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Bladder transitional cell carcinoma	1(0.1%)	1(0.1%)
Bronchial carcinoma	1(0.1%)	1(0.1%)
Cholangiocarcinoma	1(0.1%)	1(0.1%)
Hepatocellular carcinoma	1(0.1%)	1(0.1%)
Pancreatic carcinoma metastatic	1(0.1%)	1(0.1%)
Small cell lung cancer	1(0.1%)	1(0.1%)
Acute myeloid leukaemia	1(0.1%)	0
Adenocarcinoma of colon	1(0.1%)	0
Basal cell carcinoma	1(0.1%)	0
Bladder cancer recurrent	1(0.1%)	0
Breast cancer	1(0.1%)	0
Colon adenoma	1(0.1%)	0
Colorectal cancer	1(0.1%)	0
Epithelioid mesothelioma	1(0.1%)	0
Invasive lobular breast carcinoma	1(0.1%)	0
Metastases to bone	1(0.1%)	0
Metastases to lymph nodes	1(0.1%)	0
Myelodysplastic syndrome	1(0.1%)	0
Oropharyngeal squamous cell carcinoma	1(0.1%)	0
Pancreatic carcinoma stage IV	1(0.1%)	0
Plasma cell myeloma	1(0.1%)	0
Prostate cancer metastatic	1(0.1%)	0
Prostate cancer recurrent	1(0.1%)	0
Squamous cell carcinoma of the parotid gland	1(0.1%)	0
Transitional cell carcinoma recurrent	1(0.1%)	0
Oesophageal carcinoma	0	3(0.2%)
Adenocarcinoma gastric	0	1(0.1%)
Adrenal adenoma	0	1(0.1%)
Bladder neoplasm	0	1(0.1%)
Bone cancer	0	1(0.1%)
Brain neoplasm	0	1(0.1%)
Colon neoplasm	0	1(0.1%)
Colorectal adenocarcinoma	0	1(0.1%)
Endometrial cancer	0	1(0.1%)
Gastrointestinal cancer metastatic	0	1(0.1%)
Hepatic cancer metastatic	0	1(0.1%)
Invasive papillary breast carcinoma	0	1(0.1%)
Lung cancer metastatic	0	1(0.1%)
Malignant pleural effusion	0	1(0.1%)
Metastases to spine	0	1(0.1%)
Metastasis	0	1(0.1%)
Papillary renal cell carcinoma	0	1(0.1%)
Prostate cancer stage IV	0	1(0.1%)
Renal cancer	0	1(0.1%)
Renal neoplasm	0	1(0.1%)
Retroperitoneal neoplasm	0	1(0.1%)
Sarcoma	0	1(0.1%)
Skin cancer	0	1(0.1%)
Squamous cell carcinoma of the oral cavity	0	1(0.1%)
Thyroid cancer	0	1(0.1%)
Transitional cell carcinoma	0	1(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Respiratory, Thoracic And Mediastinal Disorders	32(2.4%)	28(2.1%)
Chronic obstructive pulmonary disease	5(0.4%)	3(0.2%)
Respiratory failure	5(0.4%)	2(0.1%)
Acute respiratory failure	4(0.3%)	4(0.3%)
Dyspnoea	4(0.3%)	1(0.1%)
Sleep apnoea syndrome	3(0.2%)	3(0.2%)
Pulmonary embolism	2(0.1%)	3(0.2%)
Pleural effusion	2(0.1%)	1(0.1%)
Pulmonary mass	2(0.1%)	0
Pulmonary oedema	1(0.1%)	3(0.2%)
Acute pulmonary oedema	1(0.1%)	1(0.1%)
Cough	1(0.1%)	1(0.1%)
Alveolar lung disease	1(0.1%)	0
Asthma	1(0.1%)	0
Atelectasis	1(0.1%)	0
Chronic respiratory failure	1(0.1%)	0
Dyspnoea exertional	1(0.1%)	0
Haemoptysis	1(0.1%)	0
Hypoxia	1(0.1%)	0
Interstitial lung disease	1(0.1%)	0
Pneumonia aspiration	1(0.1%)	0
Pneumonitis	1(0.1%)	0
Pulmonary hypertension	0	3(0.2%)
Aspiration	0	1(0.1%)
Epistaxis	0	1(0.1%)
Idiopathic pulmonary fibrosis	0	1(0.1%)
Pneumothorax	0	1(0.1%)
Pulmonary congestion	0	1(0.1%)
Small airways disease	0	1(0.1%)
Renal And Urinary Disorders	29(2.1%)	32(2.4%)
Acute kidney injury	14(1.0%)	22(1.6%)
Renal failure	2(0.1%)	1(0.1%)
Urinary retention	2(0.1%)	0
Chronic kidney disease	1(0.1%)	3(0.2%)
Nephrolithiasis	1(0.1%)	2(0.1%)
Ureterolithiasis	1(0.1%)	2(0.1%)
Urinary tract obstruction	1(0.1%)	1(0.1%)
Haematuria	1(0.1%)	0
Nephropathy toxic	1(0.1%)	0
Pollakiuria	1(0.1%)	0
Renal cyst	1(0.1%)	0
Renal impairment	1(0.1%)	0
Ureteric obstruction	1(0.1%)	0
Urethral stenosis	1(0.1%)	0
Hydronephrosis	0	1(0.1%)
Nephropathy	0	1(0.1%)
Pelvi-ureteric obstruction	0	1(0.1%)
Proteinuria	0	1(0.1%)
Renal colic	0	1(0.1%)
Gastrointestinal Disorders	29(2.1%)	22(1.6%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Diarrhoea	5(0.4%)	2(0.1%)
Gastrointestinal haemorrhage	3(0.2%)	2(0.1%)
Dyspepsia	2(0.1%)	0
Pancreatitis	2(0.1%)	0
Vomiting	2(0.1%)	0
Abdominal pain	1(0.1%)	3(0.2%)
Intestinal obstruction	1(0.1%)	2(0.1%)
Upper gastrointestinal haemorrhage	1(0.1%)	2(0.1%)
Rectal haemorrhage	1(0.1%)	1(0.1%)
Small intestinal obstruction	1(0.1%)	1(0.1%)
Abdominal discomfort	1(0.1%)	0
Abdominal mass	1(0.1%)	0
Colitis ischaemic	1(0.1%)	0
Constipation	1(0.1%)	0
Diarrhoea haemorrhagic	1(0.1%)	0
Duodenal perforation	1(0.1%)	0
Duodenal ulcer	1(0.1%)	0
Gastritis	1(0.1%)	0
Gastrointestinal polyp	1(0.1%)	0
Gastrointestinal ulcer	1(0.1%)	0
Glossitis	1(0.1%)	0
Intestinal mass	1(0.1%)	0
Mechanical ileus	1(0.1%)	0
Peptic ulcer	1(0.1%)	0
Abdominal wall haematoma	0	2(0.1%)
Abdominal pain lower	0	1(0.1%)
Chronic gastritis	0	1(0.1%)
Colitis ulcerative	0	1(0.1%)
Colon dysplasia	0	1(0.1%)
Diverticulum	0	1(0.1%)
Dysphagia	0	1(0.1%)
Food poisoning	0	1(0.1%)
Gastric mucosal hypertrophy	0	1(0.1%)
Haematochezia	0	1(0.1%)
Large intestine polyp	0	1(0.1%)
Oesophageal dysplasia	0	1(0.1%)
Pancreatitis acute	0	1(0.1%)
Pancreatitis chronic	0	1(0.1%)
Injury, Poisoning And Procedural Complications	26(1.9%)	26(1.9%)
Fall	3(0.2%)	3(0.2%)
Femur fracture	2(0.1%)	2(0.1%)
Hip fracture	2(0.1%)	2(0.1%)
Spinal compression fracture	2(0.1%)	2(0.1%)
Radius fracture	1(0.1%)	2(0.1%)
Road traffic accident	1(0.1%)	2(0.1%)
Brain contusion	1(0.1%)	1(0.1%)
Head injury	1(0.1%)	1(0.1%)
Humerus fracture	1(0.1%)	1(0.1%)
Procedural pain	1(0.1%)	1(0.1%)
Skin laceration	1(0.1%)	1(0.1%)
Craniocerebral injury	1(0.1%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Femoral neck fracture	1(0.1%)	0
Foot fracture	1(0.1%)	0
Gun shot wound	1(0.1%)	0
Incision site pain	1(0.1%)	0
Ligament rupture	1(0.1%)	0
Muscle injury	1(0.1%)	0
Patella fracture	1(0.1%)	0
Post procedural haemorrhage	1(0.1%)	0
Skull fractured base	1(0.1%)	0
Splenic injury	1(0.1%)	0
Tendon rupture	1(0.1%)	0
Tibia fracture	1(0.1%)	0
Traumatic fracture	1(0.1%)	0
Subdural haematoma	0	2(0.1%)
Ankle fracture	0	1(0.1%)
Epicondylitis	0	1(0.1%)
Joint dislocation	0	1(0.1%)
Limb injury	0	1(0.1%)
Multiple injuries	0	1(0.1%)
Overdose	0	1(0.1%)
Procedural haemorrhage	0	1(0.1%)
Rib fracture	0	1(0.1%)
Thermal burn	0	1(0.1%)
Nervous System Disorders	25(1.8%)	25(1.8%)
Syncope	4(0.3%)	5(0.4%)
Carotid artery stenosis	2(0.1%)	2(0.1%)
Diabetic neuropathy	2(0.1%)	1(0.1%)
Dizziness	2(0.1%)	1(0.1%)
Cognitive disorder	2(0.1%)	0
Subarachnoid haemorrhage	1(0.1%)	2(0.1%)
Carpal tunnel syndrome	1(0.1%)	1(0.1%)
Seizure	1(0.1%)	1(0.1%)
Cerebral haemorrhage	1(0.1%)	0
Facial paresis	1(0.1%)	0
Generalised tonic-clonic seizure	1(0.1%)	0
Guillain-Barre syndrome	1(0.1%)	0
Hepatic encephalopathy	1(0.1%)	0
Hypoaesthesia	1(0.1%)	0
Ischaemic stroke	1(0.1%)	0
Metabolic encephalopathy	1(0.1%)	0
Normal pressure hydrocephalus	1(0.1%)	0
Partial seizures	1(0.1%)	0
Tension headache	1(0.1%)	0
Toxic encephalopathy	1(0.1%)	0
Unresponsive to stimuli	1(0.1%)	0
Sciatica	0	2(0.1%)
Aphasia	0	1(0.1%)
Brain stem infarction	0	1(0.1%)
Cervicobrachial syndrome	0	1(0.1%)
Dementia Alzheimer's type	0	1(0.1%)
Epilepsy	0	1(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Hypertensive encephalopathy	0	1(0.1%)
Hypoglycaemic unconsciousness	0	1(0.1%)
Intraventricular haemorrhage	0	1(0.1%)
Lacunar infarction	0	1(0.1%)
Myelomalacia	0	1(0.1%)
Paraplegia	0	1(0.1%)
Presyncope	0	1(0.1%)
Spinal cord compression	0	1(0.1%)
Spinal cord haematoma	0	1(0.1%)
Spondylitic myelopathy	0	1(0.1%)
Thalamic infarction	0	1(0.1%)
Thalamus haemorrhage	0	1(0.1%)
Vascular Disorders	24(1.8%)	18(1.3%)
Hypotension	4(0.3%)	2(0.1%)
Aortic stenosis	4(0.3%)	0
Hypertension	3(0.2%)	3(0.2%)
Peripheral ischaemia	1(0.1%)	4(0.3%)
Peripheral arterial occlusive disease	1(0.1%)	2(0.1%)
Extremity necrosis	1(0.1%)	1(0.1%)
Hypertensive crisis	1(0.1%)	1(0.1%)
Peripheral vascular disorder	1(0.1%)	1(0.1%)
Thrombosis	1(0.1%)	1(0.1%)
Aortic aneurysm	1(0.1%)	0
Aortic dissection	1(0.1%)	0
Aortic occlusion	1(0.1%)	0
Hypertensive emergency	1(0.1%)	0
Lymphoedema	1(0.1%)	0
Peripheral artery occlusion	1(0.1%)	0
Thrombophlebitis	1(0.1%)	0
Varicose ulceration	1(0.1%)	0
Vasculitis	1(0.1%)	0
Hypertensive urgency	0	2(0.1%)
Peripheral artery stenosis	0	2(0.1%)
Arterial stenosis	0	1(0.1%)
Arterial thrombosis	0	1(0.1%)
Deep vein thrombosis	0	1(0.1%)
Iliac artery stenosis	0	1(0.1%)
Peripheral artery aneurysm rupture	0	1(0.1%)
Phlebitis	0	1(0.1%)
Systolic hypertension	0	1(0.1%)
Musculoskeletal And Connective Tissue Disorders	20(1.5%)	21(1.5%)
Osteoarthritis	7(0.5%)	1(0.1%)
Arthralgia	3(0.2%)	3(0.2%)
Rotator cuff syndrome	1(0.1%)	3(0.2%)
Arthritis	1(0.1%)	1(0.1%)
Back pain	1(0.1%)	1(0.1%)
Muscular weakness	1(0.1%)	1(0.1%)
Pain in extremity	1(0.1%)	1(0.1%)
Facet joint syndrome	1(0.1%)	0
Immobilisation syndrome	1(0.1%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Intervertebral disc compression	1(0.1%)	0
Intervertebral disc protrusion	1(0.1%)	0
Lumbar spinal stenosis	1(0.1%)	0
Muscle spasms	1(0.1%)	0
Spinal stenosis	0	2(0.1%)
Chondrocalcinosis pyrophosphate	0	1(0.1%)
Costochondritis	0	1(0.1%)
Flank pain	0	1(0.1%)
Gouty arthritis	0	1(0.1%)
Intervertebral disc disorder	0	1(0.1%)
Myalgia	0	1(0.1%)
Neck pain	0	1(0.1%)
Osteitis	0	1(0.1%)
Osteolysis	0	1(0.1%)
Spinal osteoarthritis	0	1(0.1%)
Cardiac Disorders	20(1.5%)	19(1.4%)
Cardiac failure acute	3(0.2%)	0
Coronary artery disease	3(0.2%)	0
Cardiac failure	2(0.1%)	5(0.4%)
Aortic valve stenosis	2(0.1%)	1(0.1%)
Angina pectoris	1(0.1%)	2(0.1%)
Cardiac arrest	1(0.1%)	2(0.1%)
Bradycardia	1(0.1%)	1(0.1%)
Acute left ventricular failure	1(0.1%)	0
Angina unstable	1(0.1%)	0
Atrioventricular block second degree	1(0.1%)	0
Cardiac failure congestive	1(0.1%)	0
Left ventricular dysfunction	1(0.1%)	0
Pulseless electrical activity	1(0.1%)	0
Sinus node dysfunction	1(0.1%)	0
Aortic valve incompetence	0	1(0.1%)
Arteriosclerosis coronary artery	0	1(0.1%)
Atrial fibrillation	0	1(0.1%)
Cardiac failure chronic	0	1(0.1%)
Cardiac tamponade	0	1(0.1%)
Cardio-respiratory arrest	0	1(0.1%)
Coronary artery perforation	0	1(0.1%)
Coronary artery stenosis	0	1(0.1%)
Left ventricular failure	0	1(0.1%)
Left ventricular hypertrophy	0	1(0.1%)
Sinoatrial block	0	1(0.1%)
Tricuspid valve incompetence	0	1(0.1%)
General Disorders And Administration Site Conditions	15(1.1%)	19(1.4%)
Fatigue	3(0.2%)	1(0.1%)
Death	2(0.1%)	4(0.3%)
Chest pain	2(0.1%)	2(0.1%)
Oedema peripheral	2(0.1%)	1(0.1%)
Pyrexia	2(0.1%)	0
Asthenia	1(0.1%)	4(0.3%)
General physical health deterioration	1(0.1%)	3(0.2%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Systemic inflammatory response syndrome	1(0.1%)	1(0.1%)
Oedema due to cardiac disease	1(0.1%)	0
Adhesion	0	1(0.1%)
Multiple organ dysfunction syndrome	0	1(0.1%)
Non-cardiac chest pain	0	1(0.1%)
Polyp	0	1(0.1%)
Surgical And Medical Procedures	12(0.9%)	9(0.7%)
Cataract operation	2(0.1%)	0
Colectomy	2(0.1%)	0
Knee arthroplasty	1(0.1%)	1(0.1%)
Bladder calculus removal	1(0.1%)	0
Carotid endarterectomy	1(0.1%)	0
Coronary artery bypass	1(0.1%)	0
Hip arthroplasty	1(0.1%)	0
Metabolic surgery	1(0.1%)	0
Parotidectomy	1(0.1%)	0
Spinal laminectomy	1(0.1%)	0
Vitrectomy	1(0.1%)	0
Intervertebral disc operation	0	2(0.1%)
Cheilectomy	0	1(0.1%)
Nasal polypectomy	0	1(0.1%)
Prostatectomy	0	1(0.1%)
Radical prostatectomy	0	1(0.1%)
Radioactive iodine therapy	0	1(0.1%)
Skin ulcer excision	0	1(0.1%)
Stent placement	0	1(0.1%)
Skin And Subcutaneous Tissue Disorders	11(0.8%)	5(0.4%)
Skin ulcer	4(0.3%)	0
Diabetic foot	3(0.2%)	2(0.1%)
Decubitus ulcer	2(0.1%)	0
Dry skin	2(0.1%)	0
Palmoplantar keratoderma	1(0.1%)	0
Skin lesion	1(0.1%)	0
Skin necrosis	1(0.1%)	0
Pemphigoid	0	2(0.1%)
Diabetic cheiroarthropathy	0	1(0.1%)
Investigations	9(0.7%)	15(1.1%)
Glomerular filtration rate decreased	3(0.2%)	3(0.2%)
Blood potassium increased	1(0.1%)	1(0.1%)
Blood testosterone decreased	1(0.1%)	0
Blood triglycerides increased	1(0.1%)	0
Haemoglobin decreased	1(0.1%)	0
International normalised ratio increased	1(0.1%)	0
Prostatic specific antigen increased	1(0.1%)	0
Influenza A virus test positive	0	2(0.1%)
Anticoagulation drug level below therapeutic	0	1(0.1%)
Blood creatinine increased	0	1(0.1%)
Blood magnesium decreased	0	1(0.1%)
Blood urine present	0	1(0.1%)

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
C-reactive protein increased	0	1(0.1%)
Electrocardiogram T wave inversion	0	1(0.1%)
Liver function test increased	0	1(0.1%)
N-terminal prohormone brain natriuretic peptide increased	0	1(0.1%)
Troponin increased	0	1(0.1%)
Urine albumin/creatinine ratio increased	0	1(0.1%)
Hepatobiliary Disorders	9(0.7%)	7(0.5%)
Cholecystitis	2(0.1%)	1(0.1%)
Cholelithiasis	2(0.1%)	1(0.1%)
Cholangitis acute	1(0.1%)	1(0.1%)
Cholecystitis acute	1(0.1%)	1(0.1%)
Bile duct stone	1(0.1%)	0
Biliary colic	1(0.1%)	0
Cholecystitis chronic	1(0.1%)	0
Gallbladder fistula	1(0.1%)	0
Non-alcoholic steatohepatitis	1(0.1%)	0
Cholangitis	0	1(0.1%)
Hepatic cirrhosis	0	1(0.1%)
Portal hypertension	0	1(0.1%)
Blood And Lymphatic System Disorders	8(0.6%)	9(0.7%)
Anaemia	5(0.4%)	5(0.4%)
Lymphadenopathy mediastinal	2(0.1%)	0
Abdominal lymphadenopathy	1(0.1%)	0
Hilar lymphadenopathy	1(0.1%)	0
Hypereosinophilic syndrome	1(0.1%)	0
Lymphadenopathy	1(0.1%)	0
Normocytic anaemia	1(0.1%)	0
Splenomegaly	1(0.1%)	0
Acquired haemophilia	0	1(0.1%)
Bicytopenia	0	1(0.1%)
Leukocytosis	0	1(0.1%)
Pancytopenia	0	1(0.1%)
Splenic embolism	0	1(0.1%)
Eye Disorders	5(0.4%)	6(0.4%)
Cataract	3(0.2%)	1(0.1%)
Diabetic retinopathy	2(0.1%)	0
Vitreous haemorrhage	1(0.1%)	2(0.1%)
Eye haemorrhage	1(0.1%)	0
Macular fibrosis	1(0.1%)	0
Glaucoma	0	1(0.1%)
Retinal haemorrhage	0	1(0.1%)
Retinal vein occlusion	0	1(0.1%)
Tractional retinal detachment	0	1(0.1%)
Reproductive System And Breast Disorders	5(0.4%)	2(0.1%)
Benign prostatic hyperplasia	2(0.1%)	1(0.1%)
Prostatitis	1(0.1%)	1(0.1%)
Breast necrosis	1(0.1%)	0
Prostatism	1(0.1%)	0

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

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Psychiatric Disorders	4 (0.3%)	5 (0.4%)
Completed suicide	2 (0.1%)	0
Depression	1 (0.1%)	1 (0.1%)
Aggression	1 (0.1%)	0
Anxiety	1 (0.1%)	0
Disorientation	1 (0.1%)	0
Delirium	0	2 (0.1%)
Delusional disorder, unspecified type	0	1 (0.1%)
Mental status changes	0	1 (0.1%)
Endocrine Disorders	2 (0.1%)	0
Hypothyroidism	1 (0.1%)	0
Primary hyperaldosteronism	1 (0.1%)	0
Ear And Labyrinth Disorders	0	2 (0.1%)
Vertigo	0	2 (0.1%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Any TEAE	122(9.0%)	89(6.6%)
Metabolism And Nutrition Disorders	31(2.3%)	14(1.0%)
Hyperkalaemia	27(2.0%)	8(0.6%)
Decreased appetite	1(0.1%)	1(0.1%)
Hyponatraemia	1(0.1%)	1(0.1%)
Diabetes mellitus	1(0.1%)	0
Hypercalcaemia	1(0.1%)	0
Diabetic ketoacidosis	0	1(0.1%)
Fluid overload	0	1(0.1%)
Gout	0	1(0.1%)
Hyperglycaemia	0	1(0.1%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	15(1.1%)	18(1.3%)
Lung neoplasm malignant	2(0.1%)	0
Lung adenocarcinoma	1(0.1%)	2(0.1%)
Colon cancer	1(0.1%)	1(0.1%)
Pancreatic carcinoma	1(0.1%)	1(0.1%)
Pancreatic carcinoma metastatic	1(0.1%)	1(0.1%)
Small cell lung cancer	1(0.1%)	1(0.1%)
Adenocarcinoma gastric	1(0.1%)	0
Brain neoplasm malignant	1(0.1%)	0
Metastases to liver	1(0.1%)	0
Metastases to lymph nodes	1(0.1%)	0
Myelodysplastic syndrome	1(0.1%)	0
Oesophageal adenocarcinoma	1(0.1%)	0
Pancreatic carcinoma stage IV	1(0.1%)	0
Prostate cancer	1(0.1%)	0
Renal cell carcinoma	1(0.1%)	0
Colon neoplasm	0	2(0.1%)
Renal neoplasm	0	2(0.1%)
Adrenal adenoma	0	1(0.1%)
Bladder cancer	0	1(0.1%)
Cervix carcinoma	0	1(0.1%)
Cholangiocarcinoma	0	1(0.1%)
Gastrointestinal cancer metastatic	0	1(0.1%)
Lung cancer metastatic	0	1(0.1%)
Lung neoplasm	0	1(0.1%)
Malignant pleural effusion	0	1(0.1%)
Oesophageal carcinoma	0	1(0.1%)
Gastrointestinal Disorders	15(1.1%)	13(1.0%)
Diarrhoea	6(0.4%)	1(0.1%)
Nausea	3(0.2%)	8(0.6%)
Vomiting	1(0.1%)	2(0.1%)
Constipation	1(0.1%)	1(0.1%)
Abdominal discomfort	1(0.1%)	0
Ascites	1(0.1%)	0
Intestinal mass	1(0.1%)	0
Mechanical ileus	1(0.1%)	0
Pancreatitis	1(0.1%)	0
Abdominal pain	0	2(0.1%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Abdominal pain upper	0	2(0.1%)
Abdominal distension	0	1(0.1%)
Diabetic gastroenteropathy	0	1(0.1%)
Dyspepsia	0	1(0.1%)
Faeces discoloured	0	1(0.1%)
Investigations	13(1.0%)	4(0.3%)
Blood potassium increased	7(0.5%)	0
Glomerular filtration rate decreased	3(0.2%)	2(0.1%)
Blood creatinine increased	1(0.1%)	0
Gamma-glutamyltransferase increased	1(0.1%)	0
Protein urine present	1(0.1%)	0
Blood glucose increased	0	1(0.1%)
Occult blood positive	0	1(0.1%)
Renal And Urinary Disorders	11(0.8%)	5(0.4%)
Acute kidney injury	6(0.4%)	1(0.1%)
Renal impairment	2(0.1%)	2(0.1%)
Renal failure	2(0.1%)	0
Diabetic nephropathy	1(0.1%)	0
Pollakiuria	0	1(0.1%)
Renal colic	0	1(0.1%)
Renal mass	0	1(0.1%)
Nervous System Disorders	10(0.7%)	13(1.0%)
Cognitive disorder	3(0.2%)	3(0.2%)
Dizziness	3(0.2%)	3(0.2%)
Dementia	2(0.1%)	2(0.1%)
Dementia Alzheimer's type	1(0.1%)	0
Tremor	1(0.1%)	0
Amnestic disorder	0	1(0.1%)
Disturbance in attention	0	1(0.1%)
Headache	0	1(0.1%)
Memory impairment	0	1(0.1%)
Presyncope	0	1(0.1%)
Somnolence	0	1(0.1%)
Spinal cord compression	0	1(0.1%)
Infections And Infestations	9(0.7%)	7(0.5%)
Pneumonia	2(0.1%)	2(0.1%)
COVID-19	1(0.1%)	1(0.1%)
COVID-19 pneumonia	1(0.1%)	1(0.1%)
Sepsis	1(0.1%)	1(0.1%)
Cellulitis	1(0.1%)	0
Medical device site infection	1(0.1%)	0
Osteomyelitis	1(0.1%)	0
Tuberculosis	1(0.1%)	0
Onychomycosis	0	1(0.1%)
Urosepsis	0	1(0.1%)
Skin And Subcutaneous Tissue Disorders	6(0.4%)	5(0.4%)
Rash	4(0.3%)	1(0.1%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Psoriasis	1(0.1%)	0
Rash papular	1(0.1%)	0
Dermatitis allergic	0	1(0.1%)
Eczema	0	1(0.1%)
Pruritus	0	1(0.1%)
Urticaria	0	1(0.1%)
Hepatobiliary Disorders	5(0.4%)	2(0.1%)
Liver disorder	2(0.1%)	1(0.1%)
Cholecystitis	1(0.1%)	0
Hepatic cirrhosis	1(0.1%)	0
Non-alcoholic steatohepatitis	1(0.1%)	0
Hepatic pain	0	1(0.1%)
Respiratory, Thoracic And Mediastinal Disorders	5(0.4%)	1(0.1%)
Respiratory failure	2(0.1%)	0
Dyspnoea	1(0.1%)	0
Interstitial lung disease	1(0.1%)	0
Oropharyngeal pain	1(0.1%)	0
Acute respiratory failure	0	1(0.1%)
General Disorders And Administration Site Conditions	3(0.2%)	4(0.3%)
Fatigue	3(0.2%)	0
Pain	1(0.1%)	0
General physical health deterioration	0	2(0.1%)
Asthenia	0	1(0.1%)
Chest pain	0	1(0.1%)
Swelling	0	1(0.1%)
Musculoskeletal And Connective Tissue Disorders	3(0.2%)	1(0.1%)
Muscle rigidity	1(0.1%)	0
Muscle spasms	1(0.1%)	0
Pain in extremity	1(0.1%)	0
Musculoskeletal pain	0	1(0.1%)
Vascular Disorders	1(0.1%)	4(0.3%)
Hypotension	1(0.1%)	0
Arterial thrombosis	0	1(0.1%)
Inferior vena cava syndrome	0	1(0.1%)
Orthostatic hypotension	0	1(0.1%)
Vein disorder	0	1(0.1%)
Injury, Poisoning And Procedural Complications	1(0.1%)	1(0.1%)
Femoral neck fracture	1(0.1%)	0
Fall	0	1(0.1%)
Eye Disorders	1(0.1%)	0
Scleritis	1(0.1%)	0
Ear And Labyrinth Disorders	0	3(0.2%)
Vertigo	0	3(0.2%)

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

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=1357)	Placebo (N=1356)
Cardiac Disorders	0	1(0.1%)
Pericardial effusion	0	1(0.1%)
Immune System Disorders	0	1(0.1%)
Hypersensitivity	0	1(0.1%)
Psychiatric Disorders	0	1(0.1%)
Confusional state	0	1(0.1%)

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

Table A2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Treatment duration (months)			
n	1357	1356	2713
Mean	34.4	35.3	34.9
SD	15.47	14.99	15.24
Median	36.3	37.3	36.9
Q1-Q3	25.3 - 47.0	26.2 - 47.4	25.8 - 47.2
Range	0.07 - 60.16	0.03 - 60.55	0.03 - 60.55

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

Table A2.1.1: Effect Measures of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		1195 (88.1%)	1192 (87.9%)	2387 (88.0%)
Number of subjects without events		162 (11.9%)	164 (12.1%)	326 (12.0%)
Odds Ratio [a]				
OR, 95% CI	1.015 [0.805, 1.279]			
p-value	0.9004			
Relative Risk [b]				
RR, 95% CI	1.002 [0.974, 1.030]			
p-value	0.9004			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.023, 0.026]			
p-value	0.9004			

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

Table A2.1.2: Effect Measures of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		1186 (87.4%)	1183 (87.2%)	2369 (87.3%)
Number of subjects without events		171 (12.6%)	173 (12.8%)	344 (12.7%)
Odds Ratio [a]				
OR, 95% CI	1.014 [0.809, 1.272]			
p-value	0.9023			
Relative Risk [b]				
RR, 95% CI	1.002 [0.973, 1.031]			
p-value	0.9023			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.023, 0.027]			
p-value	0.9023			

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

Table A2.1.3: Effect Measures of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		492 (36.3%)	511 (37.7%)	1003 (37.0%)
Number of subjects without events		865 (63.7%)	845 (62.3%)	1710 (63.0%)
Odds Ratio [a]				
OR, 95% CI	0.941 [0.805, 1.099]			
p-value	0.4411			
Relative Risk [b]				
RR, 95% CI	0.962 [0.872, 1.061]			
p-value	0.4412			
Risk Difference [c]				
RD, 95% CI	-0.014 [-0.051, 0.022]			
p-value	0.4410			

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

Table A2.1.4: Effect Measures of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		484 (35.7%)	500 (36.9%)	984 (36.3%)
Number of subjects without events		873 (64.3%)	856 (63.1%)	1729 (63.7%)
Odds Ratio [a]				
OR, 95% CI	0.949 [0.812, 1.110]			
p-value	0.5135			
Relative Risk [b]				
RR, 95% CI	0.967 [0.875, 1.069]			
p-value	0.5135			
Risk Difference [c]				
RD, 95% CI	-0.012 [-0.048, 0.024]			
p-value	0.5135			

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

Table A2.1.5: Effect Measures of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		290 (21.4%)	295 (21.8%)	585 (21.6%)
Number of subjects without events		1067 (78.6%)	1061 (78.2%)	2128 (78.4%)
Odds Ratio [a]				
OR, 95% CI	0.978 [0.814, 1.174]			
p-value	0.8076			
Relative Risk [b]				
RR, 95% CI	0.982 [0.851, 1.134]			
p-value	0.8076			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.035, 0.027]			
p-value	0.8076			

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

Table A2.1.6: Effect Measures of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		284 (20.9%)	283 (20.9%)	567 (20.9%)
Number of subjects without events		1073 (79.1%)	1073 (79.1%)	2146 (79.1%)
Odds Ratio [a]				
OR, 95% CI	1.004 [0.834, 1.208]			
p-value	0.9702			
Relative Risk [b]				
RR, 95% CI	1.003 [0.866, 1.161]			
p-value	0.9702			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.030, 0.031]			
p-value	0.9702			

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

Table A2.1.7: Effect Measures of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		122 (9.0%)	89 (6.6%)	211 (7.8%)
Number of subjects without events		1235 (91.0%)	1267 (93.4%)	2502 (92.2%)
Odds Ratio [a]				
OR, 95% CI	1.406 [1.058, 1.869]			
p-value	0.0187			
Relative Risk [b]				
RR, 95% CI	1.370 [1.053, 1.781]			
p-value	0.0189			
Risk Difference [c]				
RD, 95% CI	0.024 [0.004, 0.044]			
p-value	0.0181			

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

Table A2.1.8: Effect Measures of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		149 (11.0%)	151 (11.1%)	300 (11.1%)
Number of subjects without events		1208 (89.0%)	1205 (88.9%)	2413 (88.9%)
Odds Ratio [a]				
OR, 95% CI	0.984 [0.774, 1.251]			
p-value	0.8972			
Relative Risk [b]				
RR, 95% CI	0.986 [0.797, 1.221]			
p-value	0.8972			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.025, 0.022]			
p-value	0.8972			

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

Table A2.1.9: Effect Measures of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		90 (6.6%)	97 (7.2%)	187 (6.9%)
Number of subjects without events		1267 (93.4%)	1259 (92.8%)	2526 (93.1%)
Odds Ratio [a]				
OR, 95% CI	0.922 [0.685, 1.241]			
p-value	0.5922			
Relative Risk [b]				
RR, 95% CI	0.927 [0.703, 1.223]			
p-value	0.5923			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.024, 0.014]			
p-value	0.5921			

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

Table A2.1.10: Effect Measures of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	21 (1.5%)	35 (1.3%)
Number of subjects without events		1343 (99.0%)	1335 (98.5%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.663 [0.336, 1.309]			
p-value	0.2360			
Relative Risk [b]				
RR, 95% CI	0.666 [0.340, 1.305]			
p-value	0.2362			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.014, 0.003]			
p-value	0.2327			

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

Table A2.1.11: Effect Measures of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		217 (16.0%)	212 (15.6%)	429 (15.8%)
Number of subjects without events		1140 (84.0%)	1144 (84.4%)	2284 (84.2%)
Odds Ratio [a]				
OR, 95% CI	1.027 [0.836, 1.262]			
p-value	0.7989			
Relative Risk [b]				
RR, 95% CI	1.023 [0.860, 1.217]			
p-value	0.7989			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.024, 0.031]			
p-value	0.7989			

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

Table A2.1.12: Effect Measures of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		26 (1.9%)	20 (1.5%)	46 (1.7%)
Number of subjects without events		1331 (98.1%)	1336 (98.5%)	2667 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.305 [0.725, 2.349]			
p-value	0.3750			
Relative Risk [b]				
RR, 95% CI	1.299 [0.729, 2.316]			
p-value	0.3750			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.005, 0.014]			
p-value	0.3735			

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

Table A2.1.13: Effect Measures of Proportion of Subjects with TEAEs - Atrial fibrillation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	11 (0.8%)	28 (1.0%)
Number of subjects without events		1340 (98.7%)	1345 (99.2%)	2685 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.551 [0.724, 3.324]			
p-value	0.2589			
Relative Risk [b]				
RR, 95% CI	1.544 [0.726, 3.285]			
p-value	0.2590			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.003, 0.012]			
p-value	0.2550			

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

Table A2.1.14: Effect Measures of Proportion of Subjects with TEAEs - Bradycardia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	13 (1.0%)	37 (1.4%)
Number of subjects without events		1333 (98.2%)	1343 (99.0%)	2676 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.860 [0.943, 3.668]			
p-value	0.0733			
Relative Risk [b]				
RR, 95% CI	1.845 [0.943, 3.608]			
p-value	0.0736			
Risk Difference [c]				
RD, 95% CI	0.008 [-0.001, 0.017]			
p-value	0.0688			

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

Table A2.1.15: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	37 (2.7%)	61 (2.2%)
Number of subjects without events		1333 (98.2%)	1319 (97.3%)	2652 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.642 [0.382, 1.079]			
p-value	0.0942			
Relative Risk [b]				
RR, 95% CI	0.648 [0.390, 1.077]			
p-value	0.0944			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.021, 0.002]			
p-value	0.0916			

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

Table A2.1.16: Effect Measures of Proportion of Subjects with TEAEs - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	14 (1.0%)	25 (0.9%)
Number of subjects without events		1346 (99.2%)	1342 (99.0%)	2688 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.783 [0.354, 1.732]			
p-value	0.5464			
Relative Risk [b]				
RR, 95% CI	0.785 [0.358, 1.723]			
p-value	0.5464			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.005]			
p-value	0.5454			

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

Table A2.1.17: Effect Measures of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	17 (1.3%)	30 (1.1%)
Number of subjects without events		1344 (99.0%)	1339 (98.7%)	2683 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.762 [0.369, 1.575]			
p-value	0.4628			
Relative Risk [b]				
RR, 95% CI	0.764 [0.373, 1.567]			
p-value	0.4629			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.005]			
p-value	0.4615			

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

Table A2.1.18: Effect Measures of Proportion of Subjects with TEAEs - Mitral valve incompetence (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	8 (0.6%)	24 (0.9%)
Number of subjects without events		1341 (98.8%)	1348 (99.4%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	2.010 [0.858, 4.713]			
p-value	0.1082			
Relative Risk [b]				
RR, 95% CI	1.999 [0.858, 4.654]			
p-value	0.1084			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.001, 0.013]			
p-value	0.1011			

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

Table A2.1.19: Effect Measures of Proportion of Subjects with TEAEs - Ventricular extrasystoles (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	13 (1.0%)	24 (0.9%)
Number of subjects without events		1346 (99.2%)	1343 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.844 [0.377, 1.891]			
p-value	0.6808			
Relative Risk [b]				
RR, 95% CI	0.846 [0.380, 1.881]			
p-value	0.6808			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.006]			
p-value	0.6804			

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

Table A2.1.20: Effect Measures of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		63 (4.6%)	72 (5.3%)	135 (5.0%)
Number of subjects without events		1294 (95.4%)	1284 (94.7%)	2578 (95.0%)
Odds Ratio [a]				
OR, 95% CI	0.868 [0.614, 1.228]			
p-value	0.4246			
Relative Risk [b]				
RR, 95% CI	0.874 [0.629, 1.216]			
p-value	0.4247			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.023, 0.010]			
p-value	0.4242			

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

Table A2.1.21: Effect Measures of Proportion of Subjects with TEAEs - Tinnitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		9 (0.7%)	14 (1.0%)	23 (0.8%)
Number of subjects without events		1348 (99.3%)	1342 (99.0%)	2690 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.640 [0.276, 1.484]			
p-value	0.2982			
Relative Risk [b]				
RR, 95% CI	0.642 [0.279, 1.479]			
p-value	0.2983			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.011, 0.003]			
p-value	0.2942			

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

Table A2.1.22: Effect Measures of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		31 (2.3%)	34 (2.5%)	65 (2.4%)
Number of subjects without events		1326 (97.7%)	1322 (97.5%)	2648 (97.6%)
Odds Ratio [a]				
OR, 95% CI	0.909 [0.555, 1.488]			
p-value	0.7043			
Relative Risk [b]				
RR, 95% CI	0.911 [0.563, 1.474]			
p-value	0.7043			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.014, 0.009]			
p-value	0.7042			

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

Table A2.1.23: Effect Measures of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		44 (3.2%)	35 (2.6%)	79 (2.9%)
Number of subjects without events		1313 (96.8%)	1321 (97.4%)	2634 (97.1%)
Odds Ratio [a]				
OR, 95% CI	1.265 [0.806, 1.984]			
p-value	0.3067			
Relative Risk [b]				
RR, 95% CI	1.256 [0.811, 1.946]			
p-value	0.3068			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.006, 0.019]			
p-value	0.3056			

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

Table A2.1.24: Effect Measures of Proportion of Subjects with TEAEs - Hypothyroidism (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	13 (1.0%)	27 (1.0%)
Number of subjects without events		1343 (99.0%)	1343 (99.0%)	2686 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.077 [0.504, 2.300]			
p-value	0.8482			
Relative Risk [b]				
RR, 95% CI	1.076 [0.508, 2.281]			
p-value	0.8482			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.007, 0.008]			
p-value	0.8481			

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

Table A2.1.25: Effect Measures of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		176 (13.0%)	171 (12.6%)	347 (12.8%)
Number of subjects without events		1181 (87.0%)	1185 (87.4%)	2366 (87.2%)
Odds Ratio [a]				
OR, 95% CI	1.033 [0.824, 1.294]			
p-value	0.7794			
Relative Risk [b]				
RR, 95% CI	1.028 [0.845, 1.252]			
p-value	0.7794			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.022, 0.029]			
p-value	0.7794			

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

Table A2.1.26: Effect Measures of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		60 (4.4%)	73 (5.4%)	133 (4.9%)
Number of subjects without events		1297 (95.6%)	1283 (94.6%)	2580 (95.1%)
Odds Ratio [a]				
OR, 95% CI	0.813 [0.573, 1.154]			
p-value	0.2467			
Relative Risk [b]				
RR, 95% CI	0.821 [0.589, 1.146]			
p-value	0.2468			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.026, 0.007]			
p-value	0.2458			

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

Table A2.1.27: Effect Measures of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		29 (2.1%)	22 (1.6%)	51 (1.9%)
Number of subjects without events		1328 (97.9%)	1334 (98.4%)	2662 (98.1%)
Odds Ratio [a]				
OR, 95% CI	1.324 [0.757, 2.317]			
p-value	0.3252			
Relative Risk [b]				
RR, 95% CI	1.317 [0.761, 2.281]			
p-value	0.3253			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.005, 0.015]			
p-value	0.3236			

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

Table A2.1.28: Effect Measures of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		423 (31.2%)	399 (29.4%)	822 (30.3%)
Number of subjects without events		934 (68.8%)	957 (70.6%)	1891 (69.7%)
Odds Ratio [a]				
OR, 95% CI	1.086 [0.922, 1.280]			
p-value	0.3222			
Relative Risk [b]				
RR, 95% CI	1.059 [0.945, 1.188]			
p-value	0.3223			
Risk Difference [c]				
RD, 95% CI	0.017 [-0.017, 0.052]			
p-value	0.3221			

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

Table A2.1.29: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		22 (1.6%)	36 (2.7%)	58 (2.1%)
Number of subjects without events		1335 (98.4%)	1320 (97.3%)	2655 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.604 [0.354, 1.033]			
p-value	0.0654			
Relative Risk [b]				
RR, 95% CI	0.611 [0.361, 1.032]			
p-value	0.0656			
Risk Difference [c]				
RD, 95% CI	-0.010 [-0.021, 0.001]			
p-value	0.0626			

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

Table A2.1.30: Effect Measures of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	22 (1.6%)	40 (1.5%)
Number of subjects without events		1339 (98.7%)	1334 (98.4%)	2673 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.815 [0.435, 1.527]			
p-value	0.5232			
Relative Risk [b]				
RR, 95% CI	0.818 [0.441, 1.517]			
p-value	0.5232			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.006]			
p-value	0.5225			

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

Table A2.1.31: Effect Measures of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		88 (6.5%)	78 (5.8%)	166 (6.1%)
Number of subjects without events		1269 (93.5%)	1278 (94.2%)	2547 (93.9%)
Odds Ratio [a]				
OR, 95% CI	1.136 [0.830, 1.556]			
p-value	0.4262			
Relative Risk [b]				
RR, 95% CI	1.127 [0.839, 1.515]			
p-value	0.4263			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.011, 0.025]			
p-value	0.4259			

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

Table A2.1.32: Effect Measures of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		98 (7.2%)	97 (7.2%)	195 (7.2%)
Number of subjects without events		1259 (92.8%)	1259 (92.8%)	2518 (92.8%)
Odds Ratio [a]				
OR, 95% CI	1.010 [0.755, 1.352]			
p-value	0.9450			
Relative Risk [b]				
RR, 95% CI	1.010 [0.770, 1.323]			
p-value	0.9450			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.019, 0.020]			
p-value	0.9450			

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

Table A2.1.33: Effect Measures of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	17 (1.3%)	35 (1.3%)
Number of subjects without events		1339 (98.7%)	1339 (98.7%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	1.059 [0.543, 2.063]			
p-value	0.8667			
Relative Risk [b]				
RR, 95% CI	1.058 [0.548, 2.044]			
p-value	0.8667			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.008, 0.009]			
p-value	0.8666			

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

Table A2.1.34: Effect Measures of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		29 (2.1%)	20 (1.5%)	49 (1.8%)
Number of subjects without events		1328 (97.9%)	1336 (98.5%)	2664 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.459 [0.821, 2.592]			
p-value	0.1979			
Relative Risk [b]				
RR, 95% CI	1.449 [0.824, 2.549]			
p-value	0.1981			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.003, 0.017]			
p-value	0.1952			

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

Table A2.1.35: Effect Measures of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		42 (3.1%)	29 (2.1%)	71 (2.6%)
Number of subjects without events		1315 (96.9%)	1327 (97.9%)	2642 (97.4%)
Odds Ratio [a]				
OR, 95% CI	1.461 [0.905, 2.360]			
p-value	0.1207			
Relative Risk [b]				
RR, 95% CI	1.447 [0.907, 2.309]			
p-value	0.1210			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.002, 0.022]			
p-value	0.1185			

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

Table A2.1.36: Effect Measures of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		31 (2.3%)	16 (1.2%)	47 (1.7%)
Number of subjects without events		1326 (97.7%)	1340 (98.8%)	2666 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.958 [1.066, 3.597]			
p-value	0.0303			
Relative Risk [b]				
RR, 95% CI	1.936 [1.064, 3.523]			
p-value	0.0305			
Risk Difference [c]				
RD, 95% CI	0.011 [0.001, 0.021]			
p-value	0.0273			

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

Table A2.1.37: Effect Measures of Proportion of Subjects with TEAEs - Hiatus hernia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		10 (0.7%)	14 (1.0%)	24 (0.9%)
Number of subjects without events		1347 (99.3%)	1342 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.712 [0.315, 1.608]			
p-value	0.4133			
Relative Risk [b]				
RR, 95% CI	0.714 [0.318, 1.601]			
p-value	0.4134			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4111			

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

Table A2.1.38: Effect Measures of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		25 (1.8%)	29 (2.1%)	54 (2.0%)
Number of subjects without events		1332 (98.2%)	1327 (97.9%)	2659 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.859 [0.500, 1.474]			
p-value	0.5809			
Relative Risk [b]				
RR, 95% CI	0.861 [0.507, 1.463]			
p-value	0.5809			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.013, 0.008]			
p-value	0.5805			

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

Table A2.1.39: Effect Measures of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		50 (3.7%)	50 (3.7%)	100 (3.7%)
Number of subjects without events		1307 (96.3%)	1306 (96.3%)	2613 (96.3%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.670, 1.490]			
p-value	0.9970			
Relative Risk [b]				
RR, 95% CI	0.999 [0.680, 1.468]			
p-value	0.9970			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.014, 0.014]			
p-value	0.9970			

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

Table A2.1.40: Effect Measures of Proportion of Subjects with TEAEs - Toothache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	11 (0.8%)	24 (0.9%)
Number of subjects without events		1344 (99.0%)	1345 (99.2%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.183 [0.528, 2.649]			
p-value	0.6834			
Relative Risk [b]				
RR, 95% CI	1.181 [0.531, 2.627]			
p-value	0.6834			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.6831			

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

Table A2.1.41: Effect Measures of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		34 (2.5%)	36 (2.7%)	70 (2.6%)
Number of subjects without events		1323 (97.5%)	1320 (97.3%)	2643 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.942 [0.586, 1.515]			
p-value	0.8062			
Relative Risk [b]				
RR, 95% CI	0.944 [0.594, 1.499]			
p-value	0.8062			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.013, 0.010]			
p-value	0.8062			

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

Table A2.1.42: Effect Measures of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		258 (19.0%)	297 (21.9%)	555 (20.5%)
Number of subjects without events		1099 (81.0%)	1059 (78.1%)	2158 (79.5%)
Odds Ratio [a]				
OR, 95% CI	0.837 [0.694, 1.009]			
p-value	0.0622			
Relative Risk [b]				
RR, 95% CI	0.868 [0.748, 1.007]			
p-value	0.0624			
Risk Difference [c]				
RD, 95% CI	-0.029 [-0.059, 0.001]			
p-value	0.0619			

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

Table A2.1.43: Effect Measures of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	28 (2.1%)	46 (1.7%)
Number of subjects without events		1339 (98.7%)	1328 (97.9%)	2667 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.638 [0.351, 1.158]			
p-value	0.1395			
Relative Risk [b]				
RR, 95% CI	0.642 [0.357, 1.156]			
p-value	0.1397			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.017, 0.002]			
p-value	0.1362			

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

Table A2.1.44: Effect Measures of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		41 (3.0%)	52 (3.8%)	93 (3.4%)
Number of subjects without events		1316 (97.0%)	1304 (96.2%)	2620 (96.6%)
Odds Ratio [a]				
OR, 95% CI	0.781 [0.515, 1.185]			
p-value	0.2454			
Relative Risk [b]				
RR, 95% CI	0.788 [0.527, 1.178]			
p-value	0.2455			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.022, 0.006]			
p-value	0.2442			

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

Table A2.1.45: Effect Measures of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		45 (3.3%)	33 (2.4%)	78 (2.9%)
Number of subjects without events		1312 (96.7%)	1323 (97.6%)	2635 (97.1%)
Odds Ratio [a]				
OR, 95% CI	1.375 [0.872, 2.169]			
p-value	0.1707			
Relative Risk [b]				
RR, 95% CI	1.363 [0.875, 2.122]			
p-value	0.1709			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.004, 0.021]			
p-value	0.1688			

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

Table A2.1.46: Effect Measures of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		9 (0.7%)	21 (1.5%)	30 (1.1%)
Number of subjects without events		1348 (99.3%)	1335 (98.5%)	2683 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.424 [0.194, 0.930]			
p-value	0.0323			
Relative Risk [b]				
RR, 95% CI	0.428 [0.197, 0.932]			
p-value	0.0325			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.017, -0.001]			
p-value	0.0273			

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

Table A2.1.47: Effect Measures of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		88 (6.5%)	112 (8.3%)	200 (7.4%)
Number of subjects without events		1269 (93.5%)	1244 (91.7%)	2513 (92.6%)
Odds Ratio [a]				
OR, 95% CI	0.770 [0.576, 1.029]			
p-value	0.0776			
Relative Risk [b]				
RR, 95% CI	0.785 [0.600, 1.027]			
p-value	0.0778			
Risk Difference [c]				
RD, 95% CI	-0.018 [-0.037, 0.002]			
p-value	0.0768			

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

Table A2.1.48: Effect Measures of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		19 (1.4%)	23 (1.7%)	42 (1.5%)
Number of subjects without events		1338 (98.6%)	1333 (98.3%)	2671 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.823 [0.446, 1.518]			
p-value	0.5329			
Relative Risk [b]				
RR, 95% CI	0.825 [0.452, 1.509]			
p-value	0.5330			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.006]			
p-value	0.5323			

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

Table A2.1.49: Effect Measures of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	17 (1.3%)	34 (1.3%)
Number of subjects without events		1340 (98.7%)	1339 (98.7%)	2679 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.508, 1.966]			
p-value	0.9983			
Relative Risk [b]				
RR, 95% CI	0.999 [0.512, 1.949]			
p-value	0.9983			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9983			

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

Table A2.1.50: Effect Measures of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		77 (5.7%)	69 (5.1%)	146 (5.4%)
Number of subjects without events		1280 (94.3%)	1287 (94.9%)	2567 (94.6%)
Odds Ratio [a]				
OR, 95% CI	1.122 [0.803, 1.567]			
p-value	0.4992			
Relative Risk [b]				
RR, 95% CI	1.115 [0.813, 1.530]			
p-value	0.4992			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.011, 0.023]			
p-value	0.4989			

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

Table A2.1.51: Effect Measures of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	18 (1.3%)	35 (1.3%)
Number of subjects without events		1340 (98.7%)	1338 (98.7%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.943 [0.484, 1.838]			
p-value	0.8632			
Relative Risk [b]				
RR, 95% CI	0.944 [0.488, 1.823]			
p-value	0.8632			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.008]			
p-value	0.8632			

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

Table A2.1.52: Effect Measures of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	18 (1.3%)	34 (1.3%)
Number of subjects without events		1341 (98.8%)	1338 (98.7%)	2679 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.887 [0.450, 1.747]			
p-value	0.7285			
Relative Risk [b]				
RR, 95% CI	0.888 [0.455, 1.734]			
p-value	0.7285			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.007]			
p-value	0.7283			

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

Table A2.1.53: Effect Measures of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	17 (1.3%)	41 (1.5%)
Number of subjects without events		1333 (98.2%)	1339 (98.7%)	2672 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.418 [0.758, 2.652]			
p-value	0.2740			
Relative Risk [b]				
RR, 95% CI	1.411 [0.761, 2.614]			
p-value	0.2742			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.004, 0.014]			
p-value	0.2715			

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

Table A2.1.54: Effect Measures of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		664 (48.9%)	651 (48.0%)	1315 (48.5%)
Number of subjects without events		693 (51.1%)	705 (52.0%)	1398 (51.5%)
Odds Ratio [a]				
OR, 95% CI	1.038 [0.893, 1.206]			
p-value	0.6307			
Relative Risk [b]				
RR, 95% CI	1.019 [0.943, 1.101]			
p-value	0.6307			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.028, 0.047]			
p-value	0.6307			

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

Table A2.1.55: Effect Measures of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		77 (5.7%)	62 (4.6%)	139 (5.1%)
Number of subjects without events		1280 (94.3%)	1294 (95.4%)	2574 (94.9%)
Odds Ratio [a]				
OR, 95% CI	1.256 [0.891, 1.770]			
p-value	0.1938			
Relative Risk [b]				
RR, 95% CI	1.241 [0.896, 1.719]			
p-value	0.1940			
Risk Difference [c]				
RD, 95% CI	0.011 [-0.006, 0.028]			
p-value	0.1929			

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

Table A2.1.56: Effect Measures of Proportion of Subjects with TEAEs - COVID-19 (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		19 (1.4%)	22 (1.6%)	41 (1.5%)
Number of subjects without events		1338 (98.6%)	1334 (98.4%)	2672 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.861 [0.464, 1.598]			
p-value	0.6355			
Relative Risk [b]				
RR, 95% CI	0.863 [0.469, 1.587]			
p-value	0.6355			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.007]			
p-value	0.6352			

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

Table A2.1.57: Effect Measures of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		41 (3.0%)	33 (2.4%)	74 (2.7%)
Number of subjects without events		1316 (97.0%)	1323 (97.6%)	2639 (97.3%)
Odds Ratio [a]				
OR, 95% CI	1.249 [0.785, 1.988]			
p-value	0.3483			
Relative Risk [b]				
RR, 95% CI	1.242 [0.790, 1.951]			
p-value	0.3484			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.006, 0.018]			
p-value	0.3473			

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

Table A2.1.58: Effect Measures of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		30 (2.2%)	16 (1.2%)	46 (1.7%)
Number of subjects without events		1327 (97.8%)	1340 (98.8%)	2667 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.893 [1.027, 3.490]			
p-value	0.0407			
Relative Risk [b]				
RR, 95% CI	1.874 [1.026, 3.421]			
p-value	0.0410			
Risk Difference [c]				
RD, 95% CI	0.010 [0.001, 0.020]			
p-value	0.0374			

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

Table A2.1.59: Effect Measures of Proportion of Subjects with TEAEs - Cystitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	24 (1.8%)	44 (1.6%)
Number of subjects without events		1337 (98.5%)	1332 (98.2%)	2669 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.830 [0.456, 1.510]			
p-value	0.5421			
Relative Risk [b]				
RR, 95% CI	0.833 [0.462, 1.500]			
p-value	0.5422			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.007]			
p-value	0.5416			

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

Table A2.1.60: Effect Measures of Proportion of Subjects with TEAEs - Erysipelas (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		10 (0.7%)	14 (1.0%)	24 (0.9%)
Number of subjects without events		1347 (99.3%)	1342 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.712 [0.315, 1.608]			
p-value	0.4133			
Relative Risk [b]				
RR, 95% CI	0.714 [0.318, 1.601]			
p-value	0.4134			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4111			

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

Table A2.1.61: Effect Measures of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		29 (2.1%)	26 (1.9%)	55 (2.0%)
Number of subjects without events		1328 (97.9%)	1330 (98.1%)	2658 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.117 [0.654, 1.907]			
p-value	0.6849			
Relative Risk [b]				
RR, 95% CI	1.115 [0.660, 1.882]			
p-value	0.6850			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.008, 0.013]			
p-value	0.6848			

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

Table A2.1.62: Effect Measures of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		26 (1.9%)	26 (1.9%)	52 (1.9%)
Number of subjects without events		1331 (98.1%)	1330 (98.1%)	2661 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.577, 1.730]			
p-value	0.9979			
Relative Risk [b]				
RR, 95% CI	0.999 [0.583, 1.712]			
p-value	0.9979			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.010, 0.010]			
p-value	0.9979			

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

Table A2.1.63: Effect Measures of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		53 (3.9%)	58 (4.3%)	111 (4.1%)
Number of subjects without events		1304 (96.1%)	1298 (95.7%)	2602 (95.9%)
Odds Ratio [a]				
OR, 95% CI	0.910 [0.622, 1.330]			
p-value	0.6253			
Relative Risk [b]				
RR, 95% CI	0.913 [0.634, 1.315]			
p-value	0.6253			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.019, 0.011]			
p-value	0.6251			

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

Table A2.1.64: Effect Measures of Proportion of Subjects with TEAEs - Localised infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	10 (0.7%)	23 (0.8%)
Number of subjects without events		1344 (99.0%)	1346 (99.3%)	2690 (99.2%)
Odds Ratio [a]				
OR, 95% CI	1.302 [0.569, 2.979]			
p-value	0.5322			
Relative Risk [b]				
RR, 95% CI	1.299 [0.572, 2.952]			
p-value	0.5322			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.005, 0.009]			
p-value	0.5310			

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

Table A2.1.65: Effect Measures of Proportion of Subjects with TEAEs - Lower respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	14 (1.0%)	31 (1.1%)
Number of subjects without events		1340 (98.7%)	1342 (99.0%)	2682 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.216 [0.597, 2.477]			
p-value	0.5899			
Relative Risk [b]				
RR, 95% CI	1.213 [0.601, 2.452]			
p-value	0.5899			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.006, 0.010]			
p-value	0.5893			

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

Table A2.1.66: Effect Measures of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		139 (10.2%)	126 (9.3%)	265 (9.8%)
Number of subjects without events		1218 (89.8%)	1230 (90.7%)	2448 (90.2%)
Odds Ratio [a]				
OR, 95% CI	1.114 [0.864, 1.436]			
p-value	0.4042			
Relative Risk [b]				
RR, 95% CI	1.102 [0.877, 1.386]			
p-value	0.4043			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.013, 0.032]			
p-value	0.4040			

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

Table A2.1.67: Effect Measures of Proportion of Subjects with TEAEs - Onychomycosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	13 (1.0%)	28 (1.0%)
Number of subjects without events		1342 (98.9%)	1343 (99.0%)	2685 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.155 [0.547, 2.436]			
p-value	0.7057			
Relative Risk [b]				
RR, 95% CI	1.153 [0.551, 2.414]			
p-value	0.7057			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.7054			

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

Table A2.1.68: Effect Measures of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		21 (1.5%)	22 (1.6%)	43 (1.6%)
Number of subjects without events		1336 (98.5%)	1334 (98.4%)	2670 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.953 [0.522, 1.741]			
p-value	0.8759			
Relative Risk [b]				
RR, 95% CI	0.954 [0.527, 1.726]			
p-value	0.8759			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.009]			
p-value	0.8759			

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

Table A2.1.69: Effect Measures of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		58 (4.3%)	77 (5.7%)	135 (5.0%)
Number of subjects without events		1299 (95.7%)	1279 (94.3%)	2578 (95.0%)
Odds Ratio [a]				
OR, 95% CI	0.742 [0.523, 1.052]			
p-value	0.0936			
Relative Risk [b]				
RR, 95% CI	0.753 [0.540, 1.049]			
p-value	0.0939			
Risk Difference [c]				
RD, 95% CI	-0.014 [-0.030, 0.002]			
p-value	0.0924			

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

Table A2.1.70: Effect Measures of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		27 (2.0%)	26 (1.9%)	53 (2.0%)
Number of subjects without events		1330 (98.0%)	1330 (98.1%)	2660 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.038 [0.603, 1.789]			
p-value	0.8918			
Relative Risk [b]				
RR, 95% CI	1.038 [0.609, 1.769]			
p-value	0.8918			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.010, 0.011]			
p-value	0.8918			

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

Table A2.1.71: Effect Measures of Proportion of Subjects with TEAEs - Rhinitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	9 (0.7%)	22 (0.8%)
Number of subjects without events		1344 (99.0%)	1347 (99.3%)	2691 (99.2%)
Odds Ratio [a]				
OR, 95% CI	1.448 [0.617, 3.398]			
p-value	0.3954			
Relative Risk [b]				
RR, 95% CI	1.443 [0.619, 3.365]			
p-value	0.3955			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.004, 0.010]			
p-value	0.3927			

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

Table A2.1.72: Effect Measures of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	19 (1.4%)	36 (1.3%)
Number of subjects without events		1340 (98.7%)	1337 (98.6%)	2677 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.893 [0.462, 1.725]			
p-value	0.7356			
Relative Risk [b]				
RR, 95% CI	0.894 [0.467, 1.713]			
p-value	0.7357			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.007]			
p-value	0.7355			

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

Table A2.1.73: Effect Measures of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		93 (6.9%)	73 (5.4%)	166 (6.1%)
Number of subjects without events		1264 (93.1%)	1283 (94.6%)	2547 (93.9%)
Odds Ratio [a]				
OR, 95% CI	1.293 [0.943, 1.774]			
p-value	0.1110			
Relative Risk [b]				
RR, 95% CI	1.273 [0.946, 1.713]			
p-value	0.1113			
Risk Difference [c]				
RD, 95% CI	0.015 [-0.003, 0.033]			
p-value	0.1100			

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

Table A2.1.74: Effect Measures of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		109 (8.0%)	109 (8.0%)	218 (8.0%)
Number of subjects without events		1248 (92.0%)	1247 (92.0%)	2495 (92.0%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.758, 1.318]			
p-value	0.9955			
Relative Risk [b]				
RR, 95% CI	0.999 [0.775, 1.289]			
p-value	0.9955			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.021, 0.020]			
p-value	0.9955			

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

Table A2.1.75: Effect Measures of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		258 (19.0%)	264 (19.5%)	522 (19.2%)
Number of subjects without events		1099 (81.0%)	1092 (80.5%)	2191 (80.8%)
Odds Ratio [a]				
OR, 95% CI	0.971 [0.802, 1.175]			
p-value	0.7630			
Relative Risk [b]				
RR, 95% CI	0.977 [0.837, 1.139]			
p-value	0.7630			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.034, 0.025]			
p-value	0.7630			

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

Table A2.1.76: Effect Measures of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		40 (2.9%)	36 (2.7%)	76 (2.8%)
Number of subjects without events		1317 (97.1%)	1320 (97.3%)	2637 (97.2%)
Odds Ratio [a]				
OR, 95% CI	1.114 [0.705, 1.758]			
p-value	0.6441			
Relative Risk [b]				
RR, 95% CI	1.110 [0.712, 1.731]			
p-value	0.6441			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.009, 0.015]			
p-value	0.6440			

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

Table A2.1.77: Effect Measures of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		48 (3.5%)	42 (3.1%)	90 (3.3%)
Number of subjects without events		1309 (96.5%)	1314 (96.9%)	2623 (96.7%)
Odds Ratio [a]				
OR, 95% CI	1.147 [0.753, 1.748]			
p-value	0.5227			
Relative Risk [b]				
RR, 95% CI	1.142 [0.760, 1.716]			
p-value	0.5227			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.009, 0.018]			
p-value	0.5224			

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

Table A2.1.78: Effect Measures of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	19 (1.4%)	39 (1.4%)
Number of subjects without events		1337 (98.5%)	1337 (98.6%)	2674 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.053 [0.559, 1.981]			
p-value	0.8737			
Relative Risk [b]				
RR, 95% CI	1.052 [0.564, 1.962]			
p-value	0.8737			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.008, 0.010]			
p-value	0.8737			

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

Table A2.1.79: Effect Measures of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		41 (3.0%)	28 (2.1%)	69 (2.5%)
Number of subjects without events		1316 (97.0%)	1328 (97.9%)	2644 (97.5%)
Odds Ratio [a]				
OR, 95% CI	1.478 [0.908, 2.404]			
p-value	0.1157			
Relative Risk [b]				
RR, 95% CI	1.463 [0.910, 2.352]			
p-value	0.1160			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.002, 0.021]			
p-value	0.1134			

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

Table A2.1.80: Effect Measures of Proportion of Subjects with TEAEs - Rib fracture (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		10 (0.7%)	13 (1.0%)	23 (0.8%)
Number of subjects without events		1347 (99.3%)	1343 (99.0%)	2690 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.767 [0.335, 1.755]			
p-value	0.5299			
Relative Risk [b]				
RR, 95% CI	0.769 [0.338, 1.747]			
p-value	0.5299			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.009, 0.005]			
p-value	0.5287			

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

Table A2.1.81: Effect Measures of Proportion of Subjects with TEAEs - Skin abrasion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	13 (1.0%)	28 (1.0%)
Number of subjects without events		1342 (98.9%)	1343 (99.0%)	2685 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.155 [0.547, 2.436]			
p-value	0.7057			
Relative Risk [b]				
RR, 95% CI	1.153 [0.551, 2.414]			
p-value	0.7057			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.7054			

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

Table A2.1.82: Effect Measures of Proportion of Subjects with TEAEs - Skin laceration (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	9 (0.7%)	25 (0.9%)
Number of subjects without events		1341 (98.8%)	1347 (99.3%)	2688 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.786 [0.786, 4.055]			
p-value	0.1659			
Relative Risk [b]				
RR, 95% CI	1.776 [0.788, 4.006]			
p-value	0.1661			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.002, 0.012]			
p-value	0.1599			

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

Table A2.1.83: Effect Measures of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		341 (25.1%)	311 (22.9%)	652 (24.0%)
Number of subjects without events		1016 (74.9%)	1045 (77.1%)	2061 (76.0%)
Odds Ratio [a]				
OR, 95% CI	1.128 [0.945, 1.345]			
p-value	0.1813			
Relative Risk [b]				
RR, 95% CI	1.096 [0.958, 1.253]			
p-value	0.1815			
Risk Difference [c]				
RD, 95% CI	0.022 [-0.010, 0.054]			
p-value	0.1810			

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

Table A2.1.84: Effect Measures of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		36 (2.7%)	28 (2.1%)	64 (2.4%)
Number of subjects without events		1321 (97.3%)	1328 (97.9%)	2649 (97.6%)
Odds Ratio [a]				
OR, 95% CI	1.293 [0.784, 2.130]			
p-value	0.3142			
Relative Risk [b]				
RR, 95% CI	1.285 [0.789, 2.093]			
p-value	0.3143			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.006, 0.017]			
p-value	0.3129			

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

Table A2.1.85: Effect Measures of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		38 (2.8%)	33 (2.4%)	71 (2.6%)
Number of subjects without events		1319 (97.2%)	1323 (97.6%)	2642 (97.4%)
Odds Ratio [a]				
OR, 95% CI	1.155 [0.720, 1.853]			
p-value	0.5500			
Relative Risk [b]				
RR, 95% CI	1.151 [0.726, 1.823]			
p-value	0.5501			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.008, 0.016]			
p-value	0.5497			

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

Table A2.1.86: Effect Measures of Proportion of Subjects with TEAEs - Blood glucose increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	12 (0.9%)	26 (1.0%)
Number of subjects without events		1343 (99.0%)	1344 (99.1%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.168 [0.538, 2.534]			
p-value	0.6952			
Relative Risk [b]				
RR, 95% CI	1.166 [0.541, 2.511]			
p-value	0.6952			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.6949			

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

Table A2.1.87: Effect Measures of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		43 (3.2%)	21 (1.5%)	64 (2.4%)
Number of subjects without events		1314 (96.8%)	1335 (98.5%)	2649 (97.6%)
Odds Ratio [a]				
OR, 95% CI	2.080 [1.228, 3.525]			
p-value	0.0065			
Relative Risk [b]				
RR, 95% CI	2.046 [1.221, 3.429]			
p-value	0.0066			
Risk Difference [c]				
RD, 95% CI	0.016 [0.005, 0.028]			
p-value	0.0054			

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

Table A2.1.88: Effect Measures of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		21 (1.5%)	26 (1.9%)	47 (1.7%)
Number of subjects without events		1336 (98.5%)	1330 (98.1%)	2666 (98.3%)
Odds Ratio [a]				
OR, 95% CI	0.804 [0.450, 1.436]			
p-value	0.4612			
Relative Risk [b]				
RR, 95% CI	0.807 [0.456, 1.427]			
p-value	0.4612			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.014, 0.006]			
p-value	0.4603			

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

Table A2.1.89: Effect Measures of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		35 (2.6%)	38 (2.8%)	73 (2.7%)
Number of subjects without events		1322 (97.4%)	1318 (97.2%)	2640 (97.3%)
Odds Ratio [a]				
OR, 95% CI	0.918 [0.577, 1.463]			
p-value	0.7196			
Relative Risk [b]				
RR, 95% CI	0.920 [0.585, 1.448]			
p-value	0.7196			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.014, 0.010]			
p-value	0.7195			

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

Table A2.1.90: Effect Measures of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	15 (1.1%)	29 (1.1%)
Number of subjects without events		1343 (99.0%)	1341 (98.9%)	2684 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.932 [0.448, 1.938]			
p-value	0.8504			
Relative Risk [b]				
RR, 95% CI	0.933 [0.452, 1.925]			
p-value	0.8504			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.008, 0.007]			
p-value	0.8503			

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

Table A2.1.91: Effect Measures of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		66 (4.9%)	49 (3.6%)	115 (4.2%)
Number of subjects without events		1291 (95.1%)	1307 (96.4%)	2598 (95.8%)
Odds Ratio [a]				
OR, 95% CI	1.364 [0.935, 1.989]			
p-value	0.1073			
Relative Risk [b]				
RR, 95% CI	1.346 [0.937, 1.933]			
p-value	0.1076			
Risk Difference [c]				
RD, 95% CI	0.013 [-0.003, 0.028]			
p-value	0.1059			

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

Table A2.1.92: Effect Measures of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	14 (1.0%)	32 (1.2%)
Number of subjects without events		1339 (98.7%)	1342 (99.0%)	2681 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.289 [0.638, 2.601]			
p-value	0.4793			
Relative Risk [b]				
RR, 95% CI	1.285 [0.642, 2.573]			
p-value	0.4794			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.005, 0.011]			
p-value	0.4781			

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

Table A2.1.93: Effect Measures of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	17 (1.3%)	31 (1.1%)
Number of subjects without events		1343 (99.0%)	1339 (98.7%)	2682 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.821 [0.403, 1.672]			
p-value	0.5870			
Relative Risk [b]				
RR, 95% CI	0.823 [0.407, 1.663]			
p-value	0.5871			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.010, 0.006]			
p-value	0.5864			

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

Table A2.1.94: Effect Measures of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		532 (39.2%)	437 (32.2%)	969 (35.7%)
Number of subjects without events		825 (60.8%)	919 (67.8%)	1744 (64.3%)
Odds Ratio [a]				
OR, 95% CI	1.356 [1.158, 1.588]			
p-value	0.0002			
Relative Risk [b]				
RR, 95% CI	1.216 [1.099, 1.347]			
p-value	0.0002			
Risk Difference [c]				
RD, 95% CI	0.070 [0.034, 0.106]			
p-value	0.0001			

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

Table A2.1.95: Effect Measures of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	11 (0.8%)	31 (1.1%)
Number of subjects without events		1337 (98.5%)	1345 (99.2%)	2682 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.829 [0.873, 3.832]			
p-value	0.1096			
Relative Risk [b]				
RR, 95% CI	1.817 [0.874, 3.777]			
p-value	0.1098			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.001, 0.015]			
p-value	0.1042			

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

Table A2.1.96: Effect Measures of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	20 (1.5%)	40 (1.5%)
Number of subjects without events		1337 (98.5%)	1336 (98.5%)	2673 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.535, 1.866]			
p-value	0.9981			
Relative Risk [b]				
RR, 95% CI	0.999 [0.540, 1.849]			
p-value	0.9981			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.009, 0.009]			
p-value	0.9981			

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

Table A2.1.97: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		38 (2.8%)	38 (2.8%)	76 (2.8%)
Number of subjects without events		1319 (97.2%)	1318 (97.2%)	2637 (97.2%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.633, 1.577]			
p-value	0.9974			
Relative Risk [b]				
RR, 95% CI	0.999 [0.641, 1.557]			
p-value	0.9974			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.012, 0.012]			
p-value	0.9974			

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

Table A2.1.98: Effect Measures of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		36 (2.7%)	31 (2.3%)	67 (2.5%)
Number of subjects without events		1321 (97.3%)	1325 (97.7%)	2646 (97.5%)
Odds Ratio [a]				
OR, 95% CI	1.165 [0.716, 1.894]			
p-value	0.5386			
Relative Risk [b]				
RR, 95% CI	1.160 [0.722, 1.865]			
p-value	0.5386			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.008, 0.015]			
p-value	0.5382			

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

Table A2.1.99: Effect Measures of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		63 (4.6%)	57 (4.2%)	120 (4.4%)
Number of subjects without events		1294 (95.4%)	1299 (95.8%)	2593 (95.6%)
Odds Ratio [a]				
OR, 95% CI	1.110 [0.769, 1.601]			
p-value	0.5783			
Relative Risk [b]				
RR, 95% CI	1.104 [0.778, 1.568]			
p-value	0.5783			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.011, 0.020]			
p-value	0.5781			

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

Table A2.1.100: Effect Measures of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		46 (3.4%)	32 (2.4%)	78 (2.9%)
Number of subjects without events		1311 (96.6%)	1324 (97.6%)	2635 (97.1%)
Odds Ratio [a]				
OR, 95% CI	1.452 [0.919, 2.294]			
p-value	0.1103			
Relative Risk [b]				
RR, 95% CI	1.436 [0.921, 2.241]			
p-value	0.1106			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.002, 0.023]			
p-value	0.1083			

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

Table A2.1.101: Effect Measures of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		186 (13.7%)	84 (6.2%)	270 (10.0%)
Number of subjects without events		1171 (86.3%)	1272 (93.8%)	2443 (90.0%)
Odds Ratio [a]				
OR, 95% CI	2.405 [1.837, 3.150]			
p-value	0.0000			
Relative Risk [b]				
RR, 95% CI	2.213 [1.729, 2.831]			
p-value	0.0000			
Risk Difference [c]				
RD, 95% CI	0.075 [0.053, 0.097]			
p-value	0.0000			

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

Table A2.1.102: Effect Measures of Proportion of Subjects with TEAEs - Hypertriglyceridaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	15 (1.1%)	26 (1.0%)
Number of subjects without events		1346 (99.2%)	1341 (98.9%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.731 [0.334, 1.596]			
p-value	0.4313			
Relative Risk [b]				
RR, 95% CI	0.733 [0.338, 1.590]			
p-value	0.4314			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4294			

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

Table A2.1.103: Effect Measures of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		63 (4.6%)	35 (2.6%)	98 (3.6%)
Number of subjects without events		1294 (95.4%)	1321 (97.4%)	2615 (96.4%)
Odds Ratio [a]				
OR, 95% CI	1.838 [1.207, 2.797]			
p-value	0.0045			
Relative Risk [b]				
RR, 95% CI	1.799 [1.198, 2.700]			
p-value	0.0046			
Risk Difference [c]				
RD, 95% CI	0.021 [0.007, 0.035]			
p-value	0.0040			

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

Table A2.1.104: Effect Measures of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		89 (6.6%)	90 (6.6%)	179 (6.6%)
Number of subjects without events		1268 (93.4%)	1266 (93.4%)	2534 (93.4%)
Odds Ratio [a]				
OR, 95% CI	0.987 [0.729, 1.337]			
p-value	0.9343			
Relative Risk [b]				
RR, 95% CI	0.988 [0.744, 1.312]			
p-value	0.9343			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.019, 0.018]			
p-value	0.9343			

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

Table A2.1.105: Effect Measures of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	37 (2.7%)	54 (2.0%)
Number of subjects without events		1340 (98.7%)	1319 (97.3%)	2659 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.452 [0.253, 0.807]			
p-value	0.0073			
Relative Risk [b]				
RR, 95% CI	0.459 [0.260, 0.811]			
p-value	0.0074			
Risk Difference [c]				
RD, 95% CI	-0.015 [-0.025, -0.004]			
p-value	0.0059			

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

Table A2.1.106: Effect Measures of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		12 (0.9%)	17 (1.3%)	29 (1.1%)
Number of subjects without events		1345 (99.1%)	1339 (98.7%)	2684 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.703 [0.334, 1.477]			
p-value	0.3520			
Relative Risk [b]				
RR, 95% CI	0.705 [0.338, 1.471]			
p-value	0.3521			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.011, 0.004]			
p-value	0.3495			

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

Table A2.1.107: Effect Measures of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		21 (1.5%)	18 (1.3%)	39 (1.4%)
Number of subjects without events		1336 (98.5%)	1338 (98.7%)	2674 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.168 [0.620, 2.203]			
p-value	0.6305			
Relative Risk [b]				
RR, 95% CI	1.166 [0.624, 2.178]			
p-value	0.6305			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.007, 0.011]			
p-value	0.6301			

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

Table A2.1.108: Effect Measures of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	17 (1.3%)	37 (1.4%)
Number of subjects without events		1337 (98.5%)	1339 (98.7%)	2676 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.178 [0.614, 2.259]			
p-value	0.6214			
Relative Risk [b]				
RR, 95% CI	1.176 [0.619, 2.234]			
p-value	0.6215			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.007, 0.011]			
p-value	0.6210			

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

Table A2.1.109: Effect Measures of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		450 (33.2%)	461 (34.0%)	911 (33.6%)
Number of subjects without events		907 (66.8%)	895 (66.0%)	1802 (66.4%)
Odds Ratio [a]				
OR, 95% CI	0.963 [0.821, 1.130]			
p-value	0.6449			
Relative Risk [b]				
RR, 95% CI	0.975 [0.877, 1.084]			
p-value	0.6449			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.044, 0.027]			
p-value	0.6449			

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

Table A2.1.110: Effect Measures of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		124 (9.1%)	108 (8.0%)	232 (8.6%)
Number of subjects without events		1233 (90.9%)	1248 (92.0%)	2481 (91.4%)
Odds Ratio [a]				
OR, 95% CI	1.162 [0.887, 1.522]			
p-value	0.2749			
Relative Risk [b]				
RR, 95% CI	1.147 [0.896, 1.468]			
p-value	0.2751			
Risk Difference [c]				
RD, 95% CI	0.012 [-0.009, 0.033]			
p-value	0.2745			

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

Table A2.1.111: Effect Measures of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	15 (1.1%)	30 (1.1%)
Number of subjects without events		1342 (98.9%)	1341 (98.9%)	2683 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.487, 2.052]			
p-value	0.9984			
Relative Risk [b]				
RR, 95% CI	0.999 [0.490, 2.036]			
p-value	0.9984			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9984			

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

Table A2.1.112: Effect Measures of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		114 (8.4%)	118 (8.7%)	232 (8.6%)
Number of subjects without events		1243 (91.6%)	1238 (91.3%)	2481 (91.4%)
Odds Ratio [a]				
OR, 95% CI	0.962 [0.735, 1.259]			
p-value	0.7791			
Relative Risk [b]				
RR, 95% CI	0.965 [0.755, 1.235]			
p-value	0.7791			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.024, 0.018]			
p-value	0.7791			

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

Table A2.1.113: Effect Measures of Proportion of Subjects with TEAEs - Gouty arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		7 (0.5%)	15 (1.1%)	22 (0.8%)
Number of subjects without events		1350 (99.5%)	1341 (98.9%)	2691 (99.2%)
Odds Ratio [a]				
OR, 95% CI	0.464 [0.188, 1.141]			
p-value	0.0942			
Relative Risk [b]				
RR, 95% CI	0.466 [0.191, 1.140]			
p-value	0.0944			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.013, 0.001]			
p-value	0.0863			

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

Table A2.1.114: Effect Measures of Proportion of Subjects with TEAEs - Joint swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		4 (0.3%)	13 (1.0%)	17 (0.6%)
Number of subjects without events		1353 (99.7%)	1343 (99.0%)	2696 (99.4%)
Odds Ratio [a]				
OR, 95% CI	0.305 [0.099, 0.939]			
p-value	0.0385			
Relative Risk [b]				
RR, 95% CI	0.307 [0.101, 0.941]			
p-value	0.0387			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.013, -0.001]			
p-value	0.0283			

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

Table A2.1.115: Effect Measures of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		60 (4.4%)	41 (3.0%)	101 (3.7%)
Number of subjects without events		1297 (95.6%)	1315 (97.0%)	2612 (96.3%)
Odds Ratio [a]				
OR, 95% CI	1.484 [0.990, 2.223]			
p-value	0.0559			
Relative Risk [b]				
RR, 95% CI	1.462 [0.990, 2.160]			
p-value	0.0561			
Risk Difference [c]				
RD, 95% CI	0.014 [0.000, 0.028]			
p-value	0.0543			

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

Table A2.1.116: Effect Measures of Proportion of Subjects with TEAEs - Muscular weakness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	13 (1.0%)	24 (0.9%)
Number of subjects without events		1346 (99.2%)	1343 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.844 [0.377, 1.891]			
p-value	0.6808			
Relative Risk [b]				
RR, 95% CI	0.846 [0.380, 1.881]			
p-value	0.6808			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.006]			
p-value	0.6804			

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

Table A2.1.117: Effect Measures of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		31 (2.3%)	22 (1.6%)	53 (2.0%)
Number of subjects without events		1326 (97.7%)	1334 (98.4%)	2660 (98.0%)
Odds Ratio [a]				
OR, 95% CI	1.418 [0.817, 2.461]			
p-value	0.2150			
Relative Risk [b]				
RR, 95% CI	1.408 [0.820, 2.419]			
p-value	0.2152			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.004, 0.017]			
p-value	0.2127			

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

Table A2.1.118: Effect Measures of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		19 (1.4%)	19 (1.4%)	38 (1.4%)
Number of subjects without events		1338 (98.6%)	1337 (98.6%)	2675 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.527, 1.896]			
p-value	0.9982			
Relative Risk [b]				
RR, 95% CI	0.999 [0.531, 1.879]			
p-value	0.9982			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.009, 0.009]			
p-value	0.9982			

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

Table A2.1.119: Effect Measures of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		54 (4.0%)	60 (4.4%)	114 (4.2%)
Number of subjects without events		1303 (96.0%)	1296 (95.6%)	2599 (95.8%)
Odds Ratio [a]				
OR, 95% CI	0.895 [0.615, 1.303]			
p-value	0.5633			
Relative Risk [b]				
RR, 95% CI	0.899 [0.628, 1.289]			
p-value	0.5634			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.020, 0.011]			
p-value	0.5631			

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

Table A2.1.120: Effect Measures of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		62 (4.6%)	66 (4.9%)	128 (4.7%)
Number of subjects without events		1295 (95.4%)	1290 (95.1%)	2585 (95.3%)
Odds Ratio [a]				
OR, 95% CI	0.936 [0.656, 1.335]			
p-value	0.7141			
Relative Risk [b]				
RR, 95% CI	0.939 [0.669, 1.317]			
p-value	0.7141			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.019, 0.013]			
p-value	0.7140			

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

Table A2.1.121: Effect Measures of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	21 (1.5%)	39 (1.4%)
Number of subjects without events		1339 (98.7%)	1335 (98.5%)	2674 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.855 [0.453, 1.611]			
p-value	0.6272			
Relative Risk [b]				
RR, 95% CI	0.857 [0.458, 1.600]			
p-value	0.6272			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.007]			
p-value	0.6268			

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

Table A2.1.122: Effect Measures of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		138 (10.2%)	141 (10.4%)	279 (10.3%)
Number of subjects without events		1219 (89.8%)	1215 (89.6%)	2434 (89.7%)
Odds Ratio [a]				
OR, 95% CI	0.976 [0.761, 1.250]			
p-value	0.8445			
Relative Risk [b]				
RR, 95% CI	0.978 [0.783, 1.221]			
p-value	0.8445			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.025, 0.021]			
p-value	0.8445			

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

Table A2.1.123: Effect Measures of Proportion of Subjects with TEAEs - Basal cell carcinoma (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	18 (1.3%)	35 (1.3%)
Number of subjects without events		1340 (98.7%)	1338 (98.7%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.943 [0.484, 1.838]			
p-value	0.8632			
Relative Risk [b]				
RR, 95% CI	0.944 [0.488, 1.823]			
p-value	0.8632			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.008]			
p-value	0.8632			

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

Table A2.1.124: Effect Measures of Proportion of Subjects with TEAEs - Prostate cancer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		8 (0.6%)	16 (1.2%)	24 (0.9%)
Number of subjects without events		1349 (99.4%)	1340 (98.8%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.497 [0.212, 1.164]			
p-value	0.1074			
Relative Risk [b]				
RR, 95% CI	0.500 [0.215, 1.164]			
p-value	0.1077			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.013, 0.001]			
p-value	0.1004			

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

Table A2.1.125: Effect Measures of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		325 (23.9%)	331 (24.4%)	656 (24.2%)
Number of subjects without events		1032 (76.1%)	1025 (75.6%)	2057 (75.8%)
Odds Ratio [a]				
OR, 95% CI	0.975 [0.818, 1.163]			
p-value	0.7796			
Relative Risk [b]				
RR, 95% CI	0.981 [0.859, 1.121]			
p-value	0.7796			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.037, 0.028]			
p-value	0.7796			

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

Table A2.1.126: Effect Measures of Proportion of Subjects with TEAEs - Carotid artery stenosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	10 (0.7%)	25 (0.9%)
Number of subjects without events		1342 (98.9%)	1346 (99.3%)	2688 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.504 [0.673, 3.361]			
p-value	0.3192			
Relative Risk [b]				
RR, 95% CI	1.499 [0.676, 3.325]			
p-value	0.3194			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.004, 0.011]			
p-value	0.3158			

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

Table A2.1.127: Effect Measures of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		31 (2.3%)	28 (2.1%)	59 (2.2%)
Number of subjects without events		1326 (97.7%)	1328 (97.9%)	2654 (97.8%)
Odds Ratio [a]				
OR, 95% CI	1.109 [0.661, 1.859]			
p-value	0.6952			
Relative Risk [b]				
RR, 95% CI	1.106 [0.667, 1.834]			
p-value	0.6952			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.009, 0.013]			
p-value	0.6950			

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

Table A2.1.128: Effect Measures of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		95 (7.0%)	90 (6.6%)	185 (6.8%)
Number of subjects without events		1262 (93.0%)	1266 (93.4%)	2528 (93.2%)
Odds Ratio [a]				
OR, 95% CI	1.059 [0.786, 1.427]			
p-value	0.7072			
Relative Risk [b]				
RR, 95% CI	1.055 [0.799, 1.393]			
p-value	0.7072			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.015, 0.023]			
p-value	0.7072			

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

Table A2.1.129: Effect Measures of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		42 (3.1%)	44 (3.2%)	86 (3.2%)
Number of subjects without events		1315 (96.9%)	1312 (96.8%)	2627 (96.8%)
Odds Ratio [a]				
OR, 95% CI	0.952 [0.620, 1.464]			
p-value	0.8238			
Relative Risk [b]				
RR, 95% CI	0.954 [0.629, 1.446]			
p-value	0.8238			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.015, 0.012]			
p-value	0.8238			

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

Table A2.1.130: Effect Measures of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	14 (1.0%)	30 (1.1%)
Number of subjects without events		1341 (98.8%)	1342 (99.0%)	2683 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.144 [0.556, 2.353]			
p-value	0.7152			
Relative Risk [b]				
RR, 95% CI	1.142 [0.560, 2.331]			
p-value	0.7152			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.006, 0.009]			
p-value	0.7150			

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

Table A2.1.131: Effect Measures of Proportion of Subjects with TEAEs - Neuropathy peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	10 (0.7%)	25 (0.9%)
Number of subjects without events		1342 (98.9%)	1346 (99.3%)	2688 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.504 [0.673, 3.361]			
p-value	0.3192			
Relative Risk [b]				
RR, 95% CI	1.499 [0.676, 3.325]			
p-value	0.3194			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.004, 0.011]			
p-value	0.3158			

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

Table A2.1.132: Effect Measures of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	19 (1.4%)	35 (1.3%)
Number of subjects without events		1341 (98.8%)	1337 (98.6%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.840 [0.430, 1.640]			
p-value	0.6087			
Relative Risk [b]				
RR, 95% CI	0.841 [0.435, 1.629]			
p-value	0.6087			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.011, 0.006]			
p-value	0.6082			

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

Table A2.1.133: Effect Measures of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	32 (2.4%)	56 (2.1%)
Number of subjects without events		1333 (98.2%)	1324 (97.6%)	2657 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.745 [0.436, 1.272]			
p-value	0.2804			
Relative Risk [b]				
RR, 95% CI	0.749 [0.444, 1.265]			
p-value	0.2806			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.017, 0.005]			
p-value	0.2787			

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

Table A2.1.134: Effect Measures of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		96 (7.1%)	126 (9.3%)	222 (8.2%)
Number of subjects without events		1261 (92.9%)	1230 (90.7%)	2491 (91.8%)
Odds Ratio [a]				
OR, 95% CI	0.743 [0.563, 0.980]			
p-value	0.0356			
Relative Risk [b]				
RR, 95% CI	0.761 [0.590, 0.982]			
p-value	0.0358			
Risk Difference [c]				
RD, 95% CI	-0.022 [-0.043, -0.002]			
p-value	0.0350			

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

Table A2.1.135: Effect Measures of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		12 (0.9%)	19 (1.4%)	31 (1.1%)
Number of subjects without events		1345 (99.1%)	1337 (98.6%)	2682 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.628 [0.304, 1.298]			
p-value	0.2093			
Relative Risk [b]				
RR, 95% CI	0.631 [0.308, 1.295]			
p-value	0.2095			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.013, 0.003]			
p-value	0.2052			

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

Table A2.1.136: Effect Measures of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		25 (1.8%)	31 (2.3%)	56 (2.1%)
Number of subjects without events		1332 (98.2%)	1325 (97.7%)	2657 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.802 [0.471, 1.366]			
p-value	0.4171			
Relative Risk [b]				
RR, 95% CI	0.806 [0.478, 1.357]			
p-value	0.4172			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.015, 0.006]			
p-value	0.4162			

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

Table A2.1.137: Effect Measures of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		33 (2.4%)	38 (2.8%)	71 (2.6%)
Number of subjects without events		1324 (97.6%)	1318 (97.2%)	2642 (97.4%)
Odds Ratio [a]				
OR, 95% CI	0.864 [0.539, 1.387]			
p-value	0.5459			
Relative Risk [b]				
RR, 95% CI	0.868 [0.548, 1.375]			
p-value	0.5459			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.016, 0.008]			
p-value	0.5455			

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

Table A2.1.138: Effect Measures of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		254 (18.7%)	240 (17.7%)	494 (18.2%)
Number of subjects without events		1103 (81.3%)	1116 (82.3%)	2219 (81.8%)
Odds Ratio [a]				
OR, 95% CI	1.071 [0.881, 1.301]			
p-value	0.4919			
Relative Risk [b]				
RR, 95% CI	1.058 [0.902, 1.241]			
p-value	0.4919			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.019, 0.039]			
p-value	0.4918			

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

Table A2.1.139: Effect Measures of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		58 (4.3%)	65 (4.8%)	123 (4.5%)
Number of subjects without events		1299 (95.7%)	1291 (95.2%)	2590 (95.5%)
Odds Ratio [a]				
OR, 95% CI	0.887 [0.617, 1.274]			
p-value	0.5158			
Relative Risk [b]				
RR, 95% CI	0.892 [0.631, 1.260]			
p-value	0.5158			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.021, 0.010]			
p-value	0.5156			

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

Table A2.1.140: Effect Measures of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	17 (1.3%)	32 (1.2%)
Number of subjects without events		1342 (98.9%)	1339 (98.7%)	2681 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.880 [0.438, 1.770]			
p-value	0.7207			
Relative Risk [b]				
RR, 95% CI	0.882 [0.442, 1.758]			
p-value	0.7207			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.007]			
p-value	0.7205			

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

Table A2.1.141: Effect Measures of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		25 (1.8%)	21 (1.5%)	46 (1.7%)
Number of subjects without events		1332 (98.2%)	1335 (98.5%)	2667 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.193 [0.665, 2.142]			
p-value	0.5541			
Relative Risk [b]				
RR, 95% CI	1.190 [0.669, 2.115]			
p-value	0.5542			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.007, 0.013]			
p-value	0.5536			

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

Table A2.1.142: Effect Measures of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		19 (1.4%)	21 (1.5%)	40 (1.5%)
Number of subjects without events		1338 (98.6%)	1335 (98.5%)	2673 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.903 [0.483, 1.687]			
p-value	0.7484			
Relative Risk [b]				
RR, 95% CI	0.904 [0.488, 1.674]			
p-value	0.7484			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.011, 0.008]			
p-value	0.7483			

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

Table A2.1.143: Effect Measures of Proportion of Subjects with TEAEs - Pollakiuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		5 (0.4%)	13 (1.0%)	18 (0.7%)
Number of subjects without events		1352 (99.6%)	1343 (99.0%)	2695 (99.3%)
Odds Ratio [a]				
OR, 95% CI	0.382 [0.136, 1.075]			
p-value	0.0682			
Relative Risk [b]				
RR, 95% CI	0.384 [0.137, 1.075]			
p-value	0.0685			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.012, 0.000]			
p-value	0.0582			

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

Table A2.1.144: Effect Measures of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		28 (2.1%)	21 (1.5%)	49 (1.8%)
Number of subjects without events		1329 (97.9%)	1335 (98.5%)	2664 (98.2%)
Odds Ratio [a]				
OR, 95% CI	1.339 [0.757, 2.370]			
p-value	0.3158			
Relative Risk [b]				
RR, 95% CI	1.332 [0.760, 2.334]			
p-value	0.3159			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.005, 0.015]			
p-value	0.3140			

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

Table A2.1.145: Effect Measures of Proportion of Subjects with TEAEs - Renal failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	5 (0.4%)	20 (0.7%)
Number of subjects without events		1342 (98.9%)	1351 (99.6%)	2693 (99.3%)
Odds Ratio [a]				
OR, 95% CI	3.020 [1.095, 8.333]			
p-value	0.0328			
Relative Risk [b]				
RR, 95% CI	2.998 [1.093, 8.225]			
p-value	0.0330			
Risk Difference [c]				
RD, 95% CI	0.007 [0.001, 0.014]			
p-value	0.0248			

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

Table A2.1.146: Effect Measures of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		44 (3.2%)	32 (2.4%)	76 (2.8%)
Number of subjects without events		1313 (96.8%)	1324 (97.6%)	2637 (97.2%)
Odds Ratio [a]				
OR, 95% CI	1.387 [0.874, 2.200]			
p-value	0.1654			
Relative Risk [b]				
RR, 95% CI	1.374 [0.877, 2.153]			
p-value	0.1656			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.004, 0.021]			
p-value	0.1635			

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

Table A2.1.147: Effect Measures of Proportion of Subjects with TEAEs - Urinary incontinence (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	11 (0.8%)	29 (1.1%)
Number of subjects without events		1339 (98.7%)	1345 (99.2%)	2684 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.644 [0.773, 3.493]			
p-value	0.1964			
Relative Risk [b]				
RR, 95% CI	1.635 [0.775, 3.449]			
p-value	0.1966			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.003, 0.013]			
p-value	0.1918			

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

Table A2.1.148: Effect Measures of Proportion of Subjects with TEAEs - Urinary retention (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		10 (0.7%)	14 (1.0%)	24 (0.9%)
Number of subjects without events		1347 (99.3%)	1342 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.712 [0.315, 1.608]			
p-value	0.4133			
Relative Risk [b]				
RR, 95% CI	0.714 [0.318, 1.601]			
p-value	0.4134			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4111			

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

Table A2.1.149: Effect Measures of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		86 (6.3%)	73 (5.4%)	159 (5.9%)
Number of subjects without events		1271 (93.7%)	1283 (94.6%)	2554 (94.1%)
Odds Ratio [a]				
OR, 95% CI	1.189 [0.862, 1.640]			
p-value	0.2907			
Relative Risk [b]				
RR, 95% CI	1.177 [0.870, 1.593]			
p-value	0.2908			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.008, 0.027]			
p-value	0.2900			

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

Table A2.1.150: Effect Measures of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		38 (2.8%)	33 (2.4%)	71 (2.6%)
Number of subjects without events		1319 (97.2%)	1323 (97.6%)	2642 (97.4%)
Odds Ratio [a]				
OR, 95% CI	1.155 [0.720, 1.853]			
p-value	0.5500			
Relative Risk [b]				
RR, 95% CI	1.151 [0.726, 1.823]			
p-value	0.5501			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.008, 0.016]			
p-value	0.5497			

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

Table A2.1.151: Effect Measures of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		286 (21.1%)	267 (19.7%)	553 (20.4%)
Number of subjects without events		1071 (78.9%)	1089 (80.3%)	2160 (79.6%)
Odds Ratio [a]				
OR, 95% CI	1.089 [0.903, 1.313]			
p-value	0.3704			
Relative Risk [b]				
RR, 95% CI	1.070 [0.922, 1.242]			
p-value	0.3705			
Risk Difference [c]				
RD, 95% CI	0.014 [-0.016, 0.044]			
p-value	0.3703			

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

Table A2.1.152: Effect Measures of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	12 (0.9%)	36 (1.3%)
Number of subjects without events		1333 (98.2%)	1344 (99.1%)	2677 (98.7%)
Odds Ratio [a]				
OR, 95% CI	2.017 [1.004, 4.049]			
p-value	0.0486			
Relative Risk [b]				
RR, 95% CI	1.999 [1.004, 3.980]			
p-value	0.0488			
Risk Difference [c]				
RD, 95% CI	0.009 [0.000, 0.017]			
p-value	0.0441			

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

Table A2.1.153: Effect Measures of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		76 (5.6%)	71 (5.2%)	147 (5.4%)
Number of subjects without events		1281 (94.4%)	1285 (94.8%)	2566 (94.6%)
Odds Ratio [a]				
OR, 95% CI	1.074 [0.770, 1.497]			
p-value	0.6749			
Relative Risk [b]				
RR, 95% CI	1.070 [0.781, 1.465]			
p-value	0.6750			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.013, 0.021]			
p-value	0.6749			

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

Table A2.1.154: Effect Measures of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		60 (4.4%)	48 (3.5%)	108 (4.0%)
Number of subjects without events		1297 (95.6%)	1308 (96.5%)	2605 (96.0%)
Odds Ratio [a]				
OR, 95% CI	1.261 [0.856, 1.857]			
p-value	0.2411			
Relative Risk [b]				
RR, 95% CI	1.249 [0.861, 1.812]			
p-value	0.2413			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.006, 0.024]			
p-value	0.2401			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.155: Effect Measures of Proportion of Subjects with TEAEs - Dyspnoea exertional (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	17 (1.3%)	34 (1.3%)
Number of subjects without events		1340 (98.7%)	1339 (98.7%)	2679 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.508, 1.966]			
p-value	0.9983			
Relative Risk [b]				
RR, 95% CI	0.999 [0.512, 1.949]			
p-value	0.9983			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.008, 0.008]			
p-value	0.9983			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.156: Effect Measures of Proportion of Subjects with TEAEs - Pleural effusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	2 (0.1%)	15 (0.6%)
Number of subjects without events		1344 (99.0%)	1354 (99.9%)	2698 (99.4%)
Odds Ratio [a]				
OR, 95% CI	6.548 [1.475, 29.073]			
p-value	0.0135			
Relative Risk [b]				
RR, 95% CI	6.495 [1.469, 28.728]			
p-value	0.0136			
Risk Difference [c]				
RD, 95% CI	0.008 [0.003, 0.014]			
p-value	0.0043			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.157: Effect Measures of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	19 (1.4%)	36 (1.3%)
Number of subjects without events		1340 (98.7%)	1337 (98.6%)	2677 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.893 [0.462, 1.725]			
p-value	0.7356			
Relative Risk [b]				
RR, 95% CI	0.894 [0.467, 1.713]			
p-value	0.7357			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.007]			
p-value	0.7355			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.158: Effect Measures of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		244 (18.0%)	231 (17.0%)	475 (17.5%)
Number of subjects without events		1113 (82.0%)	1125 (83.0%)	2238 (82.5%)
Odds Ratio [a]				
OR, 95% CI	1.068 [0.876, 1.302]			
p-value	0.5171			
Relative Risk [b]				
RR, 95% CI	1.055 [0.896, 1.243]			
p-value	0.5171			
Risk Difference [c]				
RD, 95% CI	0.009 [-0.019, 0.038]			
p-value	0.5170			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.159: Effect Measures of Proportion of Subjects with TEAEs - Dermatitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	10 (0.7%)	24 (0.9%)
Number of subjects without events		1343 (99.0%)	1346 (99.3%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	1.403 [0.621, 3.170]			
p-value	0.4153			
Relative Risk [b]				
RR, 95% CI	1.399 [0.624, 3.138]			
p-value	0.4154			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.004, 0.010]			
p-value	0.4131			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.160: Effect Measures of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	13 (1.0%)	27 (1.0%)
Number of subjects without events		1343 (99.0%)	1343 (99.0%)	2686 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.077 [0.504, 2.300]			
p-value	0.8482			
Relative Risk [b]				
RR, 95% CI	1.076 [0.508, 2.281]			
p-value	0.8482			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.007, 0.008]			
p-value	0.8481			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.161: Effect Measures of Proportion of Subjects with TEAEs - Dry skin (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	16 (1.2%)	31 (1.1%)
Number of subjects without events		1342 (98.9%)	1340 (98.8%)	2682 (98.9%)
Odds Ratio [a]				
OR, 95% CI	0.936 [0.461, 1.901]			
p-value	0.8551			
Relative Risk [b]				
RR, 95% CI	0.937 [0.465, 1.887]			
p-value	0.8551			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.007]			
p-value	0.8550			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.162: Effect Measures of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		30 (2.2%)	21 (1.5%)	51 (1.9%)
Number of subjects without events		1327 (97.8%)	1335 (98.5%)	2662 (98.1%)
Odds Ratio [a]				
OR, 95% CI	1.437 [0.819, 2.523]			
p-value	0.2066			
Relative Risk [b]				
RR, 95% CI	1.428 [0.822, 2.481]			
p-value	0.2067			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.004, 0.017]			
p-value	0.2041			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.163: Effect Measures of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		46 (3.4%)	33 (2.4%)	79 (2.9%)
Number of subjects without events		1311 (96.6%)	1323 (97.6%)	2634 (97.1%)
Odds Ratio [a]				
OR, 95% CI	1.407 [0.894, 2.214]			
p-value	0.1403			
Relative Risk [b]				
RR, 95% CI	1.393 [0.896, 2.164]			
p-value	0.1406			
Risk Difference [c]				
RD, 95% CI	0.010 [-0.003, 0.022]			
p-value	0.1384			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.164: Effect Measures of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		21 (1.5%)	12 (0.9%)	33 (1.2%)
Number of subjects without events		1336 (98.5%)	1344 (99.1%)	2680 (98.8%)
Odds Ratio [a]				
OR, 95% CI	1.760 [0.863, 3.593]			
p-value	0.1202			
Relative Risk [b]				
RR, 95% CI	1.749 [0.864, 3.540]			
p-value	0.1204			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.002, 0.015]			
p-value	0.1152			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.165: Effect Measures of Proportion of Subjects with TEAEs - Skin lesion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	15 (1.1%)	26 (1.0%)
Number of subjects without events		1346 (99.2%)	1341 (98.9%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.731 [0.334, 1.596]			
p-value	0.4313			
Relative Risk [b]				
RR, 95% CI	0.733 [0.338, 1.590]			
p-value	0.4314			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4294			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.166: Effect Measures of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		33 (2.4%)	30 (2.2%)	63 (2.3%)
Number of subjects without events		1324 (97.6%)	1326 (97.8%)	2650 (97.7%)
Odds Ratio [a]				
OR, 95% CI	1.102 [0.668, 1.817]			
p-value	0.7044			
Relative Risk [b]				
RR, 95% CI	1.099 [0.674, 1.792]			
p-value	0.7045			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.009, 0.014]			
p-value	0.7043			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.167: Effect Measures of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		109 (8.0%)	101 (7.4%)	210 (7.7%)
Number of subjects without events		1248 (92.0%)	1255 (92.6%)	2503 (92.3%)
Odds Ratio [a]				
OR, 95% CI	1.085 [0.819, 1.439]			
p-value	0.5693			
Relative Risk [b]				
RR, 95% CI	1.078 [0.831, 1.399]			
p-value	0.5693			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.014, 0.026]			
p-value	0.5692			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.168: Effect Measures of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		28 (2.1%)	30 (2.2%)	58 (2.1%)
Number of subjects without events		1329 (97.9%)	1326 (97.8%)	2655 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.931 [0.553, 1.567]			
p-value	0.7885			
Relative Risk [b]				
RR, 95% CI	0.933 [0.560, 1.552]			
p-value	0.7885			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.012, 0.009]			
p-value	0.7885			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.169: Effect Measures of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		269 (19.8%)	248 (18.3%)	517 (19.1%)
Number of subjects without events		1088 (80.2%)	1108 (81.7%)	2196 (80.9%)
Odds Ratio [a]				
OR, 95% CI	1.105 [0.912, 1.338]			
p-value	0.3092			
Relative Risk [b]				
RR, 95% CI	1.084 [0.928, 1.266]			
p-value	0.3093			
Risk Difference [c]				
RD, 95% CI	0.015 [-0.014, 0.045]			
p-value	0.3089			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.170: Effect Measures of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		66 (4.9%)	106 (7.8%)	172 (6.3%)
Number of subjects without events		1291 (95.1%)	1250 (92.2%)	2541 (93.7%)
Odds Ratio [a]				
OR, 95% CI	0.603 [0.439, 0.828]			
p-value	0.0018			
Relative Risk [b]				
RR, 95% CI	0.622 [0.462, 0.838]			
p-value	0.0018			
Risk Difference [c]				
RD, 95% CI	-0.030 [-0.048, -0.011]			
p-value	0.0016			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.171: Effect Measures of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		87 (6.4%)	54 (4.0%)	141 (5.2%)
Number of subjects without events		1270 (93.6%)	1302 (96.0%)	2572 (94.8%)
Odds Ratio [a]				
OR, 95% CI	1.652 [1.166, 2.340]			
p-value	0.0047			
Relative Risk [b]				
RR, 95% CI	1.610 [1.156, 2.242]			
p-value	0.0048			
Risk Difference [c]				
RD, 95% CI	0.024 [0.008, 0.041]			
p-value	0.0043			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.172: Effect Measures of Proportion of Subjects with TEAEs - Orthostatic hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		17 (1.3%)	9 (0.7%)	26 (1.0%)
Number of subjects without events		1340 (98.7%)	1347 (99.3%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.899 [0.843, 4.275]			
p-value	0.1215			
Relative Risk [b]				
RR, 95% CI	1.887 [0.844, 4.219]			
p-value	0.1217			
Risk Difference [c]				
RD, 95% CI	0.006 [-0.001, 0.013]			
p-value	0.1151			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.173: Effect Measures of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		28 (2.1%)	19 (1.4%)	47 (1.7%)
Number of subjects without events		1329 (97.9%)	1337 (98.6%)	2666 (98.3%)
Odds Ratio [a]				
OR, 95% CI	1.483 [0.824, 2.668]			
p-value	0.1890			
Relative Risk [b]				
RR, 95% CI	1.473 [0.826, 2.624]			
p-value	0.1891			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.003, 0.016]			
p-value	0.1861			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.174: Effect Measures of Proportion of Subjects with TESAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	18 (1.3%)	32 (1.2%)
Number of subjects without events		1343 (99.0%)	1338 (98.7%)	2681 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.775 [0.384, 1.564]			
p-value	0.4767			
Relative Risk [b]				
RR, 95% CI	0.777 [0.388, 1.556]			
p-value	0.4768			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.005]			
p-value	0.4756			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.175: Effect Measures of Proportion of Subjects with TESAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	13 (1.0%)	24 (0.9%)
Number of subjects without events		1346 (99.2%)	1343 (99.0%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.844 [0.377, 1.891]			
p-value	0.6808			
Relative Risk [b]				
RR, 95% CI	0.846 [0.380, 1.881]			
p-value	0.6808			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.006]			
p-value	0.6804			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.176: Effect Measures of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	24 (1.8%)	44 (1.6%)
Number of subjects without events		1337 (98.5%)	1332 (98.2%)	2669 (98.4%)
Odds Ratio [a]				
OR, 95% CI	0.830 [0.456, 1.510]			
p-value	0.5421			
Relative Risk [b]				
RR, 95% CI	0.833 [0.462, 1.500]			
p-value	0.5422			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.012, 0.007]			
p-value	0.5416			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.177: Effect Measures of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		16 (1.2%)	11 (0.8%)	27 (1.0%)
Number of subjects without events		1341 (98.8%)	1345 (99.2%)	2686 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.459 [0.675, 3.155]			
p-value	0.3373			
Relative Risk [b]				
RR, 95% CI	1.453 [0.677, 3.120]			
p-value	0.3374			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.004, 0.011]			
p-value	0.3344			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.178: Effect Measures of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		66 (4.9%)	56 (4.1%)	122 (4.5%)
Number of subjects without events		1291 (95.1%)	1300 (95.9%)	2591 (95.5%)
Odds Ratio [a]				
OR, 95% CI	1.187 [0.824, 1.708]			
p-value	0.3569			
Relative Risk [b]				
RR, 95% CI	1.178 [0.832, 1.668]			
p-value	0.3570			
Risk Difference [c]				
RD, 95% CI	0.007 [-0.008, 0.023]			
p-value	0.3563			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.179: Effect Measures of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		21 (1.5%)	33 (2.4%)	54 (2.0%)
Number of subjects without events		1336 (98.5%)	1323 (97.6%)	2659 (98.0%)
Odds Ratio [a]				
OR, 95% CI	0.630 [0.363, 1.095]			
p-value	0.1013			
Relative Risk [b]				
RR, 95% CI	0.636 [0.370, 1.093]			
p-value	0.1016			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.019, 0.002]			
p-value	0.0983			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.180: Effect Measures of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	17 (1.3%)	32 (1.2%)
Number of subjects without events		1342 (98.9%)	1339 (98.7%)	2681 (98.8%)
Odds Ratio [a]				
OR, 95% CI	0.880 [0.438, 1.770]			
p-value	0.7207			
Relative Risk [b]				
RR, 95% CI	0.882 [0.442, 1.758]			
p-value	0.7207			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.007]			
p-value	0.7205			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.181: Effect Measures of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		154 (11.3%)	169 (12.5%)	323 (11.9%)
Number of subjects without events		1203 (88.7%)	1187 (87.5%)	2390 (88.1%)
Odds Ratio [a]				
OR, 95% CI	0.899 [0.713, 1.135]			
p-value	0.3703			
Relative Risk [b]				
RR, 95% CI	0.911 [0.742, 1.118]			
p-value	0.3703			
Risk Difference [c]				
RD, 95% CI	-0.011 [-0.036, 0.013]			
p-value	0.3700			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.182: Effect Measures of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	11 (0.8%)	29 (1.1%)
Number of subjects without events		1339 (98.7%)	1345 (99.2%)	2684 (98.9%)
Odds Ratio [a]				
OR, 95% CI	1.644 [0.773, 3.493]			
p-value	0.1964			
Relative Risk [b]				
RR, 95% CI	1.635 [0.775, 3.449]			
p-value	0.1966			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.003, 0.013]			
p-value	0.1918			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.183: Effect Measures of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		33 (2.4%)	45 (3.3%)	78 (2.9%)
Number of subjects without events		1324 (97.6%)	1311 (96.7%)	2635 (97.1%)
Odds Ratio [a]				
OR, 95% CI	0.726 [0.460, 1.145]			
p-value	0.1686			
Relative Risk [b]				
RR, 95% CI	0.733 [0.471, 1.141]			
p-value	0.1688			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.021, 0.004]			
p-value	0.1668			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.184: Effect Measures of Proportion of Subjects with TESAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		9 (0.7%)	26 (1.9%)	35 (1.3%)
Number of subjects without events		1348 (99.3%)	1330 (98.1%)	2678 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.342 [0.159, 0.732]			
p-value	0.0057			
Relative Risk [b]				
RR, 95% CI	0.346 [0.163, 0.735]			
p-value	0.0058			
Risk Difference [c]				
RD, 95% CI	-0.013 [-0.021, -0.004]			
p-value	0.0038			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.185: Effect Measures of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		47 (3.5%)	49 (3.6%)	96 (3.5%)
Number of subjects without events		1310 (96.5%)	1307 (96.4%)	2617 (96.5%)
Odds Ratio [a]				
OR, 95% CI	0.957 [0.637, 1.438]			
p-value	0.8325			
Relative Risk [b]				
RR, 95% CI	0.958 [0.647, 1.420]			
p-value	0.8325			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.015, 0.012]			
p-value	0.8325			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.186: Effect Measures of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		18 (1.3%)	19 (1.4%)	37 (1.4%)
Number of subjects without events		1339 (98.7%)	1337 (98.6%)	2676 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.946 [0.494, 1.810]			
p-value	0.8668			
Relative Risk [b]				
RR, 95% CI	0.947 [0.499, 1.796]			
p-value	0.8668			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.009, 0.008]			
p-value	0.8667			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.187: Effect Measures of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		74 (5.5%)	67 (4.9%)	141 (5.2%)
Number of subjects without events		1283 (94.5%)	1289 (95.1%)	2572 (94.8%)
Odds Ratio [a]				
OR, 95% CI	1.110 [0.790, 1.558]			
p-value	0.5480			
Relative Risk [b]				
RR, 95% CI	1.104 [0.800, 1.523]			
p-value	0.5481			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.012, 0.022]			
p-value	0.5478			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.188: Effect Measures of Proportion of Subjects with TESAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	5 (0.4%)	19 (0.7%)
Number of subjects without events		1343 (99.0%)	1351 (99.6%)	2694 (99.3%)
Odds Ratio [a]				
OR, 95% CI	2.817 [1.012, 7.842]			
p-value	0.0474			
Relative Risk [b]				
RR, 95% CI	2.798 [1.011, 7.746]			
p-value	0.0477			
Risk Difference [c]				
RD, 95% CI	0.007 [0.000, 0.013]			
p-value	0.0382			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.189: Effect Measures of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	2 (0.1%)	16 (0.6%)
Number of subjects without events		1343 (99.0%)	1354 (99.9%)	2697 (99.4%)
Odds Ratio [a]				
OR, 95% CI	7.057 [1.601, 31.112]			
p-value	0.0098			
Relative Risk [b]				
RR, 95% CI	6.995 [1.593, 30.718]			
p-value	0.0100			
Risk Difference [c]				
RD, 95% CI	0.009 [0.003, 0.015]			
p-value	0.0026			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.190: Effect Measures of Proportion of Subjects with TESAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		10 (0.7%)	16 (1.2%)	26 (1.0%)
Number of subjects without events		1347 (99.3%)	1340 (98.8%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.622 [0.281, 1.375]			
p-value	0.2406			
Relative Risk [b]				
RR, 95% CI	0.625 [0.284, 1.371]			
p-value	0.2408			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.012, 0.003]			
p-value	0.2362			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.191: Effect Measures of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		37 (2.7%)	38 (2.8%)	75 (2.8%)
Number of subjects without events		1320 (97.3%)	1318 (97.2%)	2638 (97.2%)
Odds Ratio [a]				
OR, 95% CI	0.972 [0.614, 1.539]			
p-value	0.9042			
Relative Risk [b]				
RR, 95% CI	0.973 [0.623, 1.520]			
p-value	0.9042			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.013, 0.012]			
p-value	0.9042			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.192: Effect Measures of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		63 (4.6%)	74 (5.5%)	137 (5.0%)
Number of subjects without events		1294 (95.4%)	1282 (94.5%)	2576 (95.0%)
Odds Ratio [a]				
OR, 95% CI	0.843 [0.598, 1.191]			
p-value	0.3331			
Relative Risk [b]				
RR, 95% CI	0.851 [0.613, 1.180]			
p-value	0.3332			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.025, 0.008]			
p-value	0.3325			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.193: Effect Measures of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		43 (3.2%)	50 (3.7%)	93 (3.4%)
Number of subjects without events		1314 (96.8%)	1306 (96.3%)	2620 (96.6%)
Odds Ratio [a]				
OR, 95% CI	0.855 [0.565, 1.294]			
p-value	0.4583			
Relative Risk [b]				
RR, 95% CI	0.859 [0.576, 1.283]			
p-value	0.4584			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.019, 0.009]			
p-value	0.4579			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.194: Effect Measures of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		52 (3.8%)	64 (4.7%)	116 (4.3%)
Number of subjects without events		1305 (96.2%)	1292 (95.3%)	2597 (95.7%)
Odds Ratio [a]				
OR, 95% CI	0.804 [0.553, 1.169]			
p-value	0.2539			
Relative Risk [b]				
RR, 95% CI	0.812 [0.568, 1.162]			
p-value	0.2541			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.024, 0.006]			
p-value	0.2530			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.195: Effect Measures of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	33 (2.4%)	57 (2.1%)
Number of subjects without events		1333 (98.2%)	1323 (97.6%)	2656 (97.9%)
Odds Ratio [a]				
OR, 95% CI	0.722 [0.424, 1.228]			
p-value	0.2291			
Relative Risk [b]				
RR, 95% CI	0.727 [0.432, 1.223]			
p-value	0.2293			
Risk Difference [c]				
RD, 95% CI	-0.007 [-0.017, 0.004]			
p-value	0.2271			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.196: Effect Measures of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		47 (3.5%)	45 (3.3%)	92 (3.4%)
Number of subjects without events		1310 (96.5%)	1311 (96.7%)	2621 (96.6%)
Odds Ratio [a]				
OR, 95% CI	1.045 [0.690, 1.584]			
p-value	0.8348			
Relative Risk [b]				
RR, 95% CI	1.044 [0.698, 1.560]			
p-value	0.8348			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.012, 0.015]			
p-value	0.8348			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.197: Effect Measures of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	12 (0.9%)	27 (1.0%)
Number of subjects without events		1342 (98.9%)	1344 (99.1%)	2686 (99.0%)
Odds Ratio [a]				
OR, 95% CI	1.252 [0.584, 2.684]			
p-value	0.5638			
Relative Risk [b]				
RR, 95% CI	1.249 [0.587, 2.658]			
p-value	0.5639			
Risk Difference [c]				
RD, 95% CI	0.002 [-0.005, 0.010]			
p-value	0.5630			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.198: Effect Measures of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		42 (3.1%)	41 (3.0%)	83 (3.1%)
Number of subjects without events		1315 (96.9%)	1315 (97.0%)	2630 (96.9%)
Odds Ratio [a]				
OR, 95% CI	1.024 [0.662, 1.586]			
p-value	0.9139			
Relative Risk [b]				
RR, 95% CI	1.024 [0.670, 1.564]			
p-value	0.9139			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.012, 0.014]			
p-value	0.9139			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.199: Effect Measures of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	36 (2.7%)	60 (2.2%)
Number of subjects without events		1333 (98.2%)	1320 (97.3%)	2653 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.660 [0.392, 1.113]			
p-value	0.1190			
Relative Risk [b]				
RR, 95% CI	0.666 [0.400, 1.110]			
p-value	0.1192			
Risk Difference [c]				
RD, 95% CI	-0.009 [-0.020, 0.002]			
p-value	0.1164			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.200: Effect Measures of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	19 (1.4%)	39 (1.4%)
Number of subjects without events		1337 (98.5%)	1337 (98.6%)	2674 (98.6%)
Odds Ratio [a]				
OR, 95% CI	1.053 [0.559, 1.981]			
p-value	0.8737			
Relative Risk [b]				
RR, 95% CI	1.052 [0.564, 1.962]			
p-value	0.8737			
Risk Difference [c]				
RD, 95% CI	0.001 [-0.008, 0.010]			
p-value	0.8737			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.201: Effect Measures of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		29 (2.1%)	22 (1.6%)	51 (1.9%)
Number of subjects without events		1328 (97.9%)	1334 (98.4%)	2662 (98.1%)
Odds Ratio [a]				
OR, 95% CI	1.324 [0.757, 2.317]			
p-value	0.3252			
Relative Risk [b]				
RR, 95% CI	1.317 [0.761, 2.281]			
p-value	0.3253			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.005, 0.015]			
p-value	0.3236			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.202: Effect Measures of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		15 (1.1%)	19 (1.4%)	34 (1.3%)
Number of subjects without events		1342 (98.9%)	1337 (98.6%)	2679 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.787 [0.398, 1.554]			
p-value	0.4896			
Relative Risk [b]				
RR, 95% CI	0.789 [0.403, 1.546]			
p-value	0.4897			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.011, 0.005]			
p-value	0.4886			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.203: Effect Measures of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		81 (6.0%)	86 (6.3%)	167 (6.2%)
Number of subjects without events		1276 (94.0%)	1270 (93.7%)	2546 (93.8%)
Odds Ratio [a]				
OR, 95% CI	0.937 [0.685, 1.282]			
p-value	0.6860			
Relative Risk [b]				
RR, 95% CI	0.941 [0.701, 1.263]			
p-value	0.6860			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.022, 0.014]			
p-value	0.6860			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.204: Effect Measures of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	25 (1.8%)	39 (1.4%)
Number of subjects without events		1343 (99.0%)	1331 (98.2%)	2674 (98.6%)
Odds Ratio [a]				
OR, 95% CI	0.555 [0.287, 1.072]			
p-value	0.0797			
Relative Risk [b]				
RR, 95% CI	0.560 [0.292, 1.072]			
p-value	0.0800			
Risk Difference [c]				
RD, 95% CI	-0.008 [-0.017, 0.001]			
p-value	0.0755			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.205: Effect Measures of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		26 (1.9%)	26 (1.9%)	52 (1.9%)
Number of subjects without events		1331 (98.1%)	1330 (98.1%)	2661 (98.1%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.577, 1.730]			
p-value	0.9979			
Relative Risk [b]				
RR, 95% CI	0.999 [0.583, 1.712]			
p-value	0.9979			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.010, 0.010]			
p-value	0.9979			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.206: Effect Measures of Proportion of Subjects with Severe TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		9 (0.7%)	15 (1.1%)	24 (0.9%)
Number of subjects without events		1348 (99.3%)	1341 (98.9%)	2689 (99.1%)
Odds Ratio [a]				
OR, 95% CI	0.597 [0.260, 1.369]			
p-value	0.2229			
Relative Risk [b]				
RR, 95% CI	0.600 [0.263, 1.365]			
p-value	0.2231			
Risk Difference [c]				
RD, 95% CI	-0.004 [-0.011, 0.003]			
p-value	0.2179			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.207: Effect Measures of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		45 (3.3%)	38 (2.8%)	83 (3.1%)
Number of subjects without events		1312 (96.7%)	1318 (97.2%)	2630 (96.9%)
Odds Ratio [a]				
OR, 95% CI	1.190 [0.767, 1.844]			
p-value	0.4377			
Relative Risk [b]				
RR, 95% CI	1.183 [0.773, 1.810]			
p-value	0.4378			
Risk Difference [c]				
RD, 95% CI	0.005 [-0.008, 0.018]			
p-value	0.4371			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.208: Effect Measures of Proportion of Subjects with Severe TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		13 (1.0%)	1 (0.1%)	14 (0.5%)
Number of subjects without events		1344 (99.0%)	1355 (99.9%)	2699 (99.5%)
Odds Ratio [a]				
OR, 95% CI	13.106 [1.712, 100.33]			
p-value	0.0132			
Relative Risk [b]				
RR, 95% CI	12.990 [1.702, 99.164]			
p-value	0.0134			
Risk Difference [c]				
RD, 95% CI	0.009 [0.003, 0.014]			
p-value	0.0013			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.209: Effect Measures of Proportion of Subjects with Severe TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		11 (0.8%)	15 (1.1%)	26 (1.0%)
Number of subjects without events		1346 (99.2%)	1341 (98.9%)	2687 (99.0%)
Odds Ratio [a]				
OR, 95% CI	0.731 [0.334, 1.596]			
p-value	0.4313			
Relative Risk [b]				
RR, 95% CI	0.733 [0.338, 1.590]			
p-value	0.4314			
Risk Difference [c]				
RD, 95% CI	-0.003 [-0.010, 0.004]			
p-value	0.4294			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.210: Effect Measures of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		20 (1.5%)	21 (1.5%)	41 (1.5%)
Number of subjects without events		1337 (98.5%)	1335 (98.5%)	2672 (98.5%)
Odds Ratio [a]				
OR, 95% CI	0.951 [0.513, 1.763]			
p-value	0.8731			
Relative Risk [b]				
RR, 95% CI	0.952 [0.518, 1.748]			
p-value	0.8731			
Risk Difference [c]				
RD, 95% CI	-0.001 [-0.010, 0.008]			
p-value	0.8731			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.211: Effect Measures of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		40 (2.9%)	47 (3.5%)	87 (3.2%)
Number of subjects without events		1317 (97.1%)	1309 (96.5%)	2626 (96.8%)
Odds Ratio [a]				
OR, 95% CI	0.846 [0.551, 1.298]			
p-value	0.4440			
Relative Risk [b]				
RR, 95% CI	0.850 [0.562, 1.288]			
p-value	0.4440			
Risk Difference [c]				
RD, 95% CI	-0.005 [-0.018, 0.008]			
p-value	0.4435			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.212: Effect Measures of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		25 (1.8%)	25 (1.8%)	50 (1.8%)
Number of subjects without events		1332 (98.2%)	1331 (98.2%)	2663 (98.2%)
Odds Ratio [a]				
OR, 95% CI	0.999 [0.571, 1.749]			
p-value	0.9979			
Relative Risk [b]				
RR, 95% CI	0.999 [0.577, 1.731]			
p-value	0.9979			
Risk Difference [c]				
RD, 95% CI	0.000 [-0.010, 0.010]			
p-value	0.9979			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.213: Effect Measures of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		29 (2.1%)	32 (2.4%)	61 (2.2%)
Number of subjects without events		1328 (97.9%)	1324 (97.6%)	2652 (97.8%)
Odds Ratio [a]				
OR, 95% CI	0.904 [0.544, 1.502]			
p-value	0.6956			
Relative Risk [b]				
RR, 95% CI	0.906 [0.551, 1.488]			
p-value	0.6956			
Risk Difference [c]				
RD, 95% CI	-0.002 [-0.013, 0.009]			
p-value	0.6955			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.214: Effect Measures of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		14 (1.0%)	22 (1.6%)	36 (1.3%)
Number of subjects without events		1343 (99.0%)	1334 (98.4%)	2677 (98.7%)
Odds Ratio [a]				
OR, 95% CI	0.632 [0.322, 1.241]			
p-value	0.1825			
Relative Risk [b]				
RR, 95% CI	0.636 [0.327, 1.238]			
p-value	0.1827			
Risk Difference [c]				
RD, 95% CI	-0.006 [-0.015, 0.003]			
p-value	0.1787			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.215: Effect Measures of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		32 (2.4%)	28 (2.1%)	60 (2.2%)
Number of subjects without events		1325 (97.6%)	1328 (97.9%)	2653 (97.8%)
Odds Ratio [a]				
OR, 95% CI	1.145 [0.686, 1.913]			
p-value	0.6038			
Relative Risk [b]				
RR, 95% CI	1.142 [0.692, 1.886]			
p-value	0.6038			
Risk Difference [c]				
RD, 95% CI	0.003 [-0.008, 0.014]			
p-value	0.6035			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

Table A2.1.216: Effect Measures of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone vs. Placebo	Finerenone (N=1357)	Placebo (N=1356)	Total (N=2713)
Number of subjects at risk		1357 (100.0%)	1356 (100.0%)	2713 (100.0%)
Number of subjects with events		24 (1.8%)	18 (1.3%)	42 (1.5%)
Number of subjects without events		1333 (98.2%)	1338 (98.7%)	2671 (98.5%)
Odds Ratio [a]				
OR, 95% CI	1.338 [0.723, 2.477]			
p-value	0.3537			
Relative Risk [b]				
RR, 95% CI	1.332 [0.726, 2.443]			
p-value	0.3538			
Risk Difference [c]				
RD, 95% CI	0.004 [-0.005, 0.014]			
p-value	0.3519			

Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, OR=odds ratio, PT=preferred term, RD=risk difference, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Results shown in the second column based on GLMs with classification term for treatment. The GLMs were fitted by SAS PROC GENMOD with different link-functions and/or distributions.
[a] Estimated by a GLM with binomial distribution and logit as link function, [b] Estimated by a GLM with binomial distribution and log as link function.
[c] Estimated by a GLM with binomial distribution and identity as link function. RD = absolute risk of Finerenone - absolute risk of Placebo.
Wald chi-square p-values are presented.
* = model had convergence issues.

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4.2 Disposition

Table 4.2 / 1: Subject disposition (all enrolled - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Disposition	BAY 94-8862	Placebo	Total
Number of subjects			
Enrolled			33292
Screening failures			20121
Randomized	4026	4026	8052
GCP VIOLATIONS	45	44	89
Full analysis set	3981 (100.0%)	3982 (100.0%)	7963 (100.0%)
Study drug never administered	8 (0.2%)	15 (0.4%)	23 (0.3%)
Treated	3973 (99.8%)	3967 (99.6%)	7940 (99.7%)
Did not complete treatment due COVID-19	20 (0.5%)	12 (0.3%)	32 (0.4%)
Subject decision: COVID-19 pandemic related	13 (0.3%)	7 (0.2%)	20 (0.3%)
Physician decision: COVID-19 pandemic related	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Logistical reason: COVID-19 pandemic related	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Did not complete study	11 (0.3%)	15 (0.4%)	26 (0.3%)
WITHDRAWN CONSENT	4 (0.1%)	9 (0.2%)	13 (0.2%)
LOST TO FOLLOW-UP	7 (0.2%)	6 (0.2%)	13 (0.2%)
Completed study	3970 (99.7%)	3967 (99.6%)	7937 (99.7%)

Number of subjects enrolled is the number of subjects who signed informed consent, including subjects who switched from study 16244 to study 17530.
The subject is considered as having completed the study if there is a contact with the subject after the EOS notification or if the subject died. Contact with the subject can be actual visits, phone contacts, or information available from public records, etc.
Lost to follow-up includes all study non-completers who have not withdrawn consent. This definition does not necessarily meet the reasons for non-completion of the specified study epochs.
Number of enrolled subjects and screen failures refer to the full study population.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adds.sas 26JAN2023 15:28
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Table 4.2 / 2: Disposition: End of treatment (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Completed epoch	2751 (69.1%)	2809 (70.5%)	5560 (69.8%)
Not completed	1230 (30.9%)	1173 (29.5%)	2403 (30.2%)
Primary reason			
ADVERSE EVENT	439 (11.0%)	406 (10.2%)	845 (10.6%)
DEATH	221 (5.6%)	244 (6.1%)	465 (5.8%)
WITHDRAWAL BY SUBJECT	233 (5.9%)	247 (6.2%)	480 (6.0%)
LOST TO FOLLOW-UP	5 (0.1%)	5 (0.1%)	10 (0.1%)
PREGNANCY	0	1 (<0.1%)	1 (<0.1%)
PROGRESSIVE DISEASE	0	1 (<0.1%)	1 (<0.1%)
NON-COMPLIANCE WITH STUDY DRUG	24 (0.6%)	12 (0.3%)	36 (0.5%)
PHYSICIAN DECISION	223 (5.6%)	160 (4.0%)	383 (4.8%)
TECHNICAL PROBLEMS	37 (0.9%)	51 (1.3%)	88 (1.1%)
DETERIORATION OF GENERAL CONDITIONS	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
PROTOCOL DEVIATION	11 (0.3%)	18 (0.5%)	29 (0.4%)
SITE TERMINATED BY SPONSOR	6 (0.2%)	2 (<0.1%)	8 (0.1%)
LOGISTICAL REASON	1 (<0.1%)	0	1 (<0.1%)
SUBJECT DECISION	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
SUBJECT DECISION: COVID-19 PANDEMIC RELATED	13 (0.3%)	7 (0.2%)	20 (0.3%)
PHYSICIAN DECISION: COVID-19 PANDEMIC RELATED	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
LOGISTICAL REASON: COVID-19 PANDEMIC RELATED	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
OTHER	6 (0.2%)	8 (0.2%)	14 (0.2%)

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4.3 Demographic characteristics

Table 4.3 / 1: Demographics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Race (N)			
WHITE	2650 (66.6%)	2655 (66.7%)	5305 (66.6%)
BLACK OR AFRICAN AMERICAN	173 (4.3%)	186 (4.7%)	359 (4.5%)
ASIAN	929 (23.3%)	932 (23.4%)	1861 (23.4%)
AMERICAN INDIAN OR ALASKA NATIVE	82 (2.1%)	76 (1.9%)	158 (2.0%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	12 (0.3%)	13 (0.3%)	25 (0.3%)
NOT REPORTED	12 (0.3%)	13 (0.3%)	25 (0.3%)
MULTIPLE	123 (3.1%)	107 (2.7%)	230 (2.9%)
Sex (N)			
Male	2717 (68.2%)	2813 (70.6%)	5530 (69.4%)
Female	1264 (31.8%)	1169 (29.4%)	2433 (30.6%)
Age (YEARS)			
n	3981	3982	7963
Mean	66.80	67.09	66.94
SD	8.78	8.88	8.83
Min	32.0	30.0	30.0
Q1	61.00	62.00	62.00
Median	68.00	68.00	68.00
Q3	73.00	73.00	73.00
Max	90.0	97.0	97.0
Run-in age group (years) category (N)			
18 - 44 years	50 (1.3%)	62 (1.6%)	112 (1.4%)
45 - 64 years	1393 (35.0%)	1352 (34.0%)	2745 (34.5%)
65 - 74 years	1779 (44.7%)	1766 (44.3%)	3545 (44.5%)
>= 75 years	759 (19.1%)	802 (20.1%)	1561 (19.6%)
Age group (years) category 3 (N)			
< 65 years	1443 (36.2%)	1414 (35.5%)	2857 (35.9%)
>= 65 years	2538 (63.8%)	2568 (64.5%)	5106 (64.1%)
Ethnicity (N)			
NOT HISPANIC OR LATINO	3395 (85.3%)	3416 (85.8%)	6811 (85.5%)
HISPANIC OR LATINO	576 (14.5%)	548 (13.8%)	1124 (14.1%)
NOT REPORTED	10 (0.3%)	18 (0.5%)	28 (0.4%)

Table 4.3 / 1: Demographics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Region (N)			
Europe	1718 (43.2%)	1703 (42.8%)	3421 (43.0%)
North America	692 (17.4%)	708 (17.8%)	1400 (17.6%)
Asia	1039 (26.1%)	1040 (26.1%)	2079 (26.1%)
Latin America	376 (9.4%)	375 (9.4%)	751 (9.4%)
Others	156 (3.9%)	156 (3.9%)	312 (3.9%)
Baseline Weight (kg)			
n	3972	3976	7948
Mean	87.12	87.37	87.24
SD	19.90	19.79	19.85
Min	37.6	34.0	34.0
Q1	73.00	73.20	73.00
Median	85.00	85.40	85.20
Q3	99.00	98.70	98.90
Max	182.8	188.9	188.9
Baseline weight (kg) category (N)			
missing	9 (0.2%)	6 (0.2%)	15 (0.2%)
< 60 kg	244 (6.1%)	221 (5.5%)	465 (5.8%)
60 - < 90 kg	2137 (53.7%)	2131 (53.5%)	4268 (53.6%)
>= 90 kg	1591 (40.0%)	1624 (40.8%)	3215 (40.4%)
Baseline Height (cm)			
n	3973	3981	7954
Mean	166.77	167.10	166.93
SD	9.70	9.73	9.71
Min	136.0	136.0	136.0
Q1	160.00	160.00	160.00
Median	167.00	167.50	167.30
Q3	173.00	174.00	174.00
Max	198.1	207.0	207.0

Table 4.3 / 1: Demographics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline Body Mass Index (kg/m2)			
n	3965	3975	7940
Mean	31.17	31.16	31.16
SD	5.94	5.92	5.93
Min	15.5	14.5	14.5
Q1	27.00	27.00	27.00
Median	30.40	30.40	30.40
Q3	34.40	34.60	34.50
Max	63.7	63.2	63.7
Baseline BMI (kg/m2) category 2 (N)			
missing	16 (0.4%)	7 (0.2%)	23 (0.3%)
< 30 kg/m2	1841 (46.2%)	1867 (46.9%)	3708 (46.6%)
>= 30 kg/m2	2124 (53.4%)	2108 (52.9%)	4232 (53.1%)
Baseline BMI (kg/m2) category 3 (N)			
missing	16 (0.4%)	7 (0.2%)	23 (0.3%)
< 20 kg/m2	34 (0.9%)	31 (0.8%)	65 (0.8%)
20 - < 25 kg/m2	471 (11.8%)	481 (12.1%)	952 (12.0%)
25 - < 30 kg/m2	1336 (33.6%)	1355 (34.0%)	2691 (33.8%)
30 - < 35 kg/m2	1227 (30.8%)	1179 (29.6%)	2406 (30.2%)
>= 35 kg/m2	897 (22.5%)	929 (23.3%)	1826 (22.9%)
Baseline Hip Circumference (cm)			
n	3961	3962	7923
Mean	107.44	107.51	107.47
SD	13.93	13.68	13.80
Min	36.0	36.0	36.0
Q1	98.50	99.00	99.00
Median	106.00	106.00	106.00
Q3	115.00	115.00	115.00
Max	203.2	171.0	203.2

Table 4.3 / 1: Demographics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline waist circumference (cm)			
n	3967	3969	7936
Mean	106.86	107.17	107.02
SD	15.03	15.18	15.11
Min	34.0	34.0	34.0
Q1	97.00	96.50	97.00
Median	106.00	106.00	106.00
Q3	116.00	117.00	116.80
Max	180.0	200.0	200.0
Baseline waist circumf. (cm) cat. (N)			
missing	14 (0.4%)	13 (0.3%)	27 (0.3%)
normal	461 (11.6%)	474 (11.9%)	935 (11.7%)
increased	711 (17.9%)	723 (18.2%)	1434 (18.0%)
substantially increased	2795 (70.2%)	2772 (69.6%)	5567 (69.9%)
Baseline waist-hip ratio (N)			
n	3960	3961	7921
Mean	1.00	1.00	1.00
SD	0.11	0.11	0.11
Min	0.6	0.5	0.5
Q1	0.94	0.94	0.94
Median	0.99	0.99	0.99
Q3	1.05	1.05	1.05
Max	2.5	2.4	2.5
Smoking History (N)			
NEVER	1926 (48.4%)	1930 (48.5%)	3856 (48.4%)
FORMER	1531 (38.5%)	1577 (39.6%)	3108 (39.0%)
CURRENT	524 (13.2%)	475 (11.9%)	999 (12.5%)

Table 4.3 / 1: Demographics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

TEXT	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Alcohol Use (N)			
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
ABSTINENT	2432 (61.1%)	2399 (60.2%)	4831 (60.7%)
LIGHT	1331 (33.4%)	1344 (33.8%)	2675 (33.6%)
MODERATE	201 (5.0%)	221 (5.5%)	422 (5.3%)
HEAVY	16 (0.4%)	17 (0.4%)	33 (0.4%)

Baseline waist circumference (normal [men <94cm, women<80cm], increased [men 94-102cm, women 80-88cm], substantially increased [men >102cm, women > 88cm])
Region 'Others': New Zealand, South Africa, Australia
Multiple: Subjects who reported that they belong to more than one race.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:28
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4.4 Baseline characteristics

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline potassium (mmol/L)			
n	3980	3980	7960
Arithm. Mean	4.37	4.38	4.37
Arithm. SD	0.45	0.45	0.45
Min	2.6	2.6	2.6
Q1	4.10	4.10	4.10
Median	4.40	4.40	4.40
Q3	4.70	4.70	4.70
Max	6.3	6.9	6.9
Baseline ser. potassium (mmol/L) cat.(N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
<= 4.5 mmol/L	2661 (66.8%)	2635 (66.2%)	5296 (66.5%)
> 4.5 mmol/L	1319 (33.1%)	1345 (33.8%)	2664 (33.5%)
Base. ser. potassium (mmol/L) cat.10 (N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
<=4.8 mmol/L	3432 (86.2%)	3451 (86.7%)	6883 (86.4%)
>4.8 to <=5.0 mmol/L	282 (7.1%)	267 (6.7%)	549 (6.9%)
>5.0 mmol/L	266 (6.7%)	262 (6.6%)	528 (6.6%)
Basel. potass (mmol/L) median FAS (N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
<= 4.30 mmol/L (median in FAS)	1934 (48.6%)	1915 (48.1%)	3849 (48.3%)
> 4.30 mmol/L (median in FAS)	2046 (51.4%)	2065 (51.9%)	4111 (51.6%)
Basel. potass (mmol/L) quartiles FAS (N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
<=4.1 mmol/L (<= Q1 in FAS)	1177 (29.6%)	1175 (29.5%)	2352 (29.5%)
>4.1 and <=4.3 mmol/L (>Q1 and <=Q2 in FAS)	757 (19.0%)	740 (18.6%)	1497 (18.8%)
>4.3 and <=4.6 mmol/L (>Q2 and <=Q3 in FAS)	1042 (26.2%)	1043 (26.2%)	2085 (26.2%)
>4.6 mmol/L (>Q3 in FAS)	1004 (25.2%)	1022 (25.7%)	2026 (25.4%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline Systolic Blood Pressure (mmHg)			
n	3978	3980	7958
Arithm. Mean	136.85	136.73	136.79
Arithm. SD	14.54	14.60	14.57
Min	77.0	82.3	77.0
Q1	127.33	127.00	127.00
Median	137.00	137.00	137.00
Q3	146.67	147.33	147.00
Max	197.0	195.3	197.0
Baseline SBP (mmHg) category (N)			
missing	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
< 130 mmHg	1218 (30.6%)	1221 (30.7%)	2439 (30.6%)
130 - < 160 mmHg	2593 (65.1%)	2596 (65.2%)	5189 (65.2%)
>= 160 mmHg	167 (4.2%)	163 (4.1%)	330 (4.1%)
Baseline SBP (mmHg) median for FAS (N)			
missing	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
<= 137.00 mmHg (median in FAS)	1996 (50.1%)	1993 (50.1%)	3989 (50.1%)
> 137.00 mmHg (median in FAS)	1982 (49.8%)	1987 (49.9%)	3969 (49.8%)
Baseline Diastolic Blood Pressure (mmHg)			
n	3978	3980	7958
Arithm. Mean	75.10	74.96	75.03
Arithm. SD	9.78	9.71	9.75
Min	34.7	44.3	34.7
Q1	68.67	68.67	68.67
Median	75.33	75.33	75.33
Q3	81.67	81.67	81.67
Max	109.3	107.7	109.3
Baseline Heart Rate (BEATS/MIN)			
n	3976	3980	7956
Arithm. Mean	71.98	71.75	71.87
Arithm. SD	11.62	11.45	11.54
Min	37.0	35.3	35.3
Q1	64.00	63.33	63.67
Median	71.33	71.00	71.33
Q3	79.17	79.33	79.33
Max	155.7	136.0	155.7

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline eGFR (mL/min/1.73m2)			
n	3980	3980	7960
Arithm. Mean	43.88	43.90	43.89
Arithm. SD	11.38	11.34	11.36
Min	15.8	15.8	15.8
Q1	35.10	35.15	35.10
Median	43.25	43.20	43.20
Q3	51.60	51.80	51.70
Max	107.2	109.5	109.5
Baseline eGFR (mL/min/1.73m2) cat.(N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
< 25 mL/min/1.73m2	80 (2.0%)	81 (2.0%)	161 (2.0%)
25 - < 45 mL/min/1.73m2	2090 (52.5%)	2100 (52.7%)	4190 (52.6%)
45 - < 60 mL/min/1.73m2	1490 (37.4%)	1485 (37.3%)	2975 (37.4%)
>= 60 mL/min/1.73m2	320 (8.0%)	314 (7.9%)	634 (8.0%)
Baseline eGFR (mL/min/1.73m2) cat. 4(N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
< 30 mL/min/1.73m2	436 (11.0%)	448 (11.3%)	884 (11.1%)
30 - < 60 mL/min/1.73m2	3224 (81.0%)	3218 (80.8%)	6442 (80.9%)
60 - < 90 mL/min/1.73m2	314 (7.9%)	308 (7.7%)	622 (7.8%)
>= 90 mL/min/1.73m2	6 (0.2%)	6 (0.2%)	12 (0.2%)
Screening eGFR (mL/min/1.73m2)			
n	3979	3980	7959
Arithm. Mean	43.14	43.30	43.22
Arithm. SD	9.59	9.52	9.56
Min	25.0	21.6	21.6
Q1	35.30	35.40	35.40
Median	43.40	43.50	43.50
Q3	51.30	51.35	51.30
Max	59.9	69.1	69.1
Screening eGFR (mL/min/1.73m2) cat.(N)			
missing	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
< 25 mL/min/1.73m2	0	2 (<0.1%)	2 (<0.1%)
25 - < 45 mL/min/1.73m2	2197 (55.2%)	2175 (54.6%)	4372 (54.9%)
45 - < 60 mL/min/1.73m2	1782 (44.8%)	1802 (45.3%)	3584 (45.0%)
>= 60 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Screening eGFR (mL/min/1.73m2) cat. 2			
missing	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
< 30 mL/min/1.73m2	438 (11.0%)	386 (9.7%)	824 (10.3%)
30 - < 60 mL/min/1.73m2	3541 (88.9%)	3593 (90.2%)	7134 (89.6%)
60 - < 90 mL/min/1.73m2	0	1 (<0.1%)	1 (<0.1%)
Baseline UACR (mg/g)			
n	3979	3981	7960
Geom. Mean	392.04	404.24	398.09
Geom. SD	3.90	3.85	3.87
Min	1.8	5.0	1.8
Q1	138.00	140.72	139.65
Median	444.66	452.45	448.21
Q3	1126.00	1183.61	1154.03
Max	7692.3	8806.2	8806.2
Baseline albuminuria (mg/g) cat. (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Normalbuminuria (UACR < 30 mg/g)	98 (2.5%)	84 (2.1%)	182 (2.3%)
High albuminuria (30 mg/g - < 300 mg/g)	1509 (37.9%)	1507 (37.8%)	3016 (37.9%)
Very high albuminuria (>= 300 mg/g)	2372 (59.6%)	2390 (60.0%)	4762 (59.8%)
Baseline UACR (mg/g) cat. median fas (N)			
missing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
<= 514.7 mg/g (median in FAS)	2129 (53.5%)	2109 (53.0%)	4238 (53.2%)
> 514.7 mg/g (median in FAS)	1850 (46.5%)	1872 (47.0%)	3722 (46.7%)
Base eGFR (25-< 45) + potass. > 4.5 (N)			
missing	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
NO	3217 (80.8%)	3241 (81.4%)	6458 (81.1%)
YES	763 (19.2%)	739 (18.6%)	1502 (18.9%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Baseline Creatinine (mg/dL)			
n	3980	3980	7960
Arithm. Mean	1.56	1.57	1.57
Arithm. SD	0.39	0.40	0.39
Min	0.6	0.6	0.6
Q1	1.28	1.29	1.28
Median	1.50	1.52	1.50
Q3	1.80	1.80	1.80
Max	3.4	4.6	4.6
Baseline Albumin (g/dL) in Serum			
n	3980	3980	7960
Arithm. Mean	4.16	4.16	4.16
Arithm. SD	0.33	0.33	0.33
Min	2.0	2.6	2.0
Q1	4.00	4.00	4.00
Median	4.20	4.20	4.20
Q3	4.40	4.40	4.40
Max	5.3	5.2	5.3
Baseline Hemoglobin (g/dL) in Blood			
n	3974	3978	7952
Arithm. Mean	13.02	13.02	13.02
Arithm. SD	1.68	1.68	1.68
Min	6.8	7.7	6.8
Q1	11.80	11.80	11.80
Median	13.00	13.00	13.00
Q3	14.10	14.20	14.20
Max	19.4	19.7	19.7
Baseline Hemoglobin A1C (%)			
n	3971	3975	7946
Arithm. Mean	7.63	7.60	7.62
Arithm. SD	1.31	1.31	1.31
Min	4.3	3.8	3.8
Q1	6.70	6.60	6.70
Median	7.50	7.40	7.40
Q3	8.40	8.30	8.40
Max	12.5	12.9	12.9

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Basel. Hemoglobin A1C % cat. 2 (N)			
missing	10 (0.3%)	7 (0.2%)	17 (0.2%)
<= 7.5%	2084 (52.3%)	2180 (54.7%)	4264 (53.5%)
> 7.5%	1887 (47.4%)	1795 (45.1%)	3682 (46.2%)
Basel. HBA1C (%) quartiles FAS (N)			
missing	10 (0.3%)	7 (0.2%)	17 (0.2%)
<=6.7 % (<= Q1 in FAS)	1085 (27.3%)	1142 (28.7%)	2227 (28.0%)
>6.7 and <=7.5 % (>Q1 and <=Q2 in FAS)	999 (25.1%)	1038 (26.1%)	2037 (25.6%)
>7.5 and <=8.5 % (>Q2 and <=Q3 in FAS)	991 (24.9%)	948 (23.8%)	1939 (24.4%)
>8.5 % (>Q3 in FAS)	896 (22.5%)	847 (21.3%)	1743 (21.9%)
Baseline C Reactive Protein (mg/L)			
n	3980	3979	7959
Arithm. Mean	4.76	4.63	4.70
Arithm. SD	9.37	8.77	9.07
Min	0.1	0.1	0.1
Q1	0.94	0.95	0.95
Median	2.25	2.23	2.24
Q3	5.26	5.13	5.21
Max	160.0	184.0	184.0
Basel. C Reactive Protein Quartiles (N)			
missing	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
<=0.95 % (<= Q1 in FAS)	1007 (25.3%)	985 (24.7%)	1992 (25.0%)
>0.95 and <=2.21 % (>Q1 and <=Q2 in FAS)	962 (24.2%)	995 (25.0%)	1957 (24.6%)
>2.21 and <=5.13 % (>Q2 and <=Q3 in FAS)	983 (24.7%)	1005 (25.2%)	1988 (25.0%)
>5.13 % (>Q3 in FAS)	1028 (25.8%)	994 (25.0%)	2022 (25.4%)
Stratification factor 3 (N)			
CVD present	2080 (52.2%)	2064 (51.8%)	4144 (52.0%)
CVD absent	1901 (47.8%)	1918 (48.2%)	3819 (48.0%)
Hyperkalemia (based on MLG) in MH (N)			
NO	3883 (97.5%)	3883 (97.5%)	7766 (97.5%)
YES	98 (2.5%)	99 (2.5%)	197 (2.5%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Hepatic impairment in medical history(N)			
NO	3339 (83.9%)	3377 (84.8%)	6716 (84.3%)
YES	642 (16.1%)	605 (15.2%)	1247 (15.7%)
Child Pugh (N)			
missing	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
likely Child Pugh A	3796 (95.4%)	3803 (95.5%)	7599 (95.4%)
likely Child Pugh B	177 (4.4%)	173 (4.3%)	350 (4.4%)
certain Child Pugh B	5 (0.1%)	4 (0.1%)	9 (0.1%)
Duration of diabetes (in years) (N)			
n	3973	3978	7951
Arithm. Mean	16.47	16.44	16.45
Arithm. SD	9.04	8.94	8.99
Min	0.0	0.1	0.0
Q1	10.12	10.12	10.12
Median	15.91	16.12	16.10
Q3	21.27	21.45	21.32
Max	61.3	62.1	62.1
ACEI use (N)			
NO	2561 (64.3%)	2535 (63.7%)	5096 (64.0%)
YES	1420 (35.7%)	1447 (36.3%)	2867 (36.0%)
ARB use (N)			
NO	1425 (35.8%)	1449 (36.4%)	2874 (36.1%)
YES	2556 (64.2%)	2533 (63.6%)	5089 (63.9%)
Beta blocker use at baseline (N)			
NO	1826 (45.9%)	1818 (45.7%)	3644 (45.8%)
YES	2155 (54.1%)	2164 (54.3%)	4319 (54.2%)
Diuretic use at baseline (N)			
NO	1729 (43.4%)	1682 (42.2%)	3411 (42.8%)
YES	2252 (56.6%)	2300 (57.8%)	4552 (57.2%)
Statins use at baseline (N)			
NO	968 (24.3%)	955 (24.0%)	1923 (24.1%)
YES	3013 (75.7%)	3027 (76.0%)	6040 (75.9%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Anti-diabetic use at baseline (N)			
NO	133 (3.3%)	112 (2.8%)	245 (3.1%)
YES	3848 (96.7%)	3870 (97.2%)	7718 (96.9%)
Insul. and analo. use at baseline (N)			
NO	1533 (38.5%)	1603 (40.3%)	3136 (39.4%)
YES	2448 (61.5%)	2379 (59.7%)	4827 (60.6%)
Dip pep 4 inhibitors use at baseline (N)			
NO	2886 (72.5%)	2890 (72.6%)	5776 (72.5%)
YES	1095 (27.5%)	1092 (27.4%)	2187 (27.5%)
GLP1 agonists use at baseline (N)			
NO	3694 (92.8%)	3708 (93.1%)	7402 (93.0%)
YES	287 (7.2%)	274 (6.9%)	561 (7.0%)
SGLT-2 inhib. use at baseline (N)			
NO	3795 (95.3%)	3785 (95.1%)	7580 (95.2%)
YES	186 (4.7%)	197 (4.9%)	383 (4.8%)
Biguanides use at baseline (N)			
NO	2158 (54.2%)	2178 (54.7%)	4336 (54.5%)
YES	1823 (45.8%)	1804 (45.3%)	3627 (45.5%)
Sulfonamides use at baseline (N)			
NO	2985 (75.0%)	3006 (75.5%)	5991 (75.2%)
YES	996 (25.0%)	976 (24.5%)	1972 (24.8%)
Alpha gluc. inhib. use at baseline (N)			
NO	3781 (95.0%)	3775 (94.8%)	7556 (94.9%)
YES	200 (5.0%)	207 (5.2%)	407 (5.1%)
Meglitinides use at baseline (N)			
NO	3775 (94.8%)	3779 (94.9%)	7554 (94.9%)
YES	206 (5.2%)	203 (5.1%)	409 (5.1%)

Table 4.4 / 1: Baseline characteristics (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Thiazolidinediones use at baseline (N)			
NO	3808 (95.7%)	3820 (95.9%)	7628 (95.8%)
YES	173 (4.3%)	162 (4.1%)	335 (4.2%)
Potassium supplement use at baseline (N)			
NO	3841 (96.5%)	3850 (96.7%)	7691 (96.6%)
YES	140 (3.5%)	132 (3.3%)	272 (3.4%)
Potassium lowering use at baseline (N)			
NO	3900 (98.0%)	3905 (98.1%)	7805 (98.0%)
YES	81 (2.0%)	77 (1.9%)	158 (2.0%)
Potency CYP3A4 inhibitor at baseline (N)			
strong	42 (1.1%)	34 (0.9%)	76 (1.0%)
unclassified	56 (1.4%)	50 (1.3%)	106 (1.3%)
moderate	88 (2.2%)	93 (2.3%)	181 (2.3%)
weak	2474 (62.1%)	2461 (61.8%)	4935 (62.0%)
none	1321 (33.2%)	1344 (33.8%)	2665 (33.5%)
Potency CYP3A4 inducer at baseline (N)			
strong	9 (0.2%)	7 (0.2%)	16 (0.2%)
unclassified	26 (0.7%)	25 (0.6%)	51 (0.6%)
moderate	19 (0.5%)	17 (0.4%)	36 (0.5%)
weak	158 (4.0%)	172 (4.3%)	330 (4.1%)
none	3769 (94.7%)	3761 (94.5%)	7530 (94.6%)

For classification of intake of CYP3A4 inhibitors/inducers into categories in case of multiple potencies the maximum potency will be used with the following order: strong, unclassified, moderate, weak, none.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adsl.sas 26JAN2023 15:28
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4.5 Medical History

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Number (%) of subjects with at least one medical history finding	3981 (100.0%)	3982 (100.0%)	7963 (100.0%)
Blood and lymphatic system disorders	749 (18.8%)	738 (18.5%)	1487 (18.7%)
Anaemia	467 (11.7%)	458 (11.5%)	925 (11.6%)
Anaemia folate deficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaemia macrocytic	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Anaemia megaloblastic	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Anaemia of chronic disease	13 (0.3%)	8 (0.2%)	21 (0.3%)
Anaemia vitamin B12 deficiency	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Antiphospholipid syndrome	1 (<0.1%)	0	1 (<0.1%)
Aplastic anaemia	0	1 (<0.1%)	1 (<0.1%)
Blood loss anaemia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bone marrow oedema	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coagulopathy	0	2 (<0.1%)	2 (<0.1%)
Cytopenia	0	1 (<0.1%)	1 (<0.1%)
Eosinophilia	4 (0.1%)	7 (0.2%)	11 (0.1%)
Febrile neutropenia	1 (<0.1%)	0	1 (<0.1%)
Haemolytic anaemia	0	1 (<0.1%)	1 (<0.1%)
Haemolytic uraemic syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haemorrhagic diathesis	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic disorder	1 (<0.1%)	0	1 (<0.1%)
Heparin-induced thrombocytopenia	1 (<0.1%)	0	1 (<0.1%)
Hyperchromic anaemia	2 (<0.1%)	0	2 (<0.1%)
Hypercoagulation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hyperfibrinogenaemia	0	1 (<0.1%)	1 (<0.1%)
Hypergammaglobulinaemia	0	2 (<0.1%)	2 (<0.1%)
Hypersplenism	0	1 (<0.1%)	1 (<0.1%)
Hyperviscosity syndrome	1 (<0.1%)	0	1 (<0.1%)
Hypochromic anaemia	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Immune thrombocytopenia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Increased tendency to bruise	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Iron deficiency anaemia	99 (2.5%)	85 (2.1%)	184 (2.3%)
Leukocytosis	9 (0.2%)	5 (0.1%)	14 (0.2%)
Leukopenia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Lymphadenitis	2 (<0.1%)	0	2 (<0.1%)
Lymphadenopathy	5 (0.1%)	5 (0.1%)	10 (0.1%)
Lymphadenopathy mediastinal	2 (<0.1%)	0	2 (<0.1%)
Lymphatic insufficiency	1 (<0.1%)	0	1 (<0.1%)
Lymphoid tissue hyperplasia	0	1 (<0.1%)	1 (<0.1%)
Lymphopenia	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Macrocytosis	0	1 (<0.1%)	1 (<0.1%)
Microcytic anaemia	5 (0.1%)	8 (0.2%)	13 (0.2%)
Microcytosis	0	2 (<0.1%)	2 (<0.1%)
Monoclonal B-cell lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Nephrogenic anaemia	69 (1.7%)	76 (1.9%)	145 (1.8%)
Normochromic anaemia	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Normochromic normocytic anaemia	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Normocytic anaemia	8 (0.2%)	15 (0.4%)	23 (0.3%)
Pancytopenia	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Pernicious anaemia	11 (0.3%)	5 (0.1%)	16 (0.2%)
Polycythaemia	5 (0.1%)	9 (0.2%)	14 (0.2%)
Retroperitoneal lymphadenopathy	0	1 (<0.1%)	1 (<0.1%)
Spleen disorder	1 (<0.1%)	0	1 (<0.1%)
Splenic calcification	0	1 (<0.1%)	1 (<0.1%)
Splenic granuloma	1 (<0.1%)	0	1 (<0.1%)
Splenomegaly	13 (0.3%)	14 (0.4%)	27 (0.3%)
Thrombocytopenia	32 (0.8%)	33 (0.8%)	65 (0.8%)
Thrombocytosis	5 (0.1%)	4 (0.1%)	9 (0.1%)
Cardiac disorders	2120 (53.3%)	2128 (53.4%)	4248 (53.3%)
Acute coronary syndrome	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Acute left ventricular failure	3 (<0.1%)	0	3 (<0.1%)
Acute myocardial infarction	12 (0.3%)	11 (0.3%)	23 (0.3%)
Angina pectoris	195 (4.9%)	201 (5.0%)	396 (5.0%)
Angina unstable	31 (0.8%)	32 (0.8%)	63 (0.8%)
Aortic valve calcification	3 (<0.1%)	0	3 (<0.1%)
Aortic valve disease	7 (0.2%)	7 (0.2%)	14 (0.2%)
Aortic valve disease mixed	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic valve incompetence	24 (0.6%)	30 (0.8%)	54 (0.7%)
Aortic valve sclerosis	6 (0.2%)	9 (0.2%)	15 (0.2%)
Aortic valve stenosis	19 (0.5%)	18 (0.5%)	37 (0.5%)
Arrhythmia	40 (1.0%)	34 (0.9%)	74 (0.9%)
Arrhythmia supraventricular	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Arteriosclerosis coronary artery	44 (1.1%)	53 (1.3%)	97 (1.2%)
Atrial enlargement	0	1 (<0.1%)	1 (<0.1%)
Atrial fibrillation	385 (9.7%)	348 (8.7%)	733 (9.2%)
Atrial flutter	31 (0.8%)	38 (1.0%)	69 (0.9%)
Atrial hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Atrial tachycardia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atrioventricular block	11 (0.3%)	14 (0.4%)	25 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Atrioventricular block complete	12 (0.3%)	11 (0.3%)	23 (0.3%)
Atrioventricular block first degree	77 (1.9%)	82 (2.1%)	159 (2.0%)
Atrioventricular block second degree	17 (0.4%)	4 (0.1%)	21 (0.3%)
Bifascicular block	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Bradyarrhythmia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bradycardia	26 (0.7%)	16 (0.4%)	42 (0.5%)
Brugada syndrome	1 (<0.1%)	0	1 (<0.1%)
Bundle branch block	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Bundle branch block bilateral	0	1 (<0.1%)	1 (<0.1%)
Bundle branch block left	73 (1.8%)	58 (1.5%)	131 (1.6%)
Bundle branch block right	63 (1.6%)	80 (2.0%)	143 (1.8%)
Cardiac aneurysm	0	5 (0.1%)	5 (<0.1%)
Cardiac arrest	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac discomfort	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Cardiac dysfunction	0	3 (<0.1%)	3 (<0.1%)
Cardiac failure	67 (1.7%)	109 (2.7%)	176 (2.2%)
Cardiac failure acute	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Cardiac failure chronic	139 (3.5%)	158 (4.0%)	297 (3.7%)
Cardiac failure congestive	76 (1.9%)	70 (1.8%)	146 (1.8%)
Cardiac flutter	2 (<0.1%)	0	2 (<0.1%)
Cardiac hypertrophy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Cardiac septal hypertrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cardiac tamponade	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiac valve disease	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Cardiac valve sclerosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiac ventricular thrombosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardio-respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Cardiogenic shock	0	4 (0.1%)	4 (<0.1%)
Cardiomegaly	13 (0.3%)	14 (0.4%)	27 (0.3%)
Cardiomyopathy	18 (0.5%)	24 (0.6%)	42 (0.5%)
Cardiorenal syndrome	0	2 (<0.1%)	2 (<0.1%)
Cardiovascular disorder	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Cardiovascular insufficiency	3 (<0.1%)	0	3 (<0.1%)
Carditis	0	1 (<0.1%)	1 (<0.1%)
Chronic left ventricular failure	17 (0.4%)	10 (0.3%)	27 (0.3%)
Chronic right ventricular failure	1 (<0.1%)	0	1 (<0.1%)
Chronotropic incompetence	0	1 (<0.1%)	1 (<0.1%)
Conduction disorder	2 (<0.1%)	0	2 (<0.1%)
Congestive cardiomyopathy	15 (0.4%)	7 (0.2%)	22 (0.3%)
Cor pulmonale	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Coronary artery disease	1365 (34.3%)	1415 (35.5%)	2780 (34.9%)
Coronary artery insufficiency	0	1 (<0.1%)	1 (<0.1%)
Coronary artery occlusion	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Coronary artery stenosis	13 (0.3%)	11 (0.3%)	24 (0.3%)
Defect conduction intraventricular	4 (0.1%)	5 (0.1%)	9 (0.1%)
Diabetic cardiomyopathy	0	1 (<0.1%)	1 (<0.1%)
Diastolic dysfunction	23 (0.6%)	27 (0.7%)	50 (0.6%)
Dilatation atrial	2 (<0.1%)	0	2 (<0.1%)
Dressler's syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Extrasystoles	5 (0.1%)	8 (0.2%)	13 (0.2%)
Heart valve incompetence	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hypertensive cardiomyopathy	12 (0.3%)	10 (0.3%)	22 (0.3%)
Hypertensive heart disease	70 (1.8%)	68 (1.7%)	138 (1.7%)
Intracardiac mass	0	1 (<0.1%)	1 (<0.1%)
Intracardiac thrombus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	21 (0.5%)	13 (0.3%)	34 (0.4%)
Left atrial dilatation	9 (0.2%)	6 (0.2%)	15 (0.2%)
Left atrial enlargement	6 (0.2%)	10 (0.3%)	16 (0.2%)
Left atrial hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dilatation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dysfunction	12 (0.3%)	18 (0.5%)	30 (0.4%)
Left ventricular enlargement	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Left ventricular failure	18 (0.5%)	30 (0.8%)	48 (0.6%)
Left ventricular hypertrophy	124 (3.1%)	98 (2.5%)	222 (2.8%)
Metabolic cardiomyopathy	11 (0.3%)	5 (0.1%)	16 (0.2%)
Microvascular coronary artery disease	1 (<0.1%)	0	1 (<0.1%)
Mitral valve calcification	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Mitral valve disease	8 (0.2%)	7 (0.2%)	15 (0.2%)
Mitral valve incompetence	81 (2.0%)	112 (2.8%)	193 (2.4%)
Mitral valve prolapse	7 (0.2%)	5 (0.1%)	12 (0.2%)
Mitral valve sclerosis	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Mitral valve stenosis	6 (0.2%)	6 (0.2%)	12 (0.2%)
Myocardial fibrosis	12 (0.3%)	13 (0.3%)	25 (0.3%)
Myocardial infarction	677 (17.0%)	680 (17.1%)	1357 (17.0%)
Myocardial ischaemia	184 (4.6%)	158 (4.0%)	342 (4.3%)
Myocardial necrosis	0	2 (<0.1%)	2 (<0.1%)
Myocarditis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nodal arrhythmia	1 (<0.1%)	0	1 (<0.1%)
Nodal rhythm	0	1 (<0.1%)	1 (<0.1%)
Non-obstructive cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Palpitations	11 (0.3%)	14 (0.4%)	25 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Pericardial cyst	1 (<0.1%)	0	1 (<0.1%)
Pericardial effusion	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Pericarditis	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Pericarditis adhesive	0	2 (<0.1%)	2 (<0.1%)
Pericarditis constrictive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pleuropericarditis	1 (<0.1%)	0	1 (<0.1%)
Prinzmetal angina	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Pulmonary valve disease	1 (<0.1%)	0	1 (<0.1%)
Pulmonary valve incompetence	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pulmonary valve stenosis	0	1 (<0.1%)	1 (<0.1%)
Restrictive cardiomyopathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rheumatic heart disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Right atrial dilatation	2 (<0.1%)	0	2 (<0.1%)
Right ventricular failure	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Right ventricular hypertrophy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Silent myocardial infarction	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Sinoatrial block	2 (<0.1%)	0	2 (<0.1%)
Sinus arrest	0	1 (<0.1%)	1 (<0.1%)
Sinus arrhythmia	6 (0.2%)	4 (0.1%)	10 (0.1%)
Sinus bradycardia	36 (0.9%)	27 (0.7%)	63 (0.8%)
Sinus node dysfunction	17 (0.4%)	9 (0.2%)	26 (0.3%)
Sinus tachycardia	11 (0.3%)	7 (0.2%)	18 (0.2%)
Stress cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Supraventricular extrasystoles	27 (0.7%)	18 (0.5%)	45 (0.6%)
Supraventricular tachyarrhythmia	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	20 (0.5%)	8 (0.2%)	28 (0.4%)
Systolic dysfunction	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Tachyarrhythmia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Tachycardia	10 (0.3%)	9 (0.2%)	19 (0.2%)
Tachycardia induced cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Tachycardia paroxysmal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thyrotoxic cardiomyopathy	1 (<0.1%)	0	1 (<0.1%)
Tricuspid valve disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tricuspid valve incompetence	45 (1.1%)	45 (1.1%)	90 (1.1%)
Trifascicular block	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular arrhythmia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Ventricular dysfunction	1 (<0.1%)	0	1 (<0.1%)
Ventricular dyskinesia	1 (<0.1%)	0	1 (<0.1%)
Ventricular extrasystoles	40 (1.0%)	39 (1.0%)	79 (1.0%)
Ventricular fibrillation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ventricular hypertrophy	2 (<0.1%)	5 (0.1%)	7 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Ventricular hypokinesia	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Ventricular remodelling	1 (<0.1%)	0	1 (<0.1%)
Ventricular tachycardia	7 (0.2%)	6 (0.2%)	13 (0.2%)
Wolff-Parkinson-White syndrome	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Congenital, familial and genetic disorders	218 (5.5%)	173 (4.3%)	391 (4.9%)
Accessory kidney	0	1 (<0.1%)	1 (<0.1%)
Accessory spleen	1 (<0.1%)	0	1 (<0.1%)
Adenomatous polyposis coli	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Anomalous arrangement of pancreaticobiliary duct	0	1 (<0.1%)	1 (<0.1%)
Antithrombin III deficiency	0	1 (<0.1%)	1 (<0.1%)
Arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Bicuspid aortic valve	0	2 (<0.1%)	2 (<0.1%)
Biliary hamartoma	0	1 (<0.1%)	1 (<0.1%)
Birth mark	2 (<0.1%)	0	2 (<0.1%)
Breast malformation	1 (<0.1%)	0	1 (<0.1%)
Cardiac septal defect	1 (<0.1%)	0	1 (<0.1%)
Cataract congenital	1 (<0.1%)	0	1 (<0.1%)
Cerebrovascular arteriovenous malformation	0	1 (<0.1%)	1 (<0.1%)
Coarctation of the aorta	1 (<0.1%)	0	1 (<0.1%)
Colour blindness	0	1 (<0.1%)	1 (<0.1%)
Congenital aortic dilatation	1 (<0.1%)	0	1 (<0.1%)
Congenital arterial malformation	1 (<0.1%)	0	1 (<0.1%)
Congenital cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Congenital cystic kidney disease	5 (0.1%)	11 (0.3%)	16 (0.2%)
Congenital flat feet	1 (<0.1%)	0	1 (<0.1%)
Congenital hepatobiliary anomaly	0	1 (<0.1%)	1 (<0.1%)
Congenital hypercoagulation	1 (<0.1%)	0	1 (<0.1%)
Congenital monorchidism	1 (<0.1%)	0	1 (<0.1%)
Congenital neurological disorder	0	1 (<0.1%)	1 (<0.1%)
Congenital neuropathy	0	1 (<0.1%)	1 (<0.1%)
Congenital nystagmus	1 (<0.1%)	0	1 (<0.1%)
Congenital renal cyst	10 (0.3%)	8 (0.2%)	18 (0.2%)
Congenital scoliosis	0	1 (<0.1%)	1 (<0.1%)
Congenital spondylolisthesis	1 (<0.1%)	0	1 (<0.1%)
Congenital ureteric anomaly	1 (<0.1%)	0	1 (<0.1%)
Corneal dystrophy	0	3 (<0.1%)	3 (<0.1%)
Cryptorchism	0	2 (<0.1%)	2 (<0.1%)
Cystinuria	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Dermoid cyst	1 (<0.1%)	0	1 (<0.1%)
Developmental hip dysplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dolichocolon	2 (<0.1%)	0	2 (<0.1%)
Duane's syndrome	1 (<0.1%)	0	1 (<0.1%)
Ectopic kidney	0	1 (<0.1%)	1 (<0.1%)
Ectopic thyroid	1 (<0.1%)	0	1 (<0.1%)
Exomphalos	1 (<0.1%)	0	1 (<0.1%)
Factor V Leiden carrier	0	1 (<0.1%)	1 (<0.1%)
Factor V Leiden mutation	0	2 (<0.1%)	2 (<0.1%)
Factor VIII deficiency	0	1 (<0.1%)	1 (<0.1%)
Factor X deficiency	1 (<0.1%)	0	1 (<0.1%)
Familial high density lipoprotein deficiency	1 (<0.1%)	0	1 (<0.1%)
Familial mediterranean fever	0	1 (<0.1%)	1 (<0.1%)
Familial periodic paralysis	0	1 (<0.1%)	1 (<0.1%)
Familial tremor	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fibrous dysplasia of bone	1 (<0.1%)	0	1 (<0.1%)
Fragile X syndrome	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal arteriovenous malformation	1 (<0.1%)	0	1 (<0.1%)
Gilbert's syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glucose-6-phosphate dehydrogenase deficiency	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Glycogen storage disease type I	1 (<0.1%)	0	1 (<0.1%)
Haemochromatosis trait	0	1 (<0.1%)	1 (<0.1%)
Haemophilia	0	1 (<0.1%)	1 (<0.1%)
Hamartoma	1 (<0.1%)	0	1 (<0.1%)
Hereditary ataxia	1 (<0.1%)	0	1 (<0.1%)
Hereditary haemochromatosis	1 (<0.1%)	0	1 (<0.1%)
Hereditary neuropathy with liability to pressure palsies	0	1 (<0.1%)	1 (<0.1%)
Hereditary palmoplantar keratoderma	0	1 (<0.1%)	1 (<0.1%)
Hereditary spastic paraplegia	1 (<0.1%)	0	1 (<0.1%)
Heterotaxia	1 (<0.1%)	0	1 (<0.1%)
Homocystinaemia	1 (<0.1%)	0	1 (<0.1%)
Homocystinuria	1 (<0.1%)	0	1 (<0.1%)
Hydrocele	12 (0.3%)	5 (0.1%)	17 (0.2%)
Hypertrophic cardiomyopathy	6 (0.2%)	10 (0.3%)	16 (0.2%)
Hypospadias	3 (<0.1%)	0	3 (<0.1%)
Ichthyosis	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Inborn error of bilirubin metabolism	1 (<0.1%)	0	1 (<0.1%)
Intracranial lipoma	1 (<0.1%)	0	1 (<0.1%)
Kidney duplex	1 (<0.1%)	0	1 (<0.1%)
Klinefelter's syndrome	0	1 (<0.1%)	1 (<0.1%)
Klippel-Trenaunay syndrome	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Limb malformation	1 (<0.1%)	0	1 (<0.1%)
Macroglossia	0	1 (<0.1%)	1 (<0.1%)
Methylenetetrahydrofolate reductase gene mutation	0	1 (<0.1%)	1 (<0.1%)
Muscular dystrophy	3 (<0.1%)	0	3 (<0.1%)
Myocardial bridging	1 (<0.1%)	0	1 (<0.1%)
Osteopetrosis	0	1 (<0.1%)	1 (<0.1%)
Peutz-Jeghers syndrome	1 (<0.1%)	0	1 (<0.1%)
Phimosis	16 (0.4%)	5 (0.1%)	21 (0.3%)
Polycystic liver disease	0	2 (<0.1%)	2 (<0.1%)
Porokeratosis	0	1 (<0.1%)	1 (<0.1%)
Porphyria	1 (<0.1%)	0	1 (<0.1%)
Preauricular cyst	0	1 (<0.1%)	1 (<0.1%)
Primary hypercholesterolaemia	0	2 (<0.1%)	2 (<0.1%)
Pyloric stenosis	0	1 (<0.1%)	1 (<0.1%)
Renal aplasia	8 (0.2%)	6 (0.2%)	14 (0.2%)
Renal fusion anomaly	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Renal hypoplasia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Renal malposition	0	1 (<0.1%)	1 (<0.1%)
Retinitis pigmentosa	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sacralisation	0	1 (<0.1%)	1 (<0.1%)
Sickle cell anaemia	0	1 (<0.1%)	1 (<0.1%)
Sickle cell trait	1 (<0.1%)	0	1 (<0.1%)
Spina bifida	2 (<0.1%)	0	2 (<0.1%)
Spine malformation	1 (<0.1%)	0	1 (<0.1%)
Supernumerary rib	0	1 (<0.1%)	1 (<0.1%)
Thalassaemia	4 (0.1%)	4 (0.1%)	8 (0.1%)
Thalassaemia alpha	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thalassaemia beta	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Thalassaemia minor	5 (0.1%)	5 (0.1%)	10 (0.1%)
Tilted disc syndrome	0	1 (<0.1%)	1 (<0.1%)
Transcobalamin deficiency	1 (<0.1%)	0	1 (<0.1%)
Tuberous sclerosis complex	1 (<0.1%)	0	1 (<0.1%)
Type IIa hyperlipidaemia	10 (0.3%)	7 (0.2%)	17 (0.2%)
Type IIb hyperlipidaemia	6 (0.2%)	6 (0.2%)	12 (0.2%)
Type V hyperlipidaemia	61 (1.5%)	44 (1.1%)	105 (1.3%)
Urethral atresia	1 (<0.1%)	0	1 (<0.1%)
Urinary tract malformation	1 (<0.1%)	0	1 (<0.1%)
Usher's syndrome	0	1 (<0.1%)	1 (<0.1%)
Vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery hypoplasia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitello-intestinal duct remnant	0	3 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Von Willebrand's disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Welander distal myopathy	1 (<0.1%)	0	1 (<0.1%)
Xeroderma pigmentosum	0	1 (<0.1%)	1 (<0.1%)
Ear and labyrinth disorders	246 (6.2%)	236 (5.9%)	482 (6.1%)
Auditory disorder	8 (0.2%)	2 (<0.1%)	10 (0.1%)
Aural polyp	0	1 (<0.1%)	1 (<0.1%)
Cerumen impaction	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Conductive deafness	0	1 (<0.1%)	1 (<0.1%)
Deafness	40 (1.0%)	36 (0.9%)	76 (1.0%)
Deafness bilateral	8 (0.2%)	10 (0.3%)	18 (0.2%)
Deafness neurosensory	25 (0.6%)	32 (0.8%)	57 (0.7%)
Deafness unilateral	11 (0.3%)	8 (0.2%)	19 (0.2%)
Ear canal stenosis	0	1 (<0.1%)	1 (<0.1%)
Ear discomfort	1 (<0.1%)	0	1 (<0.1%)
Ear disorder	1 (<0.1%)	0	1 (<0.1%)
Ear pain	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Ear pruritus	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	2 (<0.1%)	0	2 (<0.1%)
Excessive cerumen production	2 (<0.1%)	0	2 (<0.1%)
External ear inflammation	0	1 (<0.1%)	1 (<0.1%)
Hypoacusis	40 (1.0%)	33 (0.8%)	73 (0.9%)
Inner ear disorder	1 (<0.1%)	0	1 (<0.1%)
Meniere's disease	8 (0.2%)	9 (0.2%)	17 (0.2%)
Middle ear adhesions	0	1 (<0.1%)	1 (<0.1%)
Mixed deafness	0	2 (<0.1%)	2 (<0.1%)
Motion sickness	0	2 (<0.1%)	2 (<0.1%)
Neurosensory hypoacusis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Otolithiasis	0	1 (<0.1%)	1 (<0.1%)
Otorrhoea	2 (<0.1%)	0	2 (<0.1%)
Otosclerosis	2 (<0.1%)	0	2 (<0.1%)
Presbyacusis	4 (0.1%)	6 (0.2%)	10 (0.1%)
Sudden hearing loss	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Tinnitus	37 (0.9%)	26 (0.7%)	63 (0.8%)
Tympanic membrane perforation	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Vertigo	60 (1.5%)	54 (1.4%)	114 (1.4%)
Vertigo labyrinthine	1 (<0.1%)	0	1 (<0.1%)
Vertigo positional	13 (0.3%)	15 (0.4%)	28 (0.4%)
Vestibular ataxia	4 (0.1%)	5 (0.1%)	9 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Vestibular disorder	6 (0.2%)	4 (0.1%)	10 (0.1%)
Endocrine disorders	706 (17.7%)	678 (17.0%)	1384 (17.4%)
Acromegaly	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adrenal disorder	0	1 (<0.1%)	1 (<0.1%)
Adrenal insufficiency	0	1 (<0.1%)	1 (<0.1%)
Adrenal mass	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Androgen deficiency	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Autoimmune thyroid disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Autoimmune thyroiditis	22 (0.6%)	29 (0.7%)	51 (0.6%)
Basedow's disease	7 (0.2%)	7 (0.2%)	14 (0.2%)
Cushing's syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cushingoid	0	2 (<0.1%)	2 (<0.1%)
Diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Empty sella syndrome	0	1 (<0.1%)	1 (<0.1%)
Euthyroid sick syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Goitre	135 (3.4%)	107 (2.7%)	242 (3.0%)
Hyperaldosteronism	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Hyperparathyroidism	51 (1.3%)	41 (1.0%)	92 (1.2%)
Hyperparathyroidism primary	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Hyperparathyroidism secondary	57 (1.4%)	65 (1.6%)	122 (1.5%)
Hyperpituitarism	0	1 (<0.1%)	1 (<0.1%)
Hyperplasia adrenal	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Hyperprolactinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperthyroidism	39 (1.0%)	26 (0.7%)	65 (0.8%)
Hypogonadism	11 (0.3%)	22 (0.6%)	33 (0.4%)
Hypogonadism male	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Hypoparathyroidism	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Hypoparathyroidism secondary	0	1 (<0.1%)	1 (<0.1%)
Hypothyroidic goitre	0	2 (<0.1%)	2 (<0.1%)
Hypothyroidism	370 (9.3%)	349 (8.8%)	719 (9.0%)
Inappropriate antidiuretic hormone secretion	1 (<0.1%)	0	1 (<0.1%)
Myxoedema	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Primary hyperaldosteronism	4 (0.1%)	4 (0.1%)	8 (0.1%)
Primary hypogonadism	0	3 (<0.1%)	3 (<0.1%)
Primary hypothyroidism	10 (0.3%)	5 (0.1%)	15 (0.2%)
Secondary hyperthyroidism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Secondary hypogonadism	2 (<0.1%)	0	2 (<0.1%)
Testicular failure	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Thyroid atrophy	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Thyroid cyst	6 (0.2%)	5 (0.1%)	11 (0.1%)
Thyroid disorder	7 (0.2%)	4 (0.1%)	11 (0.1%)
Thyroid mass	41 (1.0%)	43 (1.1%)	84 (1.1%)
Thyroiditis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Thyroiditis chronic	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Thyroiditis subacute	1 (<0.1%)	0	1 (<0.1%)
Toxic goitre	1 (<0.1%)	0	1 (<0.1%)
Toxic nodular goitre	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Eye disorders	2187 (54.9%)	2178 (54.7%)	4365 (54.8%)
Age-related macular degeneration	12 (0.3%)	5 (0.1%)	17 (0.2%)
Amaurosis	4 (0.1%)	10 (0.3%)	14 (0.2%)
Amaurosis fugax	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Amblyopia	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Amblyopia strabismic	0	1 (<0.1%)	1 (<0.1%)
Angle closure glaucoma	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Aniseikonia	0	1 (<0.1%)	1 (<0.1%)
Anisometropia	0	1 (<0.1%)	1 (<0.1%)
Aphakia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arcus lipoides	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerotic retinopathy	12 (0.3%)	11 (0.3%)	23 (0.3%)
Asthenopia	7 (0.2%)	12 (0.3%)	19 (0.2%)
Astigmatism	22 (0.6%)	12 (0.3%)	34 (0.4%)
Blepharitis	10 (0.3%)	8 (0.2%)	18 (0.2%)
Blepharochalasis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blindness	8 (0.2%)	10 (0.3%)	18 (0.2%)
Blindness transient	0	1 (<0.1%)	1 (<0.1%)
Blindness unilateral	15 (0.4%)	16 (0.4%)	31 (0.4%)
Borderline glaucoma	9 (0.2%)	8 (0.2%)	17 (0.2%)
Cataract	647 (16.3%)	711 (17.9%)	1358 (17.1%)
Cataract cortical	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Cataract diabetic	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Cataract nuclear	17 (0.4%)	7 (0.2%)	24 (0.3%)
Cataract subcapsular	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Central vision loss	0	1 (<0.1%)	1 (<0.1%)
Chalazion	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Cholesterolosis bulbi	0	2 (<0.1%)	2 (<0.1%)
Chorioretinal atrophy	1 (<0.1%)	0	1 (<0.1%)
Chorioretinopathy	2 (<0.1%)	0	2 (<0.1%)
Choroidal neovascularisation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Ciliary body disorder	1 (<0.1%)	0	1 (<0.1%)
Conjunctival haemorrhage	0	6 (0.2%)	6 (<0.1%)
Conjunctival pallor	1 (<0.1%)	0	1 (<0.1%)
Conjunctivitis allergic	32 (0.8%)	20 (0.5%)	52 (0.7%)
Conjunctivochalasis	0	1 (<0.1%)	1 (<0.1%)
Corneal degeneration	1 (<0.1%)	0	1 (<0.1%)
Corneal deposits	0	1 (<0.1%)	1 (<0.1%)
Corneal disorder	0	1 (<0.1%)	1 (<0.1%)
Corneal erosion	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Corneal infiltrates	0	1 (<0.1%)	1 (<0.1%)
Corneal oedema	0	2 (<0.1%)	2 (<0.1%)
Corneal opacity	0	1 (<0.1%)	1 (<0.1%)
Corneal scar	1 (<0.1%)	0	1 (<0.1%)
Cystoid macular oedema	1 (<0.1%)	8 (0.2%)	9 (0.1%)
Dacryostenosis acquired	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Dermatochalasis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Diabetic blindness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic eye disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic ophthalmoplegia	1 (<0.1%)	0	1 (<0.1%)
Diabetic retinal oedema	18 (0.5%)	17 (0.4%)	35 (0.4%)
Diabetic retinopathy	1620 (40.7%)	1619 (40.7%)	3239 (40.7%)
Diplopia	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Dry age-related macular degeneration	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Dry eye	75 (1.9%)	67 (1.7%)	142 (1.8%)
Dysmetropsia	1 (<0.1%)	0	1 (<0.1%)
Ectropion	0	1 (<0.1%)	1 (<0.1%)
Entropion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Exfoliation glaucoma	1 (<0.1%)	0	1 (<0.1%)
Exfoliation syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Exophthalmos	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Extraocular muscle paresis	1 (<0.1%)	0	1 (<0.1%)
Exudative retinopathy	1 (<0.1%)	0	1 (<0.1%)
Eye allergy	0	2 (<0.1%)	2 (<0.1%)
Eye disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye haemorrhage	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye inflammation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye irritation	1 (<0.1%)	0	1 (<0.1%)
Eye pain	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eye pruritus	2 (<0.1%)	0	2 (<0.1%)
Eye ulcer	0	1 (<0.1%)	1 (<0.1%)
Eyelid cyst	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Eyelid oedema	0	1 (<0.1%)	1 (<0.1%)
Eyelid ptosis	9 (0.2%)	7 (0.2%)	16 (0.2%)
Floppy eyelid syndrome	0	1 (<0.1%)	1 (<0.1%)
Glaucoma	226 (5.7%)	234 (5.9%)	460 (5.8%)
Hyalosis asteroid	1 (<0.1%)	0	1 (<0.1%)
Hypermetropia	23 (0.6%)	26 (0.7%)	49 (0.6%)
Iridocyclitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Iris disorder	1 (<0.1%)	0	1 (<0.1%)
Iris neovascularisation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Keratitis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Keratoconus	0	2 (<0.1%)	2 (<0.1%)
Keratomalacia	0	1 (<0.1%)	1 (<0.1%)
Keratopathy	0	1 (<0.1%)	1 (<0.1%)
Lacrimation decreased	5 (0.1%)	4 (0.1%)	9 (0.1%)
Lacrimation increased	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Lagophthalmos	2 (<0.1%)	0	2 (<0.1%)
Lenticular opacities	0	2 (<0.1%)	2 (<0.1%)
Macular degeneration	32 (0.8%)	27 (0.7%)	59 (0.7%)
Macular fibrosis	11 (0.3%)	11 (0.3%)	22 (0.3%)
Macular hole	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Macular ischaemia	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	29 (0.7%)	35 (0.9%)	64 (0.8%)
Macular rupture	0	1 (<0.1%)	1 (<0.1%)
Macular scar	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Macular thickening	0	1 (<0.1%)	1 (<0.1%)
Maculopathy	21 (0.5%)	14 (0.4%)	35 (0.4%)
Meibomian gland dysfunction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mydriasis	1 (<0.1%)	0	1 (<0.1%)
Myopia	33 (0.8%)	31 (0.8%)	64 (0.8%)
Myopic chorioretinal degeneration	2 (<0.1%)	0	2 (<0.1%)
Narrow anterior chamber angle	0	1 (<0.1%)	1 (<0.1%)
Neovascular age-related macular degeneration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-proliferative retinopathy	0	1 (<0.1%)	1 (<0.1%)
Normal tension glaucoma	2 (<0.1%)	0	2 (<0.1%)
Ocular discomfort	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Ocular hypertension	9 (0.2%)	13 (0.3%)	22 (0.3%)
Ocular ischaemic syndrome	3 (<0.1%)	0	3 (<0.1%)
Ocular myasthenia	0	2 (<0.1%)	2 (<0.1%)
Open angle glaucoma	14 (0.4%)	16 (0.4%)	30 (0.4%)
Ophthalmoplegia	3 (<0.1%)	0	3 (<0.1%)
Optic atrophy	7 (0.2%)	2 (<0.1%)	9 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Optic disc traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Optic ischaemic neuropathy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Optic nerve cupping	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Optic neuropathy	1 (<0.1%)	0	1 (<0.1%)
Papilloedema	0	1 (<0.1%)	1 (<0.1%)
Pathologic myopia	4 (0.1%)	0	4 (<0.1%)
Periorbital oedema	1 (<0.1%)	0	1 (<0.1%)
Photophobia	0	2 (<0.1%)	2 (<0.1%)
Pinguecula	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Posterior capsule opacification	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Presbyopia	27 (0.7%)	38 (1.0%)	65 (0.8%)
Pseudo-blepharoptosis	0	1 (<0.1%)	1 (<0.1%)
Pseudopapilloedema	1 (<0.1%)	0	1 (<0.1%)
Pterygium	6 (0.2%)	8 (0.2%)	14 (0.2%)
Punctate keratitis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pupils unequal	1 (<0.1%)	0	1 (<0.1%)
Refraction disorder	5 (0.1%)	9 (0.2%)	14 (0.2%)
Retinal aneurysm	0	1 (<0.1%)	1 (<0.1%)
Retinal artery embolism	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal artery occlusion	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Retinal artery stenosis	1 (<0.1%)	0	1 (<0.1%)
Retinal artery thrombosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Retinal degeneration	8 (0.2%)	1 (<0.1%)	9 (0.1%)
Retinal depigmentation	1 (<0.1%)	0	1 (<0.1%)
Retinal detachment	20 (0.5%)	13 (0.3%)	33 (0.4%)
Retinal disorder	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Retinal drusen	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Retinal dystrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal haemorrhage	6 (0.2%)	14 (0.4%)	20 (0.3%)
Retinal infarction	0	1 (<0.1%)	1 (<0.1%)
Retinal neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Retinal oedema	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Retinal pigment epitheliopathy	0	1 (<0.1%)	1 (<0.1%)
Retinal tear	4 (0.1%)	6 (0.2%)	10 (0.1%)
Retinal vascular disorder	10 (0.3%)	9 (0.2%)	19 (0.2%)
Retinal vascular occlusion	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Retinal vascular thrombosis	0	3 (<0.1%)	3 (<0.1%)
Retinal vein occlusion	9 (0.2%)	11 (0.3%)	20 (0.3%)
Retinal vein thrombosis	5 (0.1%)	0	5 (<0.1%)
Retinopathy	5 (0.1%)	10 (0.3%)	15 (0.2%)
Retinopathy hypertensive	64 (1.6%)	45 (1.1%)	109 (1.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Retinopathy proliferative	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Retinoschisis	2 (<0.1%)	0	2 (<0.1%)
Rhegmatogenous retinal detachment	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Scleral haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Scleritis	1 (<0.1%)	0	1 (<0.1%)
Strabismus	6 (0.2%)	7 (0.2%)	13 (0.2%)
Swelling of eyelid	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tractional retinal detachment	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Trichiasis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Ulcerative keratitis	0	2 (<0.1%)	2 (<0.1%)
Uveitis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Vernal keratoconjunctivitis	0	1 (<0.1%)	1 (<0.1%)
Vision blurred	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Visual acuity reduced	5 (0.1%)	7 (0.2%)	12 (0.2%)
Visual impairment	14 (0.4%)	21 (0.5%)	35 (0.4%)
Vitreoretinal traction syndrome	0	1 (<0.1%)	1 (<0.1%)
Vitreous degeneration	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Vitreous detachment	4 (0.1%)	6 (0.2%)	10 (0.1%)
Vitreous disorder	0	1 (<0.1%)	1 (<0.1%)
Vitreous floaters	6 (0.2%)	4 (0.1%)	10 (0.1%)
Vitreous haemorrhage	32 (0.8%)	22 (0.6%)	54 (0.7%)
Vitreous opacities	7 (0.2%)	5 (0.1%)	12 (0.2%)
Vitreous prolapse	1 (<0.1%)	0	1 (<0.1%)
Xerophthalmia	0	2 (<0.1%)	2 (<0.1%)
Gastrointestinal disorders	1536 (38.6%)	1545 (38.8%)	3081 (38.7%)
Abdominal adhesions	0	2 (<0.1%)	2 (<0.1%)
Abdominal discomfort	5 (0.1%)	7 (0.2%)	12 (0.2%)
Abdominal distension	7 (0.2%)	5 (0.1%)	12 (0.2%)
Abdominal hernia	26 (0.7%)	28 (0.7%)	54 (0.7%)
Abdominal incarcerated hernia	0	2 (<0.1%)	2 (<0.1%)
Abdominal mass	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal pain	22 (0.6%)	18 (0.5%)	40 (0.5%)
Abdominal pain lower	2 (<0.1%)	0	2 (<0.1%)
Abdominal pain upper	14 (0.4%)	13 (0.3%)	27 (0.3%)
Abdominal symptom	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal wall haematoma	1 (<0.1%)	0	1 (<0.1%)
Abdominal wall oedema	0	1 (<0.1%)	1 (<0.1%)
Abnormal faeces	1 (<0.1%)	0	1 (<0.1%)
Acid peptic disease	7 (0.2%)	8 (0.2%)	15 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Alcoholic pancreatitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal fissure	4 (0.1%)	7 (0.2%)	11 (0.1%)
Anal fistula	6 (0.2%)	4 (0.1%)	10 (0.1%)
Anal haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anal incontinence	4 (0.1%)	5 (0.1%)	9 (0.1%)
Anal pruritus	1 (<0.1%)	0	1 (<0.1%)
Anal sphincter atony	1 (<0.1%)	0	1 (<0.1%)
Anorectal discomfort	0	1 (<0.1%)	1 (<0.1%)
Aphthous ulcer	1 (<0.1%)	0	1 (<0.1%)
Ascites	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Autoimmune pancreatitis	1 (<0.1%)	0	1 (<0.1%)
Barrett's oesophagus	18 (0.5%)	19 (0.5%)	37 (0.5%)
Bowel movement irregularity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breath odour	0	1 (<0.1%)	1 (<0.1%)
Brunner's gland hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Change of bowel habit	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic gastritis	138 (3.5%)	119 (3.0%)	257 (3.2%)
Coeliac artery aneurysm	1 (<0.1%)	0	1 (<0.1%)
Coeliac disease	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Colitis	9 (0.2%)	8 (0.2%)	17 (0.2%)
Colitis erosive	0	1 (<0.1%)	1 (<0.1%)
Colitis ischaemic	3 (<0.1%)	0	3 (<0.1%)
Colitis microscopic	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Colitis ulcerative	12 (0.3%)	11 (0.3%)	23 (0.3%)
Colon dysplasia	1 (<0.1%)	0	1 (<0.1%)
Constipation	240 (6.0%)	250 (6.3%)	490 (6.2%)
Crohn's disease	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Cyclic vomiting syndrome	0	1 (<0.1%)	1 (<0.1%)
Dental caries	10 (0.3%)	10 (0.3%)	20 (0.3%)
Dental cyst	1 (<0.1%)	0	1 (<0.1%)
Diabetic enteropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic gastroparesis	7 (0.2%)	5 (0.1%)	12 (0.2%)
Diaphragmatic hernia	5 (0.1%)	9 (0.2%)	14 (0.2%)
Diarrhoea	60 (1.5%)	60 (1.5%)	120 (1.5%)
Dieulafoy's vascular malformation	1 (<0.1%)	0	1 (<0.1%)
Diverticular perforation	0	2 (<0.1%)	2 (<0.1%)
Diverticulum	46 (1.2%)	42 (1.1%)	88 (1.1%)
Diverticulum gastric	1 (<0.1%)	0	1 (<0.1%)
Diverticulum intestinal	57 (1.4%)	53 (1.3%)	110 (1.4%)
Diverticulum intestinal haemorrhagic	2 (<0.1%)	0	2 (<0.1%)
Diverticulum oesophageal	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Dry mouth	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Dumping syndrome	0	2 (<0.1%)	2 (<0.1%)
Duodenal perforation	0	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Duodenal ulcer	40 (1.0%)	50 (1.3%)	90 (1.1%)
Duodenal ulcer haemorrhage	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Duodenitis	16 (0.4%)	16 (0.4%)	32 (0.4%)
Duodenogastric reflux	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Dysbiosis	0	2 (<0.1%)	2 (<0.1%)
Dyskinesia oesophageal	0	1 (<0.1%)	1 (<0.1%)
Dyspepsia	91 (2.3%)	74 (1.9%)	165 (2.1%)
Dysphagia	10 (0.3%)	10 (0.3%)	20 (0.3%)
Enlarged uvula	1 (<0.1%)	0	1 (<0.1%)
Enteritis	1 (<0.1%)	0	1 (<0.1%)
Enterocele	0	1 (<0.1%)	1 (<0.1%)
Enterocolitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Epigastric discomfort	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Epiploic appendagitis	1 (<0.1%)	0	1 (<0.1%)
Epulis	0	1 (<0.1%)	1 (<0.1%)
Erosive duodenitis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Erosive oesophagitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eructation	1 (<0.1%)	0	1 (<0.1%)
Faeces soft	0	1 (<0.1%)	1 (<0.1%)
Flatulence	7 (0.2%)	8 (0.2%)	15 (0.2%)
Functional gastrointestinal disorder	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Gastric disorder	8 (0.2%)	5 (0.1%)	13 (0.2%)
Gastric haemorrhage	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gastric hypermotility	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosa erythema	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastric mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Gastric mucosal lesion	0	1 (<0.1%)	1 (<0.1%)
Gastric perforation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastric polyps	17 (0.4%)	26 (0.7%)	43 (0.5%)
Gastric ulcer	54 (1.4%)	48 (1.2%)	102 (1.3%)
Gastric ulcer haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric ulcer perforation	0	1 (<0.1%)	1 (<0.1%)
Gastric varices	0	1 (<0.1%)	1 (<0.1%)
Gastric xanthoma	1 (<0.1%)	0	1 (<0.1%)
Gastritis	152 (3.8%)	135 (3.4%)	287 (3.6%)
Gastritis erosive	21 (0.5%)	18 (0.5%)	39 (0.5%)
Gastritis haemorrhagic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Gastritis hypertrophic	0	1 (<0.1%)	1 (<0.1%)
Gastroduodenal ulcer	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Gastrointestinal angiectasia	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal angiodysplasia	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gastrointestinal disorder	10 (0.3%)	4 (0.1%)	14 (0.2%)
Gastrointestinal haemorrhage	9 (0.2%)	11 (0.3%)	20 (0.3%)
Gastrointestinal hypomotility	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal motility disorder	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Gastrointestinal polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal scarring	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal tract mucosal pigmentation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastrointestinal ulcer	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal ulcer haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	448 (11.3%)	478 (12.0%)	926 (11.6%)
Gastrooesophageal sphincter insufficiency	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gingival bleeding	1 (<0.1%)	0	1 (<0.1%)
Gingival pain	0	1 (<0.1%)	1 (<0.1%)
Gingival recession	1 (<0.1%)	0	1 (<0.1%)
Gingival swelling	0	2 (<0.1%)	2 (<0.1%)
Haematemesis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematochezia	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Haemorrhagic necrotic pancreatitis	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoidal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Haemorrhoids	84 (2.1%)	81 (2.0%)	165 (2.1%)
Hernial eventration	0	1 (<0.1%)	1 (<0.1%)
Hiatus hernia	75 (1.9%)	72 (1.8%)	147 (1.8%)
Hyperchlorhydria	1 (<0.1%)	0	1 (<0.1%)
Ileus	5 (0.1%)	0	5 (<0.1%)
Ileus paralytic	0	1 (<0.1%)	1 (<0.1%)
Impaired gastric emptying	10 (0.3%)	13 (0.3%)	23 (0.3%)
Incarcerated umbilical hernia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Inguinal hernia	43 (1.1%)	53 (1.3%)	96 (1.2%)
Intestinal cyst	0	1 (<0.1%)	1 (<0.1%)
Intestinal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Intestinal metaplasia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Intestinal mucosal hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Intestinal obstruction	3 (<0.1%)	11 (0.3%)	14 (0.2%)
Intestinal perforation	0	3 (<0.1%)	3 (<0.1%)
Intestinal polyp	8 (0.2%)	5 (0.1%)	13 (0.2%)
Intra-abdominal fluid collection	1 (<0.1%)	0	1 (<0.1%)
Irritable bowel syndrome	40 (1.0%)	33 (0.8%)	73 (0.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Jejunal ulcer	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestinal stenosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine perforation	1 (<0.1%)	0	1 (<0.1%)
Large intestine polyp	98 (2.5%)	110 (2.8%)	208 (2.6%)
Leukoplakia oral	0	1 (<0.1%)	1 (<0.1%)
Lip disorder	1 (<0.1%)	0	1 (<0.1%)
Lip erosion	1 (<0.1%)	0	1 (<0.1%)
Lip oedema	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Lumbar hernia	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Malabsorption	1 (<0.1%)	0	1 (<0.1%)
Mallory-Weiss syndrome	1 (<0.1%)	0	1 (<0.1%)
Mesenteric arteriosclerosis	1 (<0.1%)	0	1 (<0.1%)
Mesenteric panniculitis	0	1 (<0.1%)	1 (<0.1%)
Mouth haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Mouth ulceration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nausea	21 (0.5%)	26 (0.7%)	47 (0.6%)
Obstruction gastric	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obstructive defaecation	1 (<0.1%)	0	1 (<0.1%)
Obstructive pancreatitis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Oesophageal achalasia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Oesophageal disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Oesophageal dysplasia	1 (<0.1%)	0	1 (<0.1%)
Oesophageal spasm	0	2 (<0.1%)	2 (<0.1%)
Oesophageal stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal ulcer	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Oesophagitis	28 (0.7%)	20 (0.5%)	48 (0.6%)
Oesophagitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Oral discomfort	1 (<0.1%)	0	1 (<0.1%)
Oral disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatic atrophy	0	1 (<0.1%)	1 (<0.1%)
Pancreatic calcification	0	1 (<0.1%)	1 (<0.1%)
Pancreatic cyst	12 (0.3%)	9 (0.2%)	21 (0.3%)
Pancreatic disorder	0	1 (<0.1%)	1 (<0.1%)
Pancreatic duct dilatation	0	1 (<0.1%)	1 (<0.1%)
Pancreatic failure	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Pancreatic mass	1 (<0.1%)	0	1 (<0.1%)
Pancreatic pseudocyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic steatosis	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Pancreatitis	16 (0.4%)	20 (0.5%)	36 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Pancreatitis acute	18 (0.5%)	24 (0.6%)	42 (0.5%)
Pancreatitis chronic	54 (1.4%)	31 (0.8%)	85 (1.1%)
Pancreatitis relapsing	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pancreatolithiasis	1 (<0.1%)	0	1 (<0.1%)
Paraesthesia oral	1 (<0.1%)	0	1 (<0.1%)
Parotid gland enlargement	0	3 (<0.1%)	3 (<0.1%)
Pathological tooth fracture	0	1 (<0.1%)	1 (<0.1%)
Peptic ulcer	34 (0.9%)	23 (0.6%)	57 (0.7%)
Peptic ulcer haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Periodontal disease	173 (4.3%)	180 (4.5%)	353 (4.4%)
Pharyngo-oesophageal diverticulum	2 (<0.1%)	0	2 (<0.1%)
Poor dental condition	1 (<0.1%)	0	1 (<0.1%)
Portal hypertensive gastropathy	2 (<0.1%)	0	2 (<0.1%)
Pouchitis	1 (<0.1%)	0	1 (<0.1%)
Proctalgia	1 (<0.1%)	0	1 (<0.1%)
Proctitis	1 (<0.1%)	0	1 (<0.1%)
Proctitis ulcerative	1 (<0.1%)	0	1 (<0.1%)
Pyloric sphincter insufficiency	0	1 (<0.1%)	1 (<0.1%)
Rectal haemorrhage	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Rectal polyp	6 (0.2%)	5 (0.1%)	11 (0.1%)
Rectal prolapse	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Rectal ulcer	1 (<0.1%)	0	1 (<0.1%)
Reflux gastritis	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Retching	0	1 (<0.1%)	1 (<0.1%)
Retroperitoneal fibrosis	0	1 (<0.1%)	1 (<0.1%)
Retroperitoneal haematoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland calculus	0	2 (<0.1%)	2 (<0.1%)
Salivary gland cyst	0	1 (<0.1%)	1 (<0.1%)
Salivary gland disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland mass	1 (<0.1%)	0	1 (<0.1%)
Segmental diverticular colitis	0	1 (<0.1%)	1 (<0.1%)
Small intestinal obstruction	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Splenic artery aneurysm	1 (<0.1%)	0	1 (<0.1%)
Steatorrhoea	1 (<0.1%)	0	1 (<0.1%)
Stomach mass	1 (<0.1%)	0	1 (<0.1%)
Stomatitis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Swollen tongue	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tongue dry	0	1 (<0.1%)	1 (<0.1%)
Tooth deposit	0	1 (<0.1%)	1 (<0.1%)
Tooth impacted	1 (<0.1%)	0	1 (<0.1%)
Tooth loss	5 (0.1%)	0	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Toothache	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Trichoglossia	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	55 (1.4%)	42 (1.1%)	97 (1.2%)
Upper gastrointestinal haemorrhage	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Varices oesophageal	4 (0.1%)	5 (0.1%)	9 (0.1%)
Vomiting	10 (0.3%)	12 (0.3%)	22 (0.3%)
General disorders and administration site conditions	498 (12.5%)	532 (13.4%)	1030 (12.9%)
Adhesion	0	1 (<0.1%)	1 (<0.1%)
Adverse drug reaction	0	1 (<0.1%)	1 (<0.1%)
Application site hypersensitivity	1 (<0.1%)	0	1 (<0.1%)
Asthenia	11 (0.3%)	18 (0.5%)	29 (0.4%)
Calcinosis	1 (<0.1%)	0	1 (<0.1%)
Chest discomfort	8 (0.2%)	4 (0.1%)	12 (0.2%)
Chest pain	36 (0.9%)	31 (0.8%)	67 (0.8%)
Chills	1 (<0.1%)	0	1 (<0.1%)
Chronic fatigue syndrome	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Complication associated with device	0	1 (<0.1%)	1 (<0.1%)
Cyst	15 (0.4%)	12 (0.3%)	27 (0.3%)
Disease susceptibility	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	22 (0.6%)	26 (0.7%)	48 (0.6%)
Facial pain	1 (<0.1%)	0	1 (<0.1%)
Fat tissue increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fatigue	43 (1.1%)	42 (1.1%)	85 (1.1%)
Fibrosis	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	14 (0.4%)	10 (0.3%)	24 (0.3%)
Generalised oedema	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Granuloma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gravitational oedema	0	4 (0.1%)	4 (<0.1%)
Hernia	3 (<0.1%)	8 (0.2%)	11 (0.1%)
Hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Hypothermia	0	1 (<0.1%)	1 (<0.1%)
Impaired healing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Impaired self-care	0	1 (<0.1%)	1 (<0.1%)
Inflammation	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Influenza like illness	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Injection site pain	1 (<0.1%)	0	1 (<0.1%)
Injury associated with device	0	1 (<0.1%)	1 (<0.1%)
Lithiasis	0	1 (<0.1%)	1 (<0.1%)
Localised oedema	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Malaise	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Mass	0	3 (<0.1%)	3 (<0.1%)
Medical device pain	1 (<0.1%)	0	1 (<0.1%)
Metaplasia	1 (<0.1%)	0	1 (<0.1%)
Multiple organ dysfunction syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nodule	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Non-cardiac chest pain	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Oedema	65 (1.6%)	79 (2.0%)	144 (1.8%)
Oedema due to cardiac disease	0	1 (<0.1%)	1 (<0.1%)
Oedema due to renal disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Oedema peripheral	260 (6.5%)	271 (6.8%)	531 (6.7%)
Pain	23 (0.6%)	22 (0.6%)	45 (0.6%)
Peripheral swelling	17 (0.4%)	18 (0.5%)	35 (0.4%)
Polyp	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Pseudocyst	0	1 (<0.1%)	1 (<0.1%)
Pyrexia	4 (0.1%)	6 (0.2%)	10 (0.1%)
Sensation of foreign body	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Suprapubic pain	0	1 (<0.1%)	1 (<0.1%)
Systemic inflammatory response syndrome	2 (<0.1%)	0	2 (<0.1%)
Temperature intolerance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thirst	0	1 (<0.1%)	1 (<0.1%)
Unevaluable event	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular stent stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular stent thrombosis	1 (<0.1%)	0	1 (<0.1%)
Xerosis	1 (<0.1%)	0	1 (<0.1%)
Hepatobiliary disorders	751 (18.9%)	738 (18.5%)	1489 (18.7%)
Alcoholic liver disease	6 (0.2%)	4 (0.1%)	10 (0.1%)
Bile duct stone	8 (0.2%)	7 (0.2%)	15 (0.2%)
Biliary colic	0	3 (<0.1%)	3 (<0.1%)
Biliary cyst	1 (<0.1%)	0	1 (<0.1%)
Biliary dilatation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Biliary dyskinesia	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Cholangitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cholangitis acute	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis	26 (0.7%)	24 (0.6%)	50 (0.6%)
Cholecystitis acute	8 (0.2%)	6 (0.2%)	14 (0.2%)
Cholecystitis chronic	34 (0.9%)	28 (0.7%)	62 (0.8%)
Cholelithiasis	204 (5.1%)	196 (4.9%)	400 (5.0%)
Cholestasis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Chronic hepatitis	12 (0.3%)	7 (0.2%)	19 (0.2%)
Cirrhosis alcoholic	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cryptogenic cirrhosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic hepatopathy	10 (0.3%)	10 (0.3%)	20 (0.3%)
Dilatation intrahepatic duct acquired	1 (<0.1%)	0	1 (<0.1%)
Drug-induced liver injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fatty liver alcoholic	0	2 (<0.1%)	2 (<0.1%)
Gallbladder cholesterolosis	4 (0.1%)	4 (0.1%)	8 (0.1%)
Gallbladder disorder	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gallbladder enlargement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gallbladder polyp	26 (0.7%)	39 (1.0%)	65 (0.8%)
Granulomatous liver disease	1 (<0.1%)	0	1 (<0.1%)
Hepatic calcification	2 (<0.1%)	0	2 (<0.1%)
Hepatic cirrhosis	10 (0.3%)	22 (0.6%)	32 (0.4%)
Hepatic cyst	22 (0.6%)	28 (0.7%)	50 (0.6%)
Hepatic failure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatic fibrosis	0	3 (<0.1%)	3 (<0.1%)
Hepatic function abnormal	18 (0.5%)	15 (0.4%)	33 (0.4%)
Hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Hepatic lesion	0	4 (0.1%)	4 (<0.1%)
Hepatic mass	0	3 (<0.1%)	3 (<0.1%)
Hepatic steato-fibrosis	2 (<0.1%)	0	2 (<0.1%)
Hepatic steatosis	454 (11.4%)	418 (10.5%)	872 (11.0%)
Hepatitis	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Hepatitis acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hepatitis alcoholic	0	3 (<0.1%)	3 (<0.1%)
Hepatocellular injury	4 (0.1%)	4 (0.1%)	8 (0.1%)
Hepatomegaly	9 (0.2%)	18 (0.5%)	27 (0.3%)
Hepatosplenomegaly	7 (0.2%)	4 (0.1%)	11 (0.1%)
Hyperplastic cholecystopathy	6 (0.2%)	4 (0.1%)	10 (0.1%)
Hypertransaminasaemia	0	1 (<0.1%)	1 (<0.1%)
Ischaemic hepatitis	1 (<0.1%)	0	1 (<0.1%)
Jaundice	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Liver disorder	19 (0.5%)	22 (0.6%)	41 (0.5%)
Liver injury	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Non-alcoholic steatohepatitis	11 (0.3%)	10 (0.3%)	21 (0.3%)
Nonalcoholic fatty liver disease	23 (0.6%)	20 (0.5%)	43 (0.5%)
Porcelain gallbladder	0	1 (<0.1%)	1 (<0.1%)
Portal hypertension	0	2 (<0.1%)	2 (<0.1%)
Post cholecystectomy syndrome	3 (<0.1%)	0	3 (<0.1%)
Primary biliary cholangitis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Sphincter of Oddi dysfunction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Steatohepatitis	11 (0.3%)	9 (0.2%)	20 (0.3%)
Subcapsular hepatic haematoma	1 (<0.1%)	0	1 (<0.1%)
Immune system disorders	277 (7.0%)	253 (6.4%)	530 (6.7%)
Allergic oedema	1 (<0.1%)	0	1 (<0.1%)
Allergy to animal	2 (<0.1%)	0	2 (<0.1%)
Allergy to arthropod bite	1 (<0.1%)	0	1 (<0.1%)
Allergy to arthropod sting	4 (0.1%)	5 (0.1%)	9 (0.1%)
Allergy to chemicals	2 (<0.1%)	0	2 (<0.1%)
Allergy to metals	2 (<0.1%)	0	2 (<0.1%)
Allergy to plants	1 (<0.1%)	0	1 (<0.1%)
Amyloidosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Anaphylactic reaction	1 (<0.1%)	0	1 (<0.1%)
Anaphylactic shock	1 (<0.1%)	0	1 (<0.1%)
Contrast media allergy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Drug hypersensitivity	115 (2.9%)	107 (2.7%)	222 (2.8%)
Dust allergy	3 (<0.1%)	0	3 (<0.1%)
Flour sensitivity	1 (<0.1%)	0	1 (<0.1%)
Food allergy	10 (0.3%)	9 (0.2%)	19 (0.2%)
Hypersensitivity	21 (0.5%)	18 (0.5%)	39 (0.5%)
Hypogammaglobulinaemia	1 (<0.1%)	0	1 (<0.1%)
Immunodeficiency	1 (<0.1%)	0	1 (<0.1%)
Immunodeficiency common variable	1 (<0.1%)	0	1 (<0.1%)
Iodine allergy	6 (0.2%)	9 (0.2%)	15 (0.2%)
Milk allergy	0	1 (<0.1%)	1 (<0.1%)
Mite allergy	0	2 (<0.1%)	2 (<0.1%)
Multiple allergies	7 (0.2%)	10 (0.3%)	17 (0.2%)
Mycotic allergy	2 (<0.1%)	0	2 (<0.1%)
Perennial allergy	0	1 (<0.1%)	1 (<0.1%)
Perfume sensitivity	1 (<0.1%)	0	1 (<0.1%)
Reaction to colouring	1 (<0.1%)	0	1 (<0.1%)
Reaction to food additive	0	1 (<0.1%)	1 (<0.1%)
Rubber sensitivity	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Sarcoidosis	3 (<0.1%)	8 (0.2%)	11 (0.1%)
Seasonal allergy	132 (3.3%)	111 (2.8%)	243 (3.1%)
Infections and infestations	948 (23.8%)	938 (23.6%)	1886 (23.7%)
Abdominal abscess	0	1 (<0.1%)	1 (<0.1%)
Abdominal wall abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Abscess	0	1 (<0.1%)	1 (<0.1%)
Abscess limb	4 (0.1%)	6 (0.2%)	10 (0.1%)
Abscess neck	2 (<0.1%)	0	2 (<0.1%)
Abscess soft tissue	0	1 (<0.1%)	1 (<0.1%)
Acarodermatitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Acquired immunodeficiency syndrome	0	1 (<0.1%)	1 (<0.1%)
Acute hepatitis B	0	1 (<0.1%)	1 (<0.1%)
Acute sinusitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Alveolar osteitis	0	1 (<0.1%)	1 (<0.1%)
American trypanosomiasis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Anal abscess	6 (0.2%)	7 (0.2%)	13 (0.2%)
Appendicitis	30 (0.8%)	34 (0.9%)	64 (0.8%)
Appendicitis perforated	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arthritis bacterial	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Arthritis infective	2 (<0.1%)	0	2 (<0.1%)
Aspergilloma	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic HIV infection	1 (<0.1%)	0	1 (<0.1%)
Asymptomatic bacteriuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atypical pneumonia	0	1 (<0.1%)	1 (<0.1%)
Bacteraemia	2 (<0.1%)	0	2 (<0.1%)
Bacterial disease carrier	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bacteriuria	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bartholin's abscess	0	1 (<0.1%)	1 (<0.1%)
Blister infected	0	1 (<0.1%)	1 (<0.1%)
Body tinea	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Bone abscess	0	1 (<0.1%)	1 (<0.1%)
Bone tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Borrelia infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Boutonneuse fever	0	1 (<0.1%)	1 (<0.1%)
Brain abscess	0	1 (<0.1%)	1 (<0.1%)
Bronchiolitis	0	2 (<0.1%)	2 (<0.1%)
Bronchitis	39 (1.0%)	41 (1.0%)	80 (1.0%)
Brucellosis	0	1 (<0.1%)	1 (<0.1%)
Bursitis infective	1 (<0.1%)	0	1 (<0.1%)
Candida infection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Carbuncle	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Catheter site infection	1 (<0.1%)	0	1 (<0.1%)
Cellulitis	50 (1.3%)	35 (0.9%)	85 (1.1%)
Cervicitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Chest wall abscess	0	1 (<0.1%)	1 (<0.1%)
Chikungunya virus infection	0	3 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Cholecystitis infective	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Chronic hepatitis B	6 (0.2%)	4 (0.1%)	10 (0.1%)
Chronic hepatitis C	6 (0.2%)	11 (0.3%)	17 (0.2%)
Chronic sinusitis	18 (0.5%)	19 (0.5%)	37 (0.5%)
Chronic tonsillitis	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Clostridium difficile colitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Coccidioidomycosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Conjunctivitis	38 (1.0%)	24 (0.6%)	62 (0.8%)
Coxsackie viral infection	0	1 (<0.1%)	1 (<0.1%)
Cutaneous leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Cystitis	13 (0.3%)	16 (0.4%)	29 (0.4%)
Dacryocystitis	0	1 (<0.1%)	1 (<0.1%)
Dental fistula	0	1 (<0.1%)	1 (<0.1%)
Dermatophytosis	0	2 (<0.1%)	2 (<0.1%)
Dermatophytosis of nail	20 (0.5%)	18 (0.5%)	38 (0.5%)
Device related infection	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Diabetic foot infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic gangrene	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Diverticulitis	23 (0.6%)	26 (0.7%)	49 (0.6%)
Diverticulitis intestinal haemorrhagic	1 (<0.1%)	0	1 (<0.1%)
Ear infection	5 (0.1%)	4 (0.1%)	9 (0.1%)
Ear infection fungal	0	1 (<0.1%)	1 (<0.1%)
Echinococciasis	2 (<0.1%)	0	2 (<0.1%)
Empyema	1 (<0.1%)	0	1 (<0.1%)
Encephalitis	0	2 (<0.1%)	2 (<0.1%)
Endocarditis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Endophthalmitis	0	1 (<0.1%)	1 (<0.1%)
Enteritis infectious	1 (<0.1%)	0	1 (<0.1%)
Enterococcal bacteraemia	0	1 (<0.1%)	1 (<0.1%)
Enterocolitis infectious	1 (<0.1%)	0	1 (<0.1%)
Epididymitis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Epstein-Barr virus infection	1 (<0.1%)	0	1 (<0.1%)
Erysipelas	14 (0.4%)	17 (0.4%)	31 (0.4%)
Escherichia sepsis	0	1 (<0.1%)	1 (<0.1%)
Escherichia urinary tract infection	0	2 (<0.1%)	2 (<0.1%)
External ear cellulitis	0	1 (<0.1%)	1 (<0.1%)
Eye infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye infection fungal	0	1 (<0.1%)	1 (<0.1%)
Focal peritonitis	2 (<0.1%)	0	2 (<0.1%)
Folliculitis	9 (0.2%)	6 (0.2%)	15 (0.2%)
Fournier's gangrene	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Fungal infection	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Fungal skin infection	9 (0.2%)	7 (0.2%)	16 (0.2%)
Furuncle	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Gangrene	3 (<0.1%)	10 (0.3%)	13 (0.2%)
Gastritis bacterial	0	1 (<0.1%)	1 (<0.1%)
Gastritis viral	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis	11 (0.3%)	6 (0.2%)	17 (0.2%)
Gastroenteritis norovirus	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis salmonella	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis viral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal infection	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Genital herpes	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Genitourinary tract infection	0	2 (<0.1%)	2 (<0.1%)
Gingivitis	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Groin abscess	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
HIV carrier	0	1 (<0.1%)	1 (<0.1%)
HIV infection	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic fever with renal syndrome	1 (<0.1%)	0	1 (<0.1%)
Helicobacter gastritis	8 (0.2%)	3 (<0.1%)	11 (0.1%)
Helicobacter infection	6 (0.2%)	4 (0.1%)	10 (0.1%)
Hepatic echinococciasis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis A	6 (0.2%)	8 (0.2%)	14 (0.2%)
Hepatitis B	23 (0.6%)	14 (0.4%)	37 (0.5%)
Hepatitis C	19 (0.5%)	18 (0.5%)	37 (0.5%)
Hepatitis infectious mononucleosis	0	1 (<0.1%)	1 (<0.1%)
Hepatitis viral	1 (<0.1%)	0	1 (<0.1%)
Herpes ophthalmic	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Herpes simplex	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Herpes zoster	29 (0.7%)	29 (0.7%)	58 (0.7%)
Herpes zoster reactivation	1 (<0.1%)	0	1 (<0.1%)
Histoplasmosis	0	1 (<0.1%)	1 (<0.1%)
Hordeolum	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Infected bite	1 (<0.1%)	0	1 (<0.1%)
Infected dermal cyst	0	1 (<0.1%)	1 (<0.1%)
Infected skin ulcer	2 (<0.1%)	0	2 (<0.1%)
Infection	0	4 (0.1%)	4 (<0.1%)
Infectious mononucleosis	1 (<0.1%)	0	1 (<0.1%)
Infectious pleural effusion	0	1 (<0.1%)	1 (<0.1%)
Infective keratitis	0	1 (<0.1%)	1 (<0.1%)
Infective myositis	0	1 (<0.1%)	1 (<0.1%)
Influenza	10 (0.3%)	10 (0.3%)	20 (0.3%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Intervertebral discitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Intestinal tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Joint abscess	1 (<0.1%)	0	1 (<0.1%)
Joint tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Kidney infection	2 (<0.1%)	0	2 (<0.1%)
Klebsiella infection	0	1 (<0.1%)	1 (<0.1%)
Labyrinthitis	8 (0.2%)	6 (0.2%)	14 (0.2%)
Laryngitis	4 (0.1%)	4 (0.1%)	8 (0.1%)
Latent syphilis	0	1 (<0.1%)	1 (<0.1%)
Latent tuberculosis	0	1 (<0.1%)	1 (<0.1%)
Legionella infection	0	3 (<0.1%)	3 (<0.1%)
Leishmaniasis	1 (<0.1%)	0	1 (<0.1%)
Lice infestation	0	1 (<0.1%)	1 (<0.1%)
Liver abscess	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Localised infection	8 (0.2%)	5 (0.1%)	13 (0.2%)
Lower respiratory tract infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lung abscess	1 (<0.1%)	0	1 (<0.1%)
Lyme disease	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Lymph node tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Malaria	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Mastitis	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Meningitis	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Meningitis aseptic	0	1 (<0.1%)	1 (<0.1%)
Meningitis bacterial	0	2 (<0.1%)	2 (<0.1%)
Meningitis viral	0	1 (<0.1%)	1 (<0.1%)
Molluscum contagiosum	1 (<0.1%)	0	1 (<0.1%)
Mumps	0	3 (<0.1%)	3 (<0.1%)
Myocarditis infectious	0	1 (<0.1%)	1 (<0.1%)
Myringitis	0	1 (<0.1%)	1 (<0.1%)
Nail candida	0	1 (<0.1%)	1 (<0.1%)
Nasal abscess	0	1 (<0.1%)	1 (<0.1%)
Nasopharyngitis	34 (0.9%)	29 (0.7%)	63 (0.8%)
Necrotising fasciitis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neuroborreliosis	1 (<0.1%)	0	1 (<0.1%)
Neurocysticercosis	1 (<0.1%)	0	1 (<0.1%)
Neurosyphilis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal candidiasis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Onychomycosis	66 (1.7%)	65 (1.6%)	131 (1.6%)
Ophthalmic herpes simplex	2 (<0.1%)	0	2 (<0.1%)
Ophthalmic herpes zoster	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Oral candidiasis	0	2 (<0.1%)	2 (<0.1%)
Oral fungal infection	1 (<0.1%)	0	1 (<0.1%)
Oral herpes	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Orchitis	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Osteomyelitis	20 (0.5%)	22 (0.6%)	42 (0.5%)
Osteomyelitis acute	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis chronic	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Otitis externa	6 (0.2%)	5 (0.1%)	11 (0.1%)
Otitis media	8 (0.2%)	5 (0.1%)	13 (0.2%)
Otitis media acute	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Otitis media chronic	4 (0.1%)	8 (0.2%)	12 (0.2%)
Otitis media fungal	0	1 (<0.1%)	1 (<0.1%)
Pancreatic abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paronychia	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Parotid abscess	0	1 (<0.1%)	1 (<0.1%)
Parotitis	2 (<0.1%)	0	2 (<0.1%)
Pelvic inflammatory disease	1 (<0.1%)	0	1 (<0.1%)
Perichondritis	0	1 (<0.1%)	1 (<0.1%)
Pericoronitis	0	1 (<0.1%)	1 (<0.1%)
Periodontitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Perirectal abscess	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Peritonsillar abscess	1 (<0.1%)	0	1 (<0.1%)
Periumbilical abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal abscess	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	9 (0.2%)	15 (0.4%)	24 (0.3%)
Pharyngotonsillitis	0	1 (<0.1%)	1 (<0.1%)
Pilonidal cyst	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Plasmodium falciparum infection	0	1 (<0.1%)	1 (<0.1%)
Pleurisy viral	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	57 (1.4%)	64 (1.6%)	121 (1.5%)
Pneumonia bacterial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonia influenzal	1 (<0.1%)	0	1 (<0.1%)
Pneumonia legionella	0	1 (<0.1%)	1 (<0.1%)
Pneumonia moraxella	0	1 (<0.1%)	1 (<0.1%)
Poliomyelitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Post procedural infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Postoperative wound infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Prostatic abscess	1 (<0.1%)	0	1 (<0.1%)
Psoas abscess	0	1 (<0.1%)	1 (<0.1%)
Pulmonary echinococciasis	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Pulmonary sepsis	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculoma	0	1 (<0.1%)	1 (<0.1%)
Pulmonary tuberculosis	19 (0.5%)	24 (0.6%)	43 (0.5%)
Pulpitis dental	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pustule	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pyelonephritis	9 (0.2%)	10 (0.3%)	19 (0.2%)
Pyelonephritis acute	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Pyelonephritis chronic	67 (1.7%)	56 (1.4%)	123 (1.5%)
Pyoderma	0	1 (<0.1%)	1 (<0.1%)
Pyonephrosis	0	1 (<0.1%)	1 (<0.1%)
Pyuria	0	1 (<0.1%)	1 (<0.1%)
Rectal abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal abscess	0	2 (<0.1%)	2 (<0.1%)
Renal cyst infection	0	1 (<0.1%)	1 (<0.1%)
Renal tuberculosis	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	7 (0.2%)	9 (0.2%)	16 (0.2%)
Respiratory tract infection viral	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Rhinitis	28 (0.7%)	18 (0.5%)	46 (0.6%)
Salpingo-oophoritis	2 (<0.1%)	0	2 (<0.1%)
Schistosomiasis liver	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scrotal abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	7 (0.2%)	7 (0.2%)	14 (0.2%)
Septic embolus	0	1 (<0.1%)	1 (<0.1%)
Septic shock	2 (<0.1%)	0	2 (<0.1%)
Sinusitis	25 (0.6%)	19 (0.5%)	44 (0.6%)
Skin candida	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin infection	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Soft tissue infection	3 (<0.1%)	0	3 (<0.1%)
Staphylococcal bacteraemia	1 (<0.1%)	0	1 (<0.1%)
Staphylococcal infection	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Staphylococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Sternitis	0	2 (<0.1%)	2 (<0.1%)
Stoma site abscess	1 (<0.1%)	0	1 (<0.1%)
Streptococcal sepsis	1 (<0.1%)	0	1 (<0.1%)
Strongyloidiasis	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	6 (0.2%)	5 (0.1%)	11 (0.1%)
Subdiaphragmatic abscess	0	1 (<0.1%)	1 (<0.1%)
Taeniasis	1 (<0.1%)	0	1 (<0.1%)
Tetanus	0	1 (<0.1%)	1 (<0.1%)
Tick-borne viral encephalitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tinea cruris	9 (0.2%)	2 (<0.1%)	11 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Tinea infection	10 (0.3%)	13 (0.3%)	23 (0.3%)
Tinea manuum	0	1 (<0.1%)	1 (<0.1%)
Tinea pedis	46 (1.2%)	42 (1.1%)	88 (1.1%)
Tinea versicolour	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Tonsillitis	9 (0.2%)	9 (0.2%)	18 (0.2%)
Tooth abscess	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Tooth infection	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tracheitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tracheobronchitis	0	1 (<0.1%)	1 (<0.1%)
Trematode infection	0	2 (<0.1%)	2 (<0.1%)
Trichophytosis	1 (<0.1%)	0	1 (<0.1%)
Trichuriasis	0	1 (<0.1%)	1 (<0.1%)
Tuberculosis	23 (0.6%)	12 (0.3%)	35 (0.4%)
Tuberculous laryngitis	1 (<0.1%)	0	1 (<0.1%)
Tuberculous pleurisy	1 (<0.1%)	0	1 (<0.1%)
Upper respiratory tract infection	42 (1.1%)	48 (1.2%)	90 (1.1%)
Urethritis	1 (<0.1%)	0	1 (<0.1%)
Urinary tract infection	82 (2.1%)	96 (2.4%)	178 (2.2%)
Urinary tract infection bacterial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urosepsis	7 (0.2%)	4 (0.1%)	11 (0.1%)
Vaginal infection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Varicella	0	3 (<0.1%)	3 (<0.1%)
Varicella zoster virus infection	0	1 (<0.1%)	1 (<0.1%)
Vascular device infection	0	1 (<0.1%)	1 (<0.1%)
Vestibular neuronitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Viral diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Viral hepatitis carrier	10 (0.3%)	9 (0.2%)	19 (0.2%)
Viral infection	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Viral myocarditis	1 (<0.1%)	0	1 (<0.1%)
Viral pericarditis	0	1 (<0.1%)	1 (<0.1%)
Viral upper respiratory tract infection	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vulval abscess	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vulvitis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal candidiasis	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal mycotic infection	0	1 (<0.1%)	1 (<0.1%)
Vulvovaginitis	0	1 (<0.1%)	1 (<0.1%)
Wound infection	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Injury, poisoning and procedural complications	353 (8.9%)	344 (8.6%)	697 (8.8%)
Abdominal injury	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Accident	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Acetabulum fracture	1 (<0.1%)	0	1 (<0.1%)
Animal scratch	0	1 (<0.1%)	1 (<0.1%)
Ankle fracture	15 (0.4%)	19 (0.5%)	34 (0.4%)
Arterial bypass occlusion	0	1 (<0.1%)	1 (<0.1%)
Arterial bypass thrombosis	1 (<0.1%)	0	1 (<0.1%)
Arterial injury	1 (<0.1%)	0	1 (<0.1%)
Arthropod bite	4 (0.1%)	5 (0.1%)	9 (0.1%)
Asbestosis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Auricular haematoma	1 (<0.1%)	0	1 (<0.1%)
Back injury	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Blindness traumatic	1 (<0.1%)	0	1 (<0.1%)
Bone contusion	1 (<0.1%)	0	1 (<0.1%)
Bone fissure	0	1 (<0.1%)	1 (<0.1%)
Brain contusion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Burns third degree	0	1 (<0.1%)	1 (<0.1%)
Carotid artery restenosis	1 (<0.1%)	0	1 (<0.1%)
Cartilage injury	0	1 (<0.1%)	1 (<0.1%)
Cataract operation complication	1 (<0.1%)	0	1 (<0.1%)
Cervical vertebral fracture	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Chest injury	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Clavicle fracture	7 (0.2%)	6 (0.2%)	13 (0.2%)
Compression fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Concussion	5 (0.1%)	6 (0.2%)	11 (0.1%)
Contraindicated product administered	1 (<0.1%)	0	1 (<0.1%)
Contusion	11 (0.3%)	8 (0.2%)	19 (0.2%)
Corneal abrasion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary vascular graft occlusion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Craniocerebral injury	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Deafness traumatic	0	1 (<0.1%)	1 (<0.1%)
Dislocation of sternum	0	1 (<0.1%)	1 (<0.1%)
Electric shock	0	1 (<0.1%)	1 (<0.1%)
Epicondylitis	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Exposure to communicable disease	0	2 (<0.1%)	2 (<0.1%)
Exposure to radiation	0	1 (<0.1%)	1 (<0.1%)
Exposure to toxic agent	0	1 (<0.1%)	1 (<0.1%)
Eye injury	3 (<0.1%)	0	3 (<0.1%)
Face injury	1 (<0.1%)	0	1 (<0.1%)
Facial bones fracture	6 (0.2%)	1 (<0.1%)	7 (<0.1%)
Fall	9 (0.2%)	10 (0.3%)	19 (0.2%)
Femoral neck fracture	3 (<0.1%)	0	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Femur fracture	15 (0.4%)	6 (0.2%)	21 (0.3%)
Fibula fracture	11 (0.3%)	8 (0.2%)	19 (0.2%)
Foot fracture	12 (0.3%)	13 (0.3%)	25 (0.3%)
Forearm fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Foreign body	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body in eye	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fractured coccyx	1 (<0.1%)	0	1 (<0.1%)
Fractured sacrum	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gingival injury	1 (<0.1%)	0	1 (<0.1%)
Gun shot wound	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Hand fracture	5 (0.1%)	5 (0.1%)	10 (0.1%)
Head injury	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Heart injury	0	1 (<0.1%)	1 (<0.1%)
Heat exhaustion	1 (<0.1%)	0	1 (<0.1%)
Hip fracture	6 (0.2%)	7 (0.2%)	13 (0.2%)
Humerus fracture	9 (0.2%)	14 (0.4%)	23 (0.3%)
Incision site haematoma	0	1 (<0.1%)	1 (<0.1%)
Incisional hernia	18 (0.5%)	3 (<0.1%)	21 (0.3%)
Injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Injury to brachial plexus due to birth trauma	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc injury	0	1 (<0.1%)	1 (<0.1%)
Jaw fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint dislocation	8 (0.2%)	6 (0.2%)	14 (0.2%)
Joint injury	5 (0.1%)	6 (0.2%)	11 (0.1%)
Kidney contusion	0	1 (<0.1%)	1 (<0.1%)
Kidney rupture	0	1 (<0.1%)	1 (<0.1%)
Laryngeal injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ligament rupture	4 (0.1%)	10 (0.3%)	14 (0.2%)
Ligament sprain	6 (0.2%)	14 (0.4%)	20 (0.3%)
Limb crushing injury	1 (<0.1%)	0	1 (<0.1%)
Limb injury	23 (0.6%)	19 (0.5%)	42 (0.5%)
Limb traumatic amputation	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Lower limb fracture	8 (0.2%)	15 (0.4%)	23 (0.3%)
Lumbar vertebral fracture	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Meniscus injury	16 (0.4%)	21 (0.5%)	37 (0.5%)
Mouth injury	0	1 (<0.1%)	1 (<0.1%)
Multiple fractures	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Multiple injuries	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Muscle injury	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Muscle rupture	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Muscle strain	4 (0.1%)	7 (0.2%)	11 (0.1%)
Nerve injury	0	1 (<0.1%)	1 (<0.1%)
Occupational exposure to toxic agent	1 (<0.1%)	0	1 (<0.1%)
Optic nerve injury	1 (<0.1%)	0	1 (<0.1%)
Osteochondral fracture	0	1 (<0.1%)	1 (<0.1%)
Palate injury	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Pelvic fracture	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Penetrating abdominal trauma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penis injury	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumocephalus	0	1 (<0.1%)	1 (<0.1%)
Pneumoconiosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumonitis chemical	1 (<0.1%)	0	1 (<0.1%)
Post laminectomy syndrome	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	1 (<0.1%)	0	1 (<0.1%)
Post procedural diarrhoea	1 (<0.1%)	0	1 (<0.1%)
Post procedural fistula	0	1 (<0.1%)	1 (<0.1%)
Post procedural haematoma	0	2 (<0.1%)	2 (<0.1%)
Post procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypoparathyroidism	0	1 (<0.1%)	1 (<0.1%)
Post procedural hypotension	1 (<0.1%)	0	1 (<0.1%)
Post procedural hypothyroidism	8 (0.2%)	8 (0.2%)	16 (0.2%)
Post-traumatic neck syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Post-traumatic pain	4 (0.1%)	6 (0.2%)	10 (0.1%)
Postoperative renal failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative respiratory failure	0	1 (<0.1%)	1 (<0.1%)
Postoperative thoracic procedure complication	1 (<0.1%)	0	1 (<0.1%)
Procedural haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Procedural pain	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pulmonary contusion	1 (<0.1%)	0	1 (<0.1%)
Radial nerve injury	2 (<0.1%)	0	2 (<0.1%)
Radiation injury	0	1 (<0.1%)	1 (<0.1%)
Radius fracture	4 (0.1%)	5 (0.1%)	9 (0.1%)
Reactive gastropathy	0	1 (<0.1%)	1 (<0.1%)
Rib fracture	11 (0.3%)	9 (0.2%)	20 (0.3%)
Road traffic accident	11 (0.3%)	7 (0.2%)	18 (0.2%)
Sacroiliac fracture	0	1 (<0.1%)	1 (<0.1%)
Scapula fracture	1 (<0.1%)	0	1 (<0.1%)
Scar	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Silicosis	1 (<0.1%)	0	1 (<0.1%)
Skin abrasion	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Skin graft failure	1 (<0.1%)	0	1 (<0.1%)
Skin injury	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin laceration	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Skin wound	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Skull fracture	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Soft tissue injury	1 (<0.1%)	0	1 (<0.1%)
Spinal column injury	1 (<0.1%)	0	1 (<0.1%)
Spinal compression fracture	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Spinal fracture	5 (0.1%)	6 (0.2%)	11 (0.1%)
Stab wound	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sternal fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Stoma complication	1 (<0.1%)	0	1 (<0.1%)
Stomal hernia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Stress fracture	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subcutaneous haematoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma	4 (0.1%)	5 (0.1%)	9 (0.1%)
Subdural haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Synovial rupture	0	1 (<0.1%)	1 (<0.1%)
Tendon injury	2 (<0.1%)	0	2 (<0.1%)
Tendon rupture	12 (0.3%)	8 (0.2%)	20 (0.3%)
Thermal burn	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Thoracic vertebral fracture	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Tibia fracture	8 (0.2%)	10 (0.3%)	18 (0.2%)
Tooth fracture	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Toxicity to various agents	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Traumatic arthritis	0	2 (<0.1%)	2 (<0.1%)
Traumatic arthropathy	0	1 (<0.1%)	1 (<0.1%)
Traumatic fracture	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Traumatic haemothorax	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Traumatic liver injury	0	1 (<0.1%)	1 (<0.1%)
Traumatic shock	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	1 (<0.1%)	0	1 (<0.1%)
Ulna fracture	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ulnar nerve injury	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	6 (0.2%)	19 (0.5%)	25 (0.3%)
Ureteric injury	0	1 (<0.1%)	1 (<0.1%)
Urethral stricture traumatic	0	1 (<0.1%)	1 (<0.1%)
Urinary retention postoperative	0	1 (<0.1%)	1 (<0.1%)
Vascular graft complication	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Vascular pseudoaneurysm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Wound complication	1 (<0.1%)	0	1 (<0.1%)
Wound dehiscence	0	2 (<0.1%)	2 (<0.1%)
Wound necrosis	0	1 (<0.1%)	1 (<0.1%)
Wrist fracture	10 (0.3%)	3 (<0.1%)	13 (0.2%)
Investigations	477 (12.0%)	479 (12.0%)	956 (12.0%)
Activated partial thromboplastin time prolonged	1 (<0.1%)	0	1 (<0.1%)
Alanine aminotransferase increased	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Albumin urine present	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Amylase increased	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Angiocardiogram	35 (0.9%)	24 (0.6%)	59 (0.7%)
Angiogram	17 (0.4%)	7 (0.2%)	24 (0.3%)
Angiogram cerebral	2 (<0.1%)	0	2 (<0.1%)
Angiogram retina	2 (<0.1%)	0	2 (<0.1%)
Ankle brachial index	1 (<0.1%)	0	1 (<0.1%)
Ankle brachial index decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anti factor VIII antibody positive	1 (<0.1%)	0	1 (<0.1%)
Anti factor XI antibody positive	0	1 (<0.1%)	1 (<0.1%)
Antinuclear antibody positive	0	1 (<0.1%)	1 (<0.1%)
Aortic bruit	0	1 (<0.1%)	1 (<0.1%)
Aortogram	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arterial bruit	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arteriogram	2 (<0.1%)	0	2 (<0.1%)
Arteriogram abnormal	1 (<0.1%)	0	1 (<0.1%)
Arteriogram carotid	1 (<0.1%)	0	1 (<0.1%)
Arteriogram coronary normal	1 (<0.1%)	0	1 (<0.1%)
Arteriogram renal	1 (<0.1%)	0	1 (<0.1%)
Arthroscopy	13 (0.3%)	4 (0.1%)	17 (0.2%)
Aspartate aminotransferase increased	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Aspiration pleural cavity	0	2 (<0.1%)	2 (<0.1%)
Biopsy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biopsy breast	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Biopsy bronchus	0	1 (<0.1%)	1 (<0.1%)
Biopsy colon	1 (<0.1%)	0	1 (<0.1%)
Biopsy kidney	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Biopsy liver normal	0	1 (<0.1%)	1 (<0.1%)
Biopsy lymph gland	0	1 (<0.1%)	1 (<0.1%)
Biopsy prostate	3 (<0.1%)	0	3 (<0.1%)
Biopsy skin	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Blood alkaline phosphatase increased	5 (0.1%)	7 (0.2%)	12 (0.2%)
Blood bicarbonate decreased	2 (<0.1%)	0	2 (<0.1%)
Blood calcium decreased	1 (<0.1%)	0	1 (<0.1%)
Blood chloride increased	1 (<0.1%)	0	1 (<0.1%)
Blood cholesterol increased	47 (1.2%)	53 (1.3%)	100 (1.3%)
Blood creatine increased	0	1 (<0.1%)	1 (<0.1%)
Blood creatine phosphokinase increased	45 (1.1%)	65 (1.6%)	110 (1.4%)
Blood creatinine increased	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Blood folate decreased	0	1 (<0.1%)	1 (<0.1%)
Blood folate increased	0	1 (<0.1%)	1 (<0.1%)
Blood glucose abnormal	0	1 (<0.1%)	1 (<0.1%)
Blood glucose increased	0	1 (<0.1%)	1 (<0.1%)
Blood homocysteine increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood iron decreased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Blood lactate dehydrogenase increased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood magnesium decreased	2 (<0.1%)	10 (0.3%)	12 (0.2%)
Blood magnesium increased	0	1 (<0.1%)	1 (<0.1%)
Blood parathyroid hormone increased	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Blood potassium decreased	0	3 (<0.1%)	3 (<0.1%)
Blood potassium increased	4 (0.1%)	5 (0.1%)	9 (0.1%)
Blood pressure increased	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Blood sodium decreased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Blood testosterone decreased	8 (0.2%)	7 (0.2%)	15 (0.2%)
Blood testosterone increased	1 (<0.1%)	0	1 (<0.1%)
Blood triglycerides increased	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Blood urea increased	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Blood uric acid abnormal	1 (<0.1%)	0	1 (<0.1%)
Blood uric acid increased	13 (0.3%)	18 (0.5%)	31 (0.4%)
Blood urine present	2 (<0.1%)	0	2 (<0.1%)
Blood zinc decreased	1 (<0.1%)	0	1 (<0.1%)
Body mass index increased	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Bone densitometry	2 (<0.1%)	0	2 (<0.1%)
Bone density decreased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Brain scan abnormal	0	1 (<0.1%)	1 (<0.1%)
Bronchoscopy normal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein abnormal	1 (<0.1%)	0	1 (<0.1%)
C-reactive protein increased	20 (0.5%)	23 (0.6%)	43 (0.5%)
Carbon dioxide decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiac murmur	34 (0.9%)	35 (0.9%)	69 (0.9%)
Cardiac stress test	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac stress test abnormal	3 (<0.1%)	0	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Cardiac ventriculogram	2 (<0.1%)	0	2 (<0.1%)
Cardiac ventriculogram left normal	1 (<0.1%)	0	1 (<0.1%)
Carotid bruit	5 (0.1%)	7 (0.2%)	12 (0.2%)
Carotid intima-media thickness increased	1 (<0.1%)	0	1 (<0.1%)
Catheterisation cardiac	22 (0.6%)	27 (0.7%)	49 (0.6%)
Catheterisation cardiac normal	0	1 (<0.1%)	1 (<0.1%)
Chest X-ray abnormal	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	5 (0.1%)	6 (0.2%)	11 (0.1%)
Computerised tomogram abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram coronary artery	0	1 (<0.1%)	1 (<0.1%)
Computerised tomogram head	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram head abnormal	0	1 (<0.1%)	1 (<0.1%)
Computerised tomogram pelvis abnormal	1 (<0.1%)	0	1 (<0.1%)
Computerised tomogram thorax abnormal	0	1 (<0.1%)	1 (<0.1%)
Crystal urine present	0	1 (<0.1%)	1 (<0.1%)
Culture urine positive	1 (<0.1%)	0	1 (<0.1%)
Cystoscopy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
ECG signs of myocardial infarction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
ECG signs of myocardial ischaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
ECG signs of ventricular hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Echocardiogram	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Ejection fraction decreased	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Ejection fraction normal	0	3 (<0.1%)	3 (<0.1%)
Electrocardiogram	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Electrocardiogram P wave abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram PR prolongation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram Q wave abnormal	2 (<0.1%)	0	2 (<0.1%)
Electrocardiogram Q waves	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram QRS complex abnormal	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram QT interval abnormal	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Electrocardiogram QT prolonged	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Electrocardiogram ST segment abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Electrocardiogram ST segment depression	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram ST segment elevation	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram ST-T change	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Electrocardiogram ST-T segment abnormal	3 (<0.1%)	0	3 (<0.1%)
Electrocardiogram T wave abnormal	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Electrocardiogram T wave alternans	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave amplitude decreased	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Electrocardiogram T wave biphasic	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram T wave inversion	7 (0.2%)	4 (0.1%)	11 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Electrocardiogram U-wave prominent	0	1 (<0.1%)	1 (<0.1%)
Electrocardiogram abnormal	6 (0.2%)	8 (0.2%)	14 (0.2%)
Electrocardiogram high voltage	1 (<0.1%)	0	1 (<0.1%)
Electrocardiogram repolarisation abnormality	13 (0.3%)	7 (0.2%)	20 (0.3%)
Endoscopic retrograde cholangiopancreatography	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Endoscopy	1 (<0.1%)	0	1 (<0.1%)
Endoscopy upper gastrointestinal tract	0	1 (<0.1%)	1 (<0.1%)
Enzyme activity abnormal	1 (<0.1%)	0	1 (<0.1%)
Eosinophil count increased	0	1 (<0.1%)	1 (<0.1%)
False positive investigation result	0	3 (<0.1%)	3 (<0.1%)
Femoral bruit	1 (<0.1%)	0	1 (<0.1%)
Forced vital capacity decreased	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase abnormal	1 (<0.1%)	0	1 (<0.1%)
Gamma-glutamyltransferase increased	18 (0.5%)	26 (0.7%)	44 (0.6%)
Gastric pH decreased	4 (0.1%)	5 (0.1%)	9 (0.1%)
Globulin abnormal	0	1 (<0.1%)	1 (<0.1%)
Glomerular filtration rate decreased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glucose tolerance increased	0	1 (<0.1%)	1 (<0.1%)
Glycosylated haemoglobin increased	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
HLA-B*5801 assay positive	0	1 (<0.1%)	1 (<0.1%)
Haemoglobin decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Heart rate increased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Heart rate irregular	0	1 (<0.1%)	1 (<0.1%)
Heart rate normal	0	1 (<0.1%)	1 (<0.1%)
Heart sounds abnormal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Helicobacter test positive	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Hepatic enzyme abnormal	0	1 (<0.1%)	1 (<0.1%)
Hepatic enzyme increased	9 (0.2%)	4 (0.1%)	13 (0.2%)
Hepatitis B surface antigen positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis B virus test positive	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatitis C antibody positive	3 (<0.1%)	0	3 (<0.1%)
Hepatitis C virus test positive	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
High density lipoprotein increased	1 (<0.1%)	0	1 (<0.1%)
Inflammatory marker increased	1 (<0.1%)	0	1 (<0.1%)
Influenza A virus test positive	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure decreased	1 (<0.1%)	0	1 (<0.1%)
Intraocular pressure increased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Intraocular pressure test abnormal	0	1 (<0.1%)	1 (<0.1%)
Investigation	1 (<0.1%)	0	1 (<0.1%)
Keratometry	1 (<0.1%)	0	1 (<0.1%)
Laparoscopy	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Light chain analysis decreased	1 (<0.1%)	0	1 (<0.1%)
Light chain analysis increased	0	1 (<0.1%)	1 (<0.1%)
Lipase increased	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Lipids abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipids increased	2 (<0.1%)	0	2 (<0.1%)
Lipoprotein (a) increased	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Liver function test abnormal	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Liver function test increased	3 (<0.1%)	9 (0.2%)	12 (0.2%)
Macroenzyme creatine kinase	1 (<0.1%)	0	1 (<0.1%)
Magnetic resonance imaging brain	1 (<0.1%)	0	1 (<0.1%)
Mammogram	1 (<0.1%)	0	1 (<0.1%)
Mammogram abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mean cell volume increased	1 (<0.1%)	0	1 (<0.1%)
Monocyte count increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial necrosis marker increased	1 (<0.1%)	0	1 (<0.1%)
Myocardial strain	0	2 (<0.1%)	2 (<0.1%)
N-terminal prohormone brain natriuretic peptide increased	0	1 (<0.1%)	1 (<0.1%)
Neutrophil count increased	1 (<0.1%)	0	1 (<0.1%)
Occult blood positive	0	2 (<0.1%)	2 (<0.1%)
Ophthalmological examination normal	0	1 (<0.1%)	1 (<0.1%)
Oxygen consumption increased	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Parasite stool test positive	1 (<0.1%)	0	1 (<0.1%)
Pedal pulse decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral arteriogram	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral pulse decreased	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Platelet aggregation decreased	1 (<0.1%)	0	1 (<0.1%)
Platelet count decreased	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Polymerase chain reaction positive	0	1 (<0.1%)	1 (<0.1%)
Popliteal pulse	0	1 (<0.1%)	1 (<0.1%)
Proctosigmoidoscopy	0	1 (<0.1%)	1 (<0.1%)
Prostatic specific antigen increased	11 (0.3%)	11 (0.3%)	22 (0.3%)
Pulmonary function test decreased	1 (<0.1%)	0	1 (<0.1%)
Pulmonary imaging procedure abnormal	1 (<0.1%)	0	1 (<0.1%)
Pulse absent	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pyeloscopy	1 (<0.1%)	0	1 (<0.1%)
QRS axis abnormal	11 (0.3%)	14 (0.4%)	25 (0.3%)
Red blood cell count increased	0	1 (<0.1%)	1 (<0.1%)
Red blood cell sedimentation rate increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Red cell distribution width increased	0	1 (<0.1%)	1 (<0.1%)
Renal function test abnormal	0	1 (<0.1%)	1 (<0.1%)
Scan myocardial perfusion abnormal	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Serum ferritin increased	1 (<0.1%)	0	1 (<0.1%)
Smear cervix abnormal	0	1 (<0.1%)	1 (<0.1%)
Spinal X-ray	0	1 (<0.1%)	1 (<0.1%)
Staphylococcus test positive	0	1 (<0.1%)	1 (<0.1%)
Stress echocardiogram	0	1 (<0.1%)	1 (<0.1%)
Thyroid function test abnormal	1 (<0.1%)	0	1 (<0.1%)
Thyroid function test normal	3 (<0.1%)	0	3 (<0.1%)
Thyroid gland scan abnormal	0	1 (<0.1%)	1 (<0.1%)
Thyroid hormones decreased	0	1 (<0.1%)	1 (<0.1%)
Thyroxine abnormal	0	1 (<0.1%)	1 (<0.1%)
Total lung capacity decreased	0	1 (<0.1%)	1 (<0.1%)
Transaminases increased	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Transferrin saturation decreased	1 (<0.1%)	0	1 (<0.1%)
Troponin T increased	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Troponin increased	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tuberculin test positive	0	2 (<0.1%)	2 (<0.1%)
Ultrasound Doppler	1 (<0.1%)	0	1 (<0.1%)
Ultrasound abdomen abnormal	1 (<0.1%)	0	1 (<0.1%)
Ultrasound kidney	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ultrasound kidney abnormal	2 (<0.1%)	0	2 (<0.1%)
Ultrasound scan	1 (<0.1%)	0	1 (<0.1%)
Ultrasound thyroid	1 (<0.1%)	0	1 (<0.1%)
Ultrasound thyroid abnormal	0	1 (<0.1%)	1 (<0.1%)
Ureteroscopy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary casts present	0	1 (<0.1%)	1 (<0.1%)
Urinary occult blood positive	1 (<0.1%)	0	1 (<0.1%)
Urine analysis abnormal	0	1 (<0.1%)	1 (<0.1%)
Vitamin B12 decreased	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Vitamin B12 increased	1 (<0.1%)	0	1 (<0.1%)
Vitamin D decreased	9 (0.2%)	16 (0.4%)	25 (0.3%)
Vitamin K decreased	1 (<0.1%)	0	1 (<0.1%)
Weight decreased	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Weight increased	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
White blood cell count increased	2 (<0.1%)	7 (0.2%)	9 (0.1%)
X-ray limb	0	1 (<0.1%)	1 (<0.1%)
X-ray of pelvis and hip	0	1 (<0.1%)	1 (<0.1%)
Metabolism and nutrition disorders	3981 (100.0%)	3982 (100.0%)	7963 (100.0%)
Abnormal loss of weight	0	2 (<0.1%)	2 (<0.1%)
Abnormal weight gain	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Acidosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acquired mixed hyperlipidaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Calcium deficiency	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Central obesity	34 (0.9%)	23 (0.6%)	57 (0.7%)
Decreased appetite	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Dehydration	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Diabetes mellitus	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Diabetes mellitus inadequate control	9 (0.2%)	5 (0.1%)	14 (0.2%)
Diabetic complication	1 (<0.1%)	0	1 (<0.1%)
Diabetic dyslipidaemia	2 (<0.1%)	0	2 (<0.1%)
Diabetic ketoacidosis	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Diabetic ketosis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Diabetic metabolic decompensation	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Disaccharidase deficiency	0	1 (<0.1%)	1 (<0.1%)
Dyslipidaemia	1356 (34.1%)	1335 (33.5%)	2691 (33.8%)
Electrolyte imbalance	2 (<0.1%)	0	2 (<0.1%)
Fluid overload	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Fluid retention	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Folate deficiency	9 (0.2%)	9 (0.2%)	18 (0.2%)
Food intolerance	1 (<0.1%)	0	1 (<0.1%)
Glucose tolerance impaired	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Gout	414 (10.4%)	420 (10.5%)	834 (10.5%)
Haemochromatosis	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Haemosiderosis	0	1 (<0.1%)	1 (<0.1%)
Hypercalcaemia	15 (0.4%)	20 (0.5%)	35 (0.4%)
Hyperchloraemia	1 (<0.1%)	0	1 (<0.1%)
Hypercholesterolaemia	506 (12.7%)	499 (12.5%)	1005 (12.6%)
Hypercreatininaemia	0	1 (<0.1%)	1 (<0.1%)
Hyperferritinaemia	1 (<0.1%)	0	1 (<0.1%)
Hyperglycaemia	7 (0.2%)	10 (0.3%)	17 (0.2%)
Hyperglycaemic hyperosmolar nonketotic syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperhomocysteinaemia	14 (0.4%)	6 (0.2%)	20 (0.3%)
Hyperinsulinaemic hypoglycaemia	1 (<0.1%)	0	1 (<0.1%)
Hyperkalaemia	94 (2.4%)	95 (2.4%)	189 (2.4%)
Hyperlipidaemia	1139 (28.6%)	1168 (29.3%)	2307 (29.0%)
Hypernatraemia	1 (<0.1%)	0	1 (<0.1%)
Hyperphagia	1 (<0.1%)	0	1 (<0.1%)
Hyperphosphataemia	8 (0.2%)	7 (0.2%)	15 (0.2%)
Hyperproteinaemia	0	1 (<0.1%)	1 (<0.1%)
Hypertriglyceridaemia	90 (2.3%)	86 (2.2%)	176 (2.2%)
Hyperuricaemia	733 (18.4%)	771 (19.4%)	1504 (18.9%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Hypo HDL cholesterolaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypoalbuminaemia	7 (0.2%)	8 (0.2%)	15 (0.2%)
Hypocalcaemia	9 (0.2%)	13 (0.3%)	22 (0.3%)
Hypoglycaemia	29 (0.7%)	22 (0.6%)	51 (0.6%)
Hypokalaemia	40 (1.0%)	42 (1.1%)	82 (1.0%)
Hypolipidaemia	1 (<0.1%)	0	1 (<0.1%)
Hypomagnesaemia	19 (0.5%)	13 (0.3%)	32 (0.4%)
Hypometabolism	0	1 (<0.1%)	1 (<0.1%)
Hyponatraemia	14 (0.4%)	17 (0.4%)	31 (0.4%)
Hypophosphataemia	0	4 (0.1%)	4 (<0.1%)
Hypoproteinaemia	8 (0.2%)	7 (0.2%)	15 (0.2%)
Hypouricaemia	2 (<0.1%)	0	2 (<0.1%)
Hypovitaminosis	1 (<0.1%)	9 (0.2%)	10 (0.1%)
Hypovolaemia	1 (<0.1%)	0	1 (<0.1%)
Impaired fasting glucose	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Insulin resistance	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency	37 (0.9%)	35 (0.9%)	72 (0.9%)
Ketoacidosis	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lactose intolerance	6 (0.2%)	5 (0.1%)	11 (0.1%)
Latent autoimmune diabetes in adults	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lipid metabolism disorder	14 (0.4%)	23 (0.6%)	37 (0.5%)
Lipoedema	0	1 (<0.1%)	1 (<0.1%)
Lipomatosis	0	1 (<0.1%)	1 (<0.1%)
Magnesium deficiency	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Magnesium metabolism disorder	0	1 (<0.1%)	1 (<0.1%)
Malnutrition	0	1 (<0.1%)	1 (<0.1%)
Metabolic acidosis	14 (0.4%)	20 (0.5%)	34 (0.4%)
Metabolic alkalosis	0	3 (<0.1%)	3 (<0.1%)
Metabolic disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Metabolic syndrome	29 (0.7%)	27 (0.7%)	56 (0.7%)
Obesity	1627 (40.9%)	1550 (38.9%)	3177 (39.9%)
Overweight	47 (1.2%)	44 (1.1%)	91 (1.1%)
Pancreatogenous diabetes	0	1 (<0.1%)	1 (<0.1%)
Polydipsia	1 (<0.1%)	0	1 (<0.1%)
Purine metabolism disorder	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Tetany	1 (<0.1%)	0	1 (<0.1%)
Type 2 diabetes mellitus	3980 (>99.9%)	3981 (>99.9%)	7961 (>99.9%)
Vitamin B complex deficiency	8 (0.2%)	5 (0.1%)	13 (0.2%)
Vitamin B1 deficiency	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitamin B12 deficiency	86 (2.2%)	77 (1.9%)	163 (2.0%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Vitamin C deficiency	1 (<0.1%)	0	1 (<0.1%)
Vitamin D deficiency	383 (9.6%)	372 (9.3%)	755 (9.5%)
Zinc deficiency	0	2 (<0.1%)	2 (<0.1%)
Musculoskeletal and connective tissue disorders	1582 (39.7%)	1589 (39.9%)	3171 (39.8%)
Acquired claw toe	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle deformity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ankle impingement	0	1 (<0.1%)	1 (<0.1%)
Ankylosing spondylitis	8 (0.2%)	7 (0.2%)	15 (0.2%)
Arthralgia	182 (4.6%)	180 (4.5%)	362 (4.5%)
Arthritis	81 (2.0%)	98 (2.5%)	179 (2.2%)
Arthritis reactive	1 (<0.1%)	0	1 (<0.1%)
Arthropathy	12 (0.3%)	13 (0.3%)	25 (0.3%)
Articular calcification	2 (<0.1%)	0	2 (<0.1%)
Axial spondyloarthritis	1 (<0.1%)	0	1 (<0.1%)
Axillary mass	1 (<0.1%)	0	1 (<0.1%)
Back disorder	2 (<0.1%)	12 (0.3%)	14 (0.2%)
Back pain	286 (7.2%)	313 (7.9%)	599 (7.5%)
Bone atrophy	1 (<0.1%)	0	1 (<0.1%)
Bone cyst	0	1 (<0.1%)	1 (<0.1%)
Bone disorder	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Bone formation increased	0	1 (<0.1%)	1 (<0.1%)
Bone hypertrophy	0	1 (<0.1%)	1 (<0.1%)
Bone lesion	0	1 (<0.1%)	1 (<0.1%)
Bone metabolism disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Bone pain	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Bursa disorder	0	1 (<0.1%)	1 (<0.1%)
Bursitis	18 (0.5%)	17 (0.4%)	35 (0.4%)
Calcification of muscle	1 (<0.1%)	0	1 (<0.1%)
Cervical spinal stenosis	9 (0.2%)	6 (0.2%)	15 (0.2%)
Chondrocalcinosis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Chondrocalcinosis pyrophosphate	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chondromalacia	1 (<0.1%)	0	1 (<0.1%)
Chondropathy	2 (<0.1%)	0	2 (<0.1%)
Chronic kidney disease-mineral and bone disorder	12 (0.3%)	14 (0.4%)	26 (0.3%)
Coccydynia	1 (<0.1%)	0	1 (<0.1%)
Compartment syndrome	0	1 (<0.1%)	1 (<0.1%)
Costochondritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Crystal arthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deformity thorax	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Destructive spondyloarthropathy	0	1 (<0.1%)	1 (<0.1%)
Diabetic amyotrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diastasis recti abdominis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Diffuse idiopathic skeletal hyperostosis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Dupuytren's contracture	18 (0.5%)	14 (0.4%)	32 (0.4%)
Enthesopathy	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Exostosis	13 (0.3%)	18 (0.5%)	31 (0.4%)
Extremity contracture	1 (<0.1%)	0	1 (<0.1%)
Facet joint syndrome	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Fasciitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Fibromyalgia	15 (0.4%)	17 (0.4%)	32 (0.4%)
Finger deformity	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Flank pain	5 (0.1%)	5 (0.1%)	10 (0.1%)
Foot deformity	25 (0.6%)	28 (0.7%)	53 (0.7%)
Gouty arthritis	66 (1.7%)	52 (1.3%)	118 (1.5%)
Gouty tophus	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Groin pain	0	1 (<0.1%)	1 (<0.1%)
Haemarthrosis	1 (<0.1%)	0	1 (<0.1%)
Hand deformity	0	1 (<0.1%)	1 (<0.1%)
Hypercreatinaemia	1 (<0.1%)	0	1 (<0.1%)
Inguinal mass	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc compression	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc degeneration	37 (0.9%)	26 (0.7%)	63 (0.8%)
Intervertebral disc disorder	48 (1.2%)	35 (0.9%)	83 (1.0%)
Intervertebral disc displacement	4 (0.1%)	4 (0.1%)	8 (0.1%)
Intervertebral disc protrusion	105 (2.6%)	102 (2.6%)	207 (2.6%)
Intervertebral disc space narrowing	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Jaw cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint contracture	0	2 (<0.1%)	2 (<0.1%)
Joint deposit	2 (<0.1%)	0	2 (<0.1%)
Joint effusion	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Joint instability	0	1 (<0.1%)	1 (<0.1%)
Joint noise	0	1 (<0.1%)	1 (<0.1%)
Joint range of motion decreased	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Joint stiffness	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint swelling	4 (0.1%)	6 (0.2%)	10 (0.1%)
Knee deformity	2 (<0.1%)	0	2 (<0.1%)
Kyphosis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ligament disorder	0	1 (<0.1%)	1 (<0.1%)
Limb asymmetry	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Limb discomfort	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Limb mass	0	2 (<0.1%)	2 (<0.1%)
Lumbar spinal stenosis	31 (0.8%)	32 (0.8%)	63 (0.8%)
Meniscal degeneration	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metatarsalgia	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Mobility decreased	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle atrophy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Muscle contracture	1 (<0.1%)	0	1 (<0.1%)
Muscle disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Muscle spasms	116 (2.9%)	111 (2.8%)	227 (2.9%)
Muscle tightness	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	7 (0.2%)	16 (0.4%)	23 (0.3%)
Musculoskeletal chest pain	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Musculoskeletal discomfort	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Musculoskeletal disorder	2 (<0.1%)	0	2 (<0.1%)
Musculoskeletal pain	4 (0.1%)	6 (0.2%)	10 (0.1%)
Musculoskeletal stiffness	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Myalgia	50 (1.3%)	49 (1.2%)	99 (1.2%)
Myofascial pain syndrome	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Myopathy	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Myositis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Neck mass	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Neck pain	26 (0.7%)	33 (0.8%)	59 (0.7%)
Neuropathic arthropathy	19 (0.5%)	26 (0.7%)	45 (0.6%)
Nodal osteoarthritis	0	1 (<0.1%)	1 (<0.1%)
Oligoarthritis	1 (<0.1%)	0	1 (<0.1%)
Osteitis	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Osteitis deformans	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Osteoarthritis	544 (13.7%)	533 (13.4%)	1077 (13.5%)
Osteoarthropathy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Osteochondrosis	48 (1.2%)	54 (1.4%)	102 (1.3%)
Osteolysis	0	2 (<0.1%)	2 (<0.1%)
Osteonecrosis	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Osteopenia	39 (1.0%)	34 (0.9%)	73 (0.9%)
Osteoporosis	122 (3.1%)	126 (3.2%)	248 (3.1%)
Osteoporosis postmenopausal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteoporotic fracture	1 (<0.1%)	0	1 (<0.1%)
Osteosclerosis	3 (<0.1%)	0	3 (<0.1%)
Pain in extremity	65 (1.6%)	67 (1.7%)	132 (1.7%)
Pain in jaw	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Patellofemoral pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pathological fracture	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Periarthritis	33 (0.8%)	30 (0.8%)	63 (0.8%)
Plantar fascial fibromatosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Plantar fasciitis	7 (0.2%)	12 (0.3%)	19 (0.2%)
Plica syndrome	1 (<0.1%)	0	1 (<0.1%)
Polyarthritis	5 (0.1%)	11 (0.3%)	16 (0.2%)
Polymyalgia rheumatica	9 (0.2%)	10 (0.3%)	19 (0.2%)
Polymyositis	1 (<0.1%)	0	1 (<0.1%)
Prognathism	0	1 (<0.1%)	1 (<0.1%)
Pseudarthrosis	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	4 (0.1%)	8 (0.2%)	12 (0.2%)
Rhabdomyolysis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Rheumatic disorder	6 (0.2%)	4 (0.1%)	10 (0.1%)
Rheumatic fever	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rheumatoid arthritis	31 (0.8%)	32 (0.8%)	63 (0.8%)
Rotator cuff syndrome	56 (1.4%)	33 (0.8%)	89 (1.1%)
Sacroiliitis	3 (<0.1%)	0	3 (<0.1%)
Sarcopenia	0	1 (<0.1%)	1 (<0.1%)
Scleroderma	1 (<0.1%)	0	1 (<0.1%)
Scoliosis	6 (0.2%)	13 (0.3%)	19 (0.2%)
Senile osteoporosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Seronegative arthritis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sjogren's syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Soft tissue disorder	2 (<0.1%)	0	2 (<0.1%)
Soft tissue mass	0	2 (<0.1%)	2 (<0.1%)
Soft tissue swelling	1 (<0.1%)	0	1 (<0.1%)
Spinal deformity	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Spinal disorder	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Spinal ligament ossification	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal osteoarthritis	169 (4.2%)	165 (4.1%)	334 (4.2%)
Spinal pain	18 (0.5%)	18 (0.5%)	36 (0.5%)
Spinal retrolisthesis	0	2 (<0.1%)	2 (<0.1%)
Spinal stenosis	45 (1.1%)	46 (1.2%)	91 (1.1%)
Spondylitis	3 (<0.1%)	8 (0.2%)	11 (0.1%)
Spondyloarthropathy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Spondylolisthesis	14 (0.4%)	11 (0.3%)	25 (0.3%)
Spondylolysis	2 (<0.1%)	0	2 (<0.1%)
Still's disease	1 (<0.1%)	0	1 (<0.1%)
Symphysiolysis	0	1 (<0.1%)	1 (<0.1%)
Synovial cyst	5 (0.1%)	7 (0.2%)	12 (0.2%)
Synovitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Systemic lupus erythematosus	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Temporomandibular joint syndrome	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Tendon calcification	0	1 (<0.1%)	1 (<0.1%)
Tendon disorder	4 (0.1%)	6 (0.2%)	10 (0.1%)
Tendon pain	1 (<0.1%)	0	1 (<0.1%)
Tendonitis	10 (0.3%)	15 (0.4%)	25 (0.3%)
Tenosynovitis	10 (0.3%)	4 (0.1%)	14 (0.2%)
Tenosynovitis stenosans	4 (0.1%)	5 (0.1%)	9 (0.1%)
Torticollis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Trigger finger	36 (0.9%)	19 (0.5%)	55 (0.7%)
Vertebral foraminal stenosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Vertebral osteophyte	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	576 (14.5%)	600 (15.1%)	1176 (14.8%)
Acoustic neuroma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Acrochordon	6 (0.2%)	5 (0.1%)	11 (0.1%)
Acute myeloid leukaemia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma gastric	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma of colon	8 (0.2%)	3 (<0.1%)	11 (0.1%)
Adenoma benign	5 (0.1%)	4 (0.1%)	9 (0.1%)
Adrenal adenoma	19 (0.5%)	13 (0.3%)	32 (0.4%)
Adrenal gland cancer	0	2 (<0.1%)	2 (<0.1%)
Adrenal neoplasm	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Angiolipoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyofibroblastoma	1 (<0.1%)	0	1 (<0.1%)
Angiomyolipoma	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Anogenital warts	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Appendix adenoma	0	1 (<0.1%)	1 (<0.1%)
B-cell lymphoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal cell carcinoma	44 (1.1%)	43 (1.1%)	87 (1.1%)
Benign breast neoplasm	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Benign ear neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign endocrine neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign female reproductive tract neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign gastrointestinal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign hepatic neoplasm	4 (0.1%)	0	4 (<0.1%)
Benign laryngeal neoplasm	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Benign lung neoplasm	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Benign mediastinal neoplasm	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Benign neoplasm	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Benign neoplasm of adrenal gland	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Benign neoplasm of bladder	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of choroid	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of orbit	0	1 (<0.1%)	1 (<0.1%)
Benign neoplasm of prostate	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Benign neoplasm of skin	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Benign neoplasm of thyroid gland	5 (0.1%)	5 (0.1%)	10 (0.1%)
Benign neoplasm of urethra	0	1 (<0.1%)	1 (<0.1%)
Benign nipple neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign ovarian tumour	0	2 (<0.1%)	2 (<0.1%)
Benign penile neoplasm	1 (<0.1%)	0	1 (<0.1%)
Benign renal neoplasm	0	2 (<0.1%)	2 (<0.1%)
Benign salivary gland neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Benign soft tissue neoplasm	0	1 (<0.1%)	1 (<0.1%)
Benign uterine neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder cancer	14 (0.4%)	20 (0.5%)	34 (0.4%)
Bladder cancer recurrent	2 (<0.1%)	0	2 (<0.1%)
Bladder neoplasm	4 (0.1%)	8 (0.2%)	12 (0.2%)
Bladder papilloma	0	1 (<0.1%)	1 (<0.1%)
Bladder transitional cell carcinoma	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Blepharal papilloma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone cancer	0	1 (<0.1%)	1 (<0.1%)
Bone neoplasm	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Bowen's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Brain neoplasm	1 (<0.1%)	0	1 (<0.1%)
Brain neoplasm benign	0	2 (<0.1%)	2 (<0.1%)
Breast adenoma	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	34 (0.9%)	24 (0.6%)	58 (0.7%)
Breast cancer in situ	0	1 (<0.1%)	1 (<0.1%)
Breast fibroma	0	1 (<0.1%)	1 (<0.1%)
Breast neoplasm	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Bronchioloalveolar carcinoma	1 (<0.1%)	0	1 (<0.1%)
Carcinoid tumour of the gastrointestinal tract	1 (<0.1%)	0	1 (<0.1%)
Carcinoma in situ	0	1 (<0.1%)	1 (<0.1%)
Cervix carcinoma	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Cholesteatoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chondroma	0	1 (<0.1%)	1 (<0.1%)
Chronic lymphocytic leukaemia	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Chronic lymphocytic leukaemia stage 0	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Chronic myeloid leukaemia	0	1 (<0.1%)	1 (<0.1%)
Chronic myelomonocytic leukaemia	1 (<0.1%)	0	1 (<0.1%)
Clear cell renal cell carcinoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colon adenoma	21 (0.5%)	10 (0.3%)	31 (0.4%)
Colon cancer	20 (0.5%)	26 (0.7%)	46 (0.6%)
Colon cancer stage 0	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colon neoplasm	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Colorectal adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Dermatofibrosarcoma protuberans	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysplastic naevus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ear neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enchondromatosis	2 (<0.1%)	0	2 (<0.1%)
Endobronchial lipoma	1 (<0.1%)	0	1 (<0.1%)
Endometrial cancer	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Essential thrombocythaemia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Extranodal marginal zone B-cell lymphoma (MALT type)	0	1 (<0.1%)	1 (<0.1%)
Eye naevus	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Female reproductive neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Fibroadenoma of breast	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Fibroma	0	2 (<0.1%)	2 (<0.1%)
Fibromatosis	1 (<0.1%)	0	1 (<0.1%)
Fibrous histiocytoma	1 (<0.1%)	0	1 (<0.1%)
Focal nodular hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Gallbladder cancer	0	2 (<0.1%)	2 (<0.1%)
Gallbladder neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastric adenoma	2 (<0.1%)	0	2 (<0.1%)
Gastric cancer	5 (0.1%)	5 (0.1%)	10 (0.1%)
Gastric neoplasm	0	1 (<0.1%)	1 (<0.1%)
Gastric sarcoma	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal stromal tumour	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal submucosal tumour	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Gastrointestinal tract adenoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Germ cell neoplasm	1 (<0.1%)	0	1 (<0.1%)
Gingival cancer	1 (<0.1%)	0	1 (<0.1%)
Glomus tumour	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	4 (0.1%)	0	4 (<0.1%)
Haemangioma of bone	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haemangioma of liver	10 (0.3%)	10 (0.3%)	20 (0.3%)
Haemangioma of skin	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Haemangioma of spleen	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hair follicle tumour benign	1 (<0.1%)	0	1 (<0.1%)
Hepatic cancer	0	2 (<0.1%)	2 (<0.1%)
Hepatic cancer metastatic	1 (<0.1%)	0	1 (<0.1%)
Hepatic neoplasm	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Hepatocellular carcinoma	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypergammaglobulinaemia benign monoclonal	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Intra-abdominal haemangioma	1 (<0.1%)	0	1 (<0.1%)
Intraductal papillary mucinous neoplasm	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Intraductal proliferative breast lesion	1 (<0.1%)	0	1 (<0.1%)
Intraocular melanoma	1 (<0.1%)	0	1 (<0.1%)
Invasive ductal breast carcinoma	2 (<0.1%)	0	2 (<0.1%)
Iris melanoma	0	1 (<0.1%)	1 (<0.1%)
Juvenile angiofibroma	0	1 (<0.1%)	1 (<0.1%)
Kaposi's sarcoma	0	1 (<0.1%)	1 (<0.1%)
Large granular lymphocytosis	1 (<0.1%)	0	1 (<0.1%)
Large intestine benign neoplasm	5 (0.1%)	10 (0.3%)	15 (0.2%)
Laryngeal cancer	0	2 (<0.1%)	2 (<0.1%)
Laryngeal neoplasm	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Laryngeal squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Leiomyoma	1 (<0.1%)	0	1 (<0.1%)
Lentigo maligna	1 (<0.1%)	0	1 (<0.1%)
Leukaemia	0	3 (<0.1%)	3 (<0.1%)
Light chain disease	0	1 (<0.1%)	1 (<0.1%)
Lip neoplasm malignant stage unspecified	1 (<0.1%)	0	1 (<0.1%)
Lip squamous cell carcinoma	5 (0.1%)	0	5 (<0.1%)
Lipoma	18 (0.5%)	21 (0.5%)	39 (0.5%)
Liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Lung adenocarcinoma	0	1 (<0.1%)	1 (<0.1%)
Lung carcinoma cell type unspecified stage 0	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm malignant	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Lymphangioma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lymphoma	1 (<0.1%)	0	1 (<0.1%)
Malignant lymphoid neoplasm	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	10 (0.3%)	13 (0.3%)	23 (0.3%)
Malignant melanoma in situ	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Malignant melanoma stage IV	1 (<0.1%)	0	1 (<0.1%)
Malignant neoplasm of eyelid	1 (<0.1%)	0	1 (<0.1%)
Malignant urinary tract neoplasm	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Melanocytic naevus	6 (0.2%)	4 (0.1%)	10 (0.1%)
Meningioma	7 (0.2%)	7 (0.2%)	14 (0.2%)
Meningioma benign	1 (<0.1%)	0	1 (<0.1%)
Metastases to liver	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Metastases to lung	0	4 (0.1%)	4 (<0.1%)
Metastatic malignant melanoma	1 (<0.1%)	0	1 (<0.1%)
Monoclonal gammopathy	6 (0.2%)	6 (0.2%)	12 (0.2%)
Myelodysplastic syndrome	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Myeloid leukaemia	1 (<0.1%)	0	1 (<0.1%)
Nasal sinus cancer	0	1 (<0.1%)	1 (<0.1%)
Neoplasm	2 (<0.1%)	0	2 (<0.1%)
Neoplasm malignant	0	1 (<0.1%)	1 (<0.1%)
Neoplasm prostate	7 (0.2%)	5 (0.1%)	12 (0.2%)
Neoplasm skin	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Neuroendocrine tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurofibroma	0	2 (<0.1%)	2 (<0.1%)
Nodular melanoma	0	1 (<0.1%)	1 (<0.1%)
Non-Hodgkin's lymphoma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Non-secretory adenoma of pituitary	0	1 (<0.1%)	1 (<0.1%)
Non-small cell lung cancer	1 (<0.1%)	0	1 (<0.1%)
Ocular lymphoma	1 (<0.1%)	0	1 (<0.1%)
Oesophageal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oesophageal papilloma	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Oral haemangioma	1 (<0.1%)	0	1 (<0.1%)
Oral neoplasm	0	1 (<0.1%)	1 (<0.1%)
Oral papilloma	0	1 (<0.1%)	1 (<0.1%)
Osteoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian adenoma	1 (<0.1%)	0	1 (<0.1%)
Ovarian cancer	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Ovarian epithelial cancer	1 (<0.1%)	0	1 (<0.1%)
Ovarian germ cell teratoma benign	1 (<0.1%)	0	1 (<0.1%)
Ovarian neoplasm	3 (<0.1%)	0	3 (<0.1%)
Pancreatic neoplasm	2 (<0.1%)	0	2 (<0.1%)
Papillary cystadenoma lymphomatosum	3 (<0.1%)	0	3 (<0.1%)
Papillary thyroid cancer	1 (<0.1%)	0	1 (<0.1%)
Paraproteinaemia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Parathyroid tumour benign	4 (0.1%)	5 (0.1%)	9 (0.1%)
Penile cancer	1 (<0.1%)	0	1 (<0.1%)
Penile squamous cell carcinoma	0	1 (<0.1%)	1 (<0.1%)
Pituitary tumour benign	7 (0.2%)	5 (0.1%)	12 (0.2%)
Plasma cell myeloma	3 (<0.1%)	4 (0.1%)	7 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Plasma cell myeloma in remission	0	1 (<0.1%)	1 (<0.1%)
Pleomorphic adenoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pleomorphic liposarcoma	1 (<0.1%)	0	1 (<0.1%)
Polycythaemia vera	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Prolactin-producing pituitary tumour	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prostate cancer	53 (1.3%)	74 (1.9%)	127 (1.6%)
Prostate cancer recurrent	2 (<0.1%)	0	2 (<0.1%)
Prostate cancer stage I	1 (<0.1%)	0	1 (<0.1%)
Prostatic adenoma	18 (0.5%)	15 (0.4%)	33 (0.4%)
Rectal adenocarcinoma	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rectal cancer	11 (0.3%)	5 (0.1%)	16 (0.2%)
Rectal neoplasm	0	1 (<0.1%)	1 (<0.1%)
Rectosigmoid cancer	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	15 (0.4%)	7 (0.2%)	22 (0.3%)
Renal cell carcinoma	13 (0.3%)	12 (0.3%)	25 (0.3%)
Renal haemangioma	1 (<0.1%)	0	1 (<0.1%)
Renal hamartoma	5 (0.1%)	6 (0.2%)	11 (0.1%)
Renal neoplasm	2 (<0.1%)	8 (0.2%)	10 (0.1%)
Renal oncocytoma	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Salivary gland adenoma	1 (<0.1%)	0	1 (<0.1%)
Salivary gland cancer	0	1 (<0.1%)	1 (<0.1%)
Salivary gland neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Seborrhoeic keratosis	20 (0.5%)	21 (0.5%)	41 (0.5%)
Seminoma	0	2 (<0.1%)	2 (<0.1%)
Skin cancer	6 (0.2%)	10 (0.3%)	16 (0.2%)
Skin papilloma	7 (0.2%)	8 (0.2%)	15 (0.2%)
Small intestine carcinoma	0	1 (<0.1%)	1 (<0.1%)
Spindle cell sarcoma	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma	3 (<0.1%)	9 (0.2%)	12 (0.2%)
Squamous cell carcinoma of lung	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Squamous cell carcinoma of pharynx	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma of skin	7 (0.2%)	8 (0.2%)	15 (0.2%)
Squamous cell carcinoma of the tongue	1 (<0.1%)	0	1 (<0.1%)
Superficial spreading melanoma stage unspecified	0	1 (<0.1%)	1 (<0.1%)
Sweat gland tumour	0	1 (<0.1%)	1 (<0.1%)
Teratoma	0	1 (<0.1%)	1 (<0.1%)
Testicular neoplasm	1 (<0.1%)	0	1 (<0.1%)
Testis cancer	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Throat cancer	0	2 (<0.1%)	2 (<0.1%)
Thyroid B-cell lymphoma	0	1 (<0.1%)	1 (<0.1%)
Thyroid adenoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Thyroid cancer	5 (0.1%)	5 (0.1%)	10 (0.1%)
Thyroid neoplasm	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tongue neoplasm	1 (<0.1%)	0	1 (<0.1%)
Tongue neoplasm benign	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tongue neoplasm malignant stage unspecified	0	2 (<0.1%)	2 (<0.1%)
Tonsil cancer	0	1 (<0.1%)	1 (<0.1%)
Tonsillar neoplasm	0	1 (<0.1%)	1 (<0.1%)
Transitional cell cancer of the renal pelvis and ureter	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Transitional cell carcinoma urethra	1 (<0.1%)	0	1 (<0.1%)
Ureteric cancer	1 (<0.1%)	0	1 (<0.1%)
Urinary tract neoplasm	0	1 (<0.1%)	1 (<0.1%)
Uterine cancer	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Uterine leiomyoma	41 (1.0%)	42 (1.1%)	83 (1.0%)
Vaginal cancer	0	1 (<0.1%)	1 (<0.1%)
Waldenstrom's macroglobulinaemia	0	1 (<0.1%)	1 (<0.1%)
Nervous system disorders	2090 (52.5%)	2098 (52.7%)	4188 (52.6%)
Acoustic neuritis	0	2 (<0.1%)	2 (<0.1%)
Allodynia	0	3 (<0.1%)	3 (<0.1%)
Amnesia	13 (0.3%)	14 (0.4%)	27 (0.3%)
Amnestic disorder	1 (<0.1%)	0	1 (<0.1%)
Anosmia	0	1 (<0.1%)	1 (<0.1%)
Aphasia	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Arachnoid cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arachnoiditis	1 (<0.1%)	0	1 (<0.1%)
Areflexia	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Ataxia	5 (0.1%)	0	5 (<0.1%)
Athetosis	0	1 (<0.1%)	1 (<0.1%)
Autoimmune neuropathy	0	1 (<0.1%)	1 (<0.1%)
Autonomic nervous system imbalance	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Autonomic neuropathy	5 (0.1%)	5 (0.1%)	10 (0.1%)
Axonal neuropathy	2 (<0.1%)	0	2 (<0.1%)
Balance disorder	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Basal ganglia haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal ganglia infarction	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Basilar artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Basilar artery stenosis	0	2 (<0.1%)	2 (<0.1%)
Bradykinesia	0	1 (<0.1%)	1 (<0.1%)
Brain injury	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Brain oedema	0	1 (<0.1%)	1 (<0.1%)
Brain stem haematoma	0	1 (<0.1%)	1 (<0.1%)
Brain stem haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Brain stem infarction	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Brain stem stroke	1 (<0.1%)	0	1 (<0.1%)
Burning feet syndrome	1 (<0.1%)	0	1 (<0.1%)
Burning sensation	1 (<0.1%)	0	1 (<0.1%)
Cardiac autonomic neuropathy	3 (<0.1%)	0	3 (<0.1%)
Carotid arteriosclerosis	93 (2.3%)	92 (2.3%)	185 (2.3%)
Carotid artery aneurysm	2 (<0.1%)	0	2 (<0.1%)
Carotid artery disease	9 (0.2%)	18 (0.5%)	27 (0.3%)
Carotid artery insufficiency	1 (<0.1%)	0	1 (<0.1%)
Carotid artery occlusion	11 (0.3%)	8 (0.2%)	19 (0.2%)
Carotid artery stenosis	91 (2.3%)	85 (2.1%)	176 (2.2%)
Carotid artery thrombosis	1 (<0.1%)	0	1 (<0.1%)
Carpal tunnel syndrome	68 (1.7%)	70 (1.8%)	138 (1.7%)
Central nervous system lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Central nervous system necrosis	0	1 (<0.1%)	1 (<0.1%)
Cerebellar ataxia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar atrophy	0	1 (<0.1%)	1 (<0.1%)
Cerebellar haemorrhage	0	2 (<0.1%)	2 (<0.1%)
Cerebellar ischaemia	1 (<0.1%)	0	1 (<0.1%)
Cerebellar stroke	0	1 (<0.1%)	1 (<0.1%)
Cerebellar syndrome	1 (<0.1%)	0	1 (<0.1%)
Cerebral arteriosclerosis	25 (0.6%)	35 (0.9%)	60 (0.8%)
Cerebral artery embolism	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cerebral artery occlusion	0	4 (0.1%)	4 (<0.1%)
Cerebral artery stenosis	6 (0.2%)	5 (0.1%)	11 (0.1%)
Cerebral atrophy	14 (0.4%)	11 (0.3%)	25 (0.3%)
Cerebral circulatory failure	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cerebral cyst	1 (<0.1%)	0	1 (<0.1%)
Cerebral disorder	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	5 (0.1%)	8 (0.2%)	13 (0.2%)
Cerebral hypoperfusion	3 (<0.1%)	0	3 (<0.1%)
Cerebral infarction	32 (0.8%)	19 (0.5%)	51 (0.6%)
Cerebral ischaemia	31 (0.8%)	20 (0.5%)	51 (0.6%)
Cerebral microangiopathy	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Cerebral small vessel ischaemic disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cerebral thrombosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrosclerosis	0	1 (<0.1%)	1 (<0.1%)
Cerebrospinal fluid leakage	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Cerebrovascular accident	31 (0.8%)	27 (0.7%)	58 (0.7%)
Cerebrovascular disorder	51 (1.3%)	61 (1.5%)	112 (1.4%)
Cerebrovascular insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cerebrovascular stenosis	1 (<0.1%)	0	1 (<0.1%)
Cervical cord compression	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	6 (0.2%)	11 (0.3%)	17 (0.2%)
Cervicobrachial syndrome	9 (0.2%)	11 (0.3%)	20 (0.3%)
Circadian rhythm sleep disorder	0	1 (<0.1%)	1 (<0.1%)
Clonus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cluster headache	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Cognitive disorder	9 (0.2%)	4 (0.1%)	13 (0.2%)
Cogwheel rigidity	1 (<0.1%)	0	1 (<0.1%)
Complex regional pain syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coordination abnormal	0	1 (<0.1%)	1 (<0.1%)
Cubital tunnel syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Decreased vibratory sense	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Dementia	8 (0.2%)	8 (0.2%)	16 (0.2%)
Dementia Alzheimer's type	8 (0.2%)	4 (0.1%)	12 (0.2%)
Demyelinating polyneuropathy	1 (<0.1%)	0	1 (<0.1%)
Demyelination	2 (<0.1%)	0	2 (<0.1%)
Diabetic autonomic neuropathy	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Diabetic coma	0	2 (<0.1%)	2 (<0.1%)
Diabetic encephalopathy	7 (0.2%)	4 (0.1%)	11 (0.1%)
Diabetic mononeuropathy	0	2 (<0.1%)	2 (<0.1%)
Diabetic neuropathy	1004 (25.2%)	967 (24.3%)	1971 (24.8%)
Diplegia	0	1 (<0.1%)	1 (<0.1%)
Disturbance in attention	1 (<0.1%)	0	1 (<0.1%)
Dizziness	72 (1.8%)	63 (1.6%)	135 (1.7%)
Dizziness postural	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Drop attacks	0	1 (<0.1%)	1 (<0.1%)
Dural arteriovenous fistula	1 (<0.1%)	0	1 (<0.1%)
Dysaesthesia	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dysarthria	7 (0.2%)	1 (<0.1%)	8 (0.1%)
Dysgeusia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dyslalia	0	1 (<0.1%)	1 (<0.1%)
Dysmetria	1 (<0.1%)	0	1 (<0.1%)
Embolic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Encephalomalacia	0	2 (<0.1%)	2 (<0.1%)
Encephalopathy	30 (0.8%)	25 (0.6%)	55 (0.7%)
Epilepsy	15 (0.4%)	6 (0.2%)	21 (0.3%)
Essential tremor	12 (0.3%)	17 (0.4%)	29 (0.4%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Extrapyramidal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial nerve disorder	2 (<0.1%)	0	2 (<0.1%)
Facial paralysis	20 (0.5%)	37 (0.9%)	57 (0.7%)
Facial paresis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Fine motor skill dysfunction	1 (<0.1%)	0	1 (<0.1%)
Frontal lobe epilepsy	0	1 (<0.1%)	1 (<0.1%)
Frontotemporal dementia	0	1 (<0.1%)	1 (<0.1%)
Gait spastic	1 (<0.1%)	0	1 (<0.1%)
Generalised tonic-clonic seizure	0	2 (<0.1%)	2 (<0.1%)
Guillain-Barre syndrome	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Haemorrhage intracranial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haemorrhagic cerebral infarction	0	1 (<0.1%)	1 (<0.1%)
Haemorrhagic stroke	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Head discomfort	0	1 (<0.1%)	1 (<0.1%)
Head titubation	1 (<0.1%)	0	1 (<0.1%)
Headache	75 (1.9%)	71 (1.8%)	146 (1.8%)
Hemianaesthesia	2 (<0.1%)	0	2 (<0.1%)
Hemianopia	1 (<0.1%)	0	1 (<0.1%)
Hemianopia homonymous	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Hemiparesis	20 (0.5%)	23 (0.6%)	43 (0.5%)
Hemiplegia	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Horner's syndrome	1 (<0.1%)	0	1 (<0.1%)
Hydrocephalus	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperaesthesia	0	2 (<0.1%)	2 (<0.1%)
Hyperreflexia	0	2 (<0.1%)	2 (<0.1%)
Hypersomnia	0	3 (<0.1%)	3 (<0.1%)
Hypertensive encephalopathy	6 (0.2%)	7 (0.2%)	13 (0.2%)
Hypertonia	14 (0.4%)	19 (0.5%)	33 (0.4%)
Hypoaesthesia	36 (0.9%)	31 (0.8%)	67 (0.8%)
Hyporeflexia	0	1 (<0.1%)	1 (<0.1%)
Hyposmia	1 (<0.1%)	0	1 (<0.1%)
Hypoxic-ischaemic encephalopathy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
IIIrd nerve paralysis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
IIIrd nerve paresis	1 (<0.1%)	0	1 (<0.1%)
Intellectual disability	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intention tremor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Internal capsule infarction	0	1 (<0.1%)	1 (<0.1%)
Intracranial aneurysm	9 (0.2%)	7 (0.2%)	16 (0.2%)
Intracranial pressure increased	0	1 (<0.1%)	1 (<0.1%)
Intraventricular haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Ischaemic cerebral infarction	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Ischaemic stroke	540 (13.6%)	549 (13.8%)	1089 (13.7%)
Lacunar infarction	30 (0.8%)	14 (0.4%)	44 (0.6%)
Lacunar stroke	1 (<0.1%)	0	1 (<0.1%)
Lateral medullary syndrome	0	1 (<0.1%)	1 (<0.1%)
Lethargy	1 (<0.1%)	0	1 (<0.1%)
Loss of consciousness	0	2 (<0.1%)	2 (<0.1%)
Lumbar radiculopathy	8 (0.2%)	12 (0.3%)	20 (0.3%)
Lumbosacral plexopathy	1 (<0.1%)	0	1 (<0.1%)
Lumbosacral plexus lesion	0	2 (<0.1%)	2 (<0.1%)
Lumbosacral radiculopathy	5 (0.1%)	5 (0.1%)	10 (0.1%)
Memory impairment	9 (0.2%)	10 (0.3%)	19 (0.2%)
Meralgia paraesthetica	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Metabolic encephalopathy	4 (0.1%)	7 (0.2%)	11 (0.1%)
Migraine	22 (0.6%)	19 (0.5%)	41 (0.5%)
Migraine with aura	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Migraine without aura	0	2 (<0.1%)	2 (<0.1%)
Mononeuritis	1 (<0.1%)	0	1 (<0.1%)
Mononeuropathy	2 (<0.1%)	0	2 (<0.1%)
Mononeuropathy multiplex	0	1 (<0.1%)	1 (<0.1%)
Monoparesis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Monoplegia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Morton's neuralgia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Movement disorder	0	2 (<0.1%)	2 (<0.1%)
Multiple sclerosis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Muscle contractions involuntary	2 (<0.1%)	0	2 (<0.1%)
Muscle spasticity	0	1 (<0.1%)	1 (<0.1%)
Muscle tone disorder	1 (<0.1%)	0	1 (<0.1%)
Myasthenia gravis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Myelomalacia	1 (<0.1%)	0	1 (<0.1%)
Myelopathy	8 (0.2%)	5 (0.1%)	13 (0.2%)
Myoclonus	0	1 (<0.1%)	1 (<0.1%)
Narcolepsy	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Nervous system disorder	1 (<0.1%)	0	1 (<0.1%)
Neuralgia	36 (0.9%)	21 (0.5%)	57 (0.7%)
Neuralgic amyotrophy	2 (<0.1%)	0	2 (<0.1%)
Neuritis	2 (<0.1%)	0	2 (<0.1%)
Neuritis cranial	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neurological symptom	1 (<0.1%)	0	1 (<0.1%)
Neuropathy peripheral	195 (4.9%)	219 (5.5%)	414 (5.2%)
Normal pressure hydrocephalus	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Occipital neuralgia	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Optic neuritis	3 (<0.1%)	0	3 (<0.1%)
Orthostatic intolerance	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paraesthesia	29 (0.7%)	18 (0.5%)	47 (0.6%)
Paralysis	1 (<0.1%)	0	1 (<0.1%)
Paralysis recurrent laryngeal nerve	2 (<0.1%)	0	2 (<0.1%)
Paraparesis	1 (<0.1%)	0	1 (<0.1%)
Paresis	1 (<0.1%)	0	1 (<0.1%)
Parkinson's disease	15 (0.4%)	21 (0.5%)	36 (0.5%)
Parkinsonian rest tremor	0	1 (<0.1%)	1 (<0.1%)
Parkinsonism	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Parosmia	1 (<0.1%)	0	1 (<0.1%)
Partial seizures	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Perineurial cyst	1 (<0.1%)	0	1 (<0.1%)
Periodic limb movement disorder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral nerve lesion	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve paresis	0	2 (<0.1%)	2 (<0.1%)
Peripheral sensorimotor neuropathy	6 (0.2%)	9 (0.2%)	15 (0.2%)
Peripheral sensory neuropathy	8 (0.2%)	6 (0.2%)	14 (0.2%)
Peroneal nerve palsy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Phantom limb syndrome	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Piriformis syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Polyneuropathy	61 (1.5%)	73 (1.8%)	134 (1.7%)
Poor quality sleep	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Post herpetic neuralgia	7 (0.2%)	6 (0.2%)	13 (0.2%)
Post polio syndrome	1 (<0.1%)	0	1 (<0.1%)
Post stroke epilepsy	1 (<0.1%)	0	1 (<0.1%)
Post-traumatic epilepsy	1 (<0.1%)	0	1 (<0.1%)
Posterior reversible encephalopathy syndrome	0	1 (<0.1%)	1 (<0.1%)
Postictal paralysis	1 (<0.1%)	0	1 (<0.1%)
Postural tremor	2 (<0.1%)	0	2 (<0.1%)
Precerebral arteriosclerosis	1 (<0.1%)	0	1 (<0.1%)
Precerebral artery occlusion	1 (<0.1%)	0	1 (<0.1%)
Presyncope	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Quadrantanopia	0	1 (<0.1%)	1 (<0.1%)
Quadriplegia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radial nerve palsy	1 (<0.1%)	0	1 (<0.1%)
Radicular pain	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Radiculopathy	10 (0.3%)	9 (0.2%)	19 (0.2%)
Resting tremor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Restless legs syndrome	26 (0.7%)	21 (0.5%)	47 (0.6%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Reversible ischaemic neurological deficit	1 (<0.1%)	0	1 (<0.1%)
Sciatic nerve neuropathy	0	1 (<0.1%)	1 (<0.1%)
Sciatica	57 (1.4%)	54 (1.4%)	111 (1.4%)
Seizure	9 (0.2%)	5 (0.1%)	14 (0.2%)
Seizure like phenomena	1 (<0.1%)	0	1 (<0.1%)
Senile dementia	2 (<0.1%)	0	2 (<0.1%)
Sensory disturbance	0	1 (<0.1%)	1 (<0.1%)
Sleep deficit	0	1 (<0.1%)	1 (<0.1%)
Somnolence	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Spinal claudication	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Spinal cord compression	1 (<0.1%)	0	1 (<0.1%)
Spinal cord haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Spinal cord ischaemia	0	1 (<0.1%)	1 (<0.1%)
Spondylitic myelopathy	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Stupor	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	7 (0.2%)	5 (0.1%)	12 (0.2%)
Subdural effusion	1 (<0.1%)	0	1 (<0.1%)
Syncope	29 (0.7%)	19 (0.5%)	48 (0.6%)
Tardive dyskinesia	2 (<0.1%)	0	2 (<0.1%)
Tension headache	9 (0.2%)	5 (0.1%)	14 (0.2%)
Thalamic infarction	1 (<0.1%)	0	1 (<0.1%)
Thoracic outlet syndrome	1 (<0.1%)	0	1 (<0.1%)
Thrombotic cerebral infarction	1 (<0.1%)	0	1 (<0.1%)
Transient global amnesia	0	1 (<0.1%)	1 (<0.1%)
Transient ischaemic attack	79 (2.0%)	64 (1.6%)	143 (1.8%)
Tremor	17 (0.4%)	15 (0.4%)	32 (0.4%)
Trigeminal nerve disorder	0	1 (<0.1%)	1 (<0.1%)
Trigeminal neuralgia	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Ulnar nerve palsy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ulnar tunnel syndrome	0	1 (<0.1%)	1 (<0.1%)
Upper motor neurone lesion	1 (<0.1%)	0	1 (<0.1%)
VIth nerve disorder	0	1 (<0.1%)	1 (<0.1%)
VIth nerve paralysis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
VIth nerve paresis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular dementia	0	2 (<0.1%)	2 (<0.1%)
Vascular encephalopathy	26 (0.7%)	32 (0.8%)	58 (0.7%)
Vascular headache	1 (<0.1%)	0	1 (<0.1%)
Vertebral artery aneurysm	0	1 (<0.1%)	1 (<0.1%)
Vertebral artery arteriosclerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Vertebral artery stenosis	6 (0.2%)	10 (0.3%)	16 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Vertebrobasilar dolichoectasia	0	1 (<0.1%)	1 (<0.1%)
Vertebrobasilar insufficiency	7 (0.2%)	7 (0.2%)	14 (0.2%)
Vertigo CNS origin	0	1 (<0.1%)	1 (<0.1%)
Visual field defect	5 (0.1%)	5 (0.1%)	10 (0.1%)
Vocal cord paralysis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Vocal cord paresis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
White matter lesion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pregnancy, puerperium and perinatal conditions	9 (0.2%)	12 (0.3%)	21 (0.3%)
Abortion incomplete	0	1 (<0.1%)	1 (<0.1%)
Abortion spontaneous	0	1 (<0.1%)	1 (<0.1%)
Cephalo-pelvic disproportion	0	1 (<0.1%)	1 (<0.1%)
Delivery	0	1 (<0.1%)	1 (<0.1%)
Ectopic pregnancy	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Gestational diabetes	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Postpartum haemorrhage	0	1 (<0.1%)	1 (<0.1%)
Pre-eclampsia	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Previous caesarean section	0	1 (<0.1%)	1 (<0.1%)
Ruptured ectopic pregnancy	1 (<0.1%)	0	1 (<0.1%)
Product issues	0	3 (<0.1%)	3 (<0.1%)
Device breakage	0	1 (<0.1%)	1 (<0.1%)
Device dislocation	0	2 (<0.1%)	2 (<0.1%)
Psychiatric disorders	672 (16.9%)	705 (17.7%)	1377 (17.3%)
Abnormal dreams	1 (<0.1%)	0	1 (<0.1%)
Acute stress disorder	1 (<0.1%)	0	1 (<0.1%)
Adjustment disorder	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Adjustment disorder with anxiety	0	1 (<0.1%)	1 (<0.1%)
Adjustment disorder with depressed mood	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Adjustment disorder with mixed anxiety and depressed mood	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Affect lability	0	2 (<0.1%)	2 (<0.1%)
Affective disorder	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Agitation	0	1 (<0.1%)	1 (<0.1%)
Agoraphobia	1 (<0.1%)	0	1 (<0.1%)
Alcohol abuse	8 (0.2%)	4 (0.1%)	12 (0.2%)
Alcoholism	5 (0.1%)	6 (0.2%)	11 (0.1%)
Antisocial personality disorder	0	1 (<0.1%)	1 (<0.1%)
Anxiety	145 (3.6%)	175 (4.4%)	320 (4.0%)
Anxiety disorder	18 (0.5%)	25 (0.6%)	43 (0.5%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Attention deficit hyperactivity disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Behaviour disorder	1 (<0.1%)	0	1 (<0.1%)
Bipolar I disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bipolar disorder	8 (0.2%)	14 (0.4%)	22 (0.3%)
Breathing-related sleep disorder	1 (<0.1%)	0	1 (<0.1%)
Bruxism	0	1 (<0.1%)	1 (<0.1%)
Bulimia nervosa	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Conversion disorder	1 (<0.1%)	0	1 (<0.1%)
Delirium	0	3 (<0.1%)	3 (<0.1%)
Depressed mood	5 (0.1%)	7 (0.2%)	12 (0.2%)
Depression	290 (7.3%)	296 (7.4%)	586 (7.4%)
Depressive symptom	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Dermatillomania	0	1 (<0.1%)	1 (<0.1%)
Dissociative amnesia	1 (<0.1%)	0	1 (<0.1%)
Drug abuse	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Drug dependence	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Epileptic psychosis	0	1 (<0.1%)	1 (<0.1%)
Factitious disorder	0	1 (<0.1%)	1 (<0.1%)
Generalised anxiety disorder	5 (0.1%)	5 (0.1%)	10 (0.1%)
Genito-pelvic pain/penetration disorder	1 (<0.1%)	0	1 (<0.1%)
Hallucination	0	2 (<0.1%)	2 (<0.1%)
Hallucination, visual	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Illness anxiety disorder	1 (<0.1%)	0	1 (<0.1%)
Initial insomnia	0	3 (<0.1%)	3 (<0.1%)
Insomnia	218 (5.5%)	227 (5.7%)	445 (5.6%)
Libido decreased	2 (<0.1%)	0	2 (<0.1%)
Major depression	18 (0.5%)	20 (0.5%)	38 (0.5%)
Mental disorder	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Mental disorder due to a general medical condition	0	2 (<0.1%)	2 (<0.1%)
Middle insomnia	0	1 (<0.1%)	1 (<0.1%)
Mixed anxiety and depressive disorder	6 (0.2%)	10 (0.3%)	16 (0.2%)
Mood altered	1 (<0.1%)	0	1 (<0.1%)
Mood disorder due to a general medical condition	0	2 (<0.1%)	2 (<0.1%)
Mood swings	1 (<0.1%)	0	1 (<0.1%)
Nervousness	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neurologic somatic symptom disorder	0	1 (<0.1%)	1 (<0.1%)
Neurosis	5 (0.1%)	4 (0.1%)	9 (0.1%)
Nicotine dependence	5 (0.1%)	8 (0.2%)	13 (0.2%)
Nightmare	1 (<0.1%)	0	1 (<0.1%)
Organic brain syndrome	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Panic attack	0	1 (<0.1%)	1 (<0.1%)
Panic disorder	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Panic reaction	1 (<0.1%)	0	1 (<0.1%)
Persistent depressive disorder	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Personality disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phobia of driving	0	1 (<0.1%)	1 (<0.1%)
Post-traumatic stress disorder	17 (0.4%)	13 (0.3%)	30 (0.4%)
Pseudodementia	0	1 (<0.1%)	1 (<0.1%)
Psychosexual disorder	0	1 (<0.1%)	1 (<0.1%)
Psychotic disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Schizoid personality disorder	1 (<0.1%)	0	1 (<0.1%)
Schizophrenia	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Sleep disorder	35 (0.9%)	33 (0.8%)	68 (0.9%)
Social anxiety disorder	0	1 (<0.1%)	1 (<0.1%)
Somatic symptom disorder	0	3 (<0.1%)	3 (<0.1%)
Stress	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Substance abuse	1 (<0.1%)	0	1 (<0.1%)
Suicide attempt	2 (<0.1%)	0	2 (<0.1%)
Tearfulness	0	1 (<0.1%)	1 (<0.1%)
Tic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tobacco abuse	9 (0.2%)	9 (0.2%)	18 (0.2%)
Renal and urinary disorders	3981 (100.0%)	3982 (100.0%)	7963 (100.0%)
Acquired cystic kidney disease	13 (0.3%)	10 (0.3%)	23 (0.3%)
Acute kidney injury	45 (1.1%)	47 (1.2%)	92 (1.2%)
Albuminuria	192 (4.8%)	161 (4.0%)	353 (4.4%)
Azotaemia	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Bladder disorder	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Bladder diverticulum	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Bladder dysfunction	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Bladder leukoplakia	1 (<0.1%)	0	1 (<0.1%)
Bladder mass	2 (<0.1%)	0	2 (<0.1%)
Bladder neck obstruction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder neck sclerosis	1 (<0.1%)	0	1 (<0.1%)
Bladder outlet obstruction	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Bladder prolapse	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Bladder tamponade	1 (<0.1%)	0	1 (<0.1%)
Bladder trabeculation	1 (<0.1%)	0	1 (<0.1%)
C3 glomerulopathy	0	1 (<0.1%)	1 (<0.1%)
Calculus bladder	6 (0.2%)	4 (0.1%)	10 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Calculus urethral	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Calculus urinary	50 (1.3%)	37 (0.9%)	87 (1.1%)
Chronic kidney disease	3981 (100.0%)	3982 (100.0%)	7963 (100.0%)
Chyluria	1 (<0.1%)	0	1 (<0.1%)
Costovertebral angle tenderness	1 (<0.1%)	0	1 (<0.1%)
Crystalluria	0	1 (<0.1%)	1 (<0.1%)
Cystitis interstitial	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Detrusor sphincter dyssynergia	0	1 (<0.1%)	1 (<0.1%)
Diabetic nephropathy	359 (9.0%)	372 (9.3%)	731 (9.2%)
Dysuria	13 (0.3%)	14 (0.4%)	27 (0.3%)
End stage renal disease	1 (<0.1%)	0	1 (<0.1%)
Focal segmental glomerulosclerosis	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Genitourinary symptom	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Glomerulonephritis acute	0	1 (<0.1%)	1 (<0.1%)
Glomerulonephritis chronic	18 (0.5%)	14 (0.4%)	32 (0.4%)
Glomerulonephritis membranoproliferative	1 (<0.1%)	0	1 (<0.1%)
Glomerulonephritis membranous	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glomerulonephropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glomerulosclerosis	0	1 (<0.1%)	1 (<0.1%)
Glycosuria	0	1 (<0.1%)	1 (<0.1%)
Haematuria	46 (1.2%)	50 (1.3%)	96 (1.2%)
Hydronephrosis	23 (0.6%)	22 (0.6%)	45 (0.6%)
Hypertensive nephropathy	19 (0.5%)	13 (0.3%)	32 (0.4%)
Hypertonic bladder	17 (0.4%)	17 (0.4%)	34 (0.4%)
Hyperuricosuria	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypocitraturia	0	1 (<0.1%)	1 (<0.1%)
Hypotonic urinary bladder	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
IgA nephropathy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Incontinence	9 (0.2%)	5 (0.1%)	14 (0.2%)
Intercapillary glomerulosclerosis	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Ischaemic nephropathy	1 (<0.1%)	0	1 (<0.1%)
Kidney enlargement	2 (<0.1%)	0	2 (<0.1%)
Kidney fibrosis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Kidney small	1 (<0.1%)	0	1 (<0.1%)
Leukocyturia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lower urinary tract symptoms	12 (0.3%)	6 (0.2%)	18 (0.2%)
Lupus nephritis	1 (<0.1%)	0	1 (<0.1%)
Microalbuminuria	109 (2.7%)	98 (2.5%)	207 (2.6%)
Micturition disorder	0	3 (<0.1%)	3 (<0.1%)
Micturition urgency	3 (<0.1%)	5 (0.1%)	8 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Nephritic syndrome	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Nephritis	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Nephroangiosclerosis	9 (0.2%)	9 (0.2%)	18 (0.2%)
Nephrocalcinosis	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Nephrogenic diabetes insipidus	0	1 (<0.1%)	1 (<0.1%)
Nephrolithiasis	242 (6.1%)	250 (6.3%)	492 (6.2%)
Nephropathy	28 (0.7%)	19 (0.5%)	47 (0.6%)
Nephropathy toxic	1 (<0.1%)	0	1 (<0.1%)
Nephroptosis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Nephrosclerosis	9 (0.2%)	6 (0.2%)	15 (0.2%)
Nephrotic syndrome	5 (0.1%)	16 (0.4%)	21 (0.3%)
Neurogenic bladder	15 (0.4%)	14 (0.4%)	29 (0.4%)
Nocturia	30 (0.8%)	51 (1.3%)	81 (1.0%)
Obstructive nephropathy	0	1 (<0.1%)	1 (<0.1%)
Oedematous kidney	4 (0.1%)	0	4 (<0.1%)
Pelvi-ureteric obstruction	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	8 (0.2%)	16 (0.4%)	24 (0.3%)
Polyuria	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Post infection glomerulonephritis	1 (<0.1%)	0	1 (<0.1%)
Proteinuria	213 (5.4%)	227 (5.7%)	440 (5.5%)
Pyelocaliectasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Reduced bladder capacity	1 (<0.1%)	0	1 (<0.1%)
Reflux nephropathy	0	1 (<0.1%)	1 (<0.1%)
Renal arteriosclerosis	0	2 (<0.1%)	2 (<0.1%)
Renal artery arteriosclerosis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Renal artery fibromuscular dysplasia	0	1 (<0.1%)	1 (<0.1%)
Renal artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Renal artery stenosis	10 (0.3%)	12 (0.3%)	22 (0.3%)
Renal atrophy	12 (0.3%)	7 (0.2%)	19 (0.2%)
Renal colic	30 (0.8%)	14 (0.4%)	44 (0.6%)
Renal cyst	215 (5.4%)	223 (5.6%)	438 (5.5%)
Renal disorder	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Renal failure	24 (0.6%)	24 (0.6%)	48 (0.6%)
Renal hypertension	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal impairment	9 (0.2%)	4 (0.1%)	13 (0.2%)
Renal injury	0	1 (<0.1%)	1 (<0.1%)
Renal mass	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Renal pain	0	1 (<0.1%)	1 (<0.1%)
Renal tubular acidosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal tubular necrosis	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Renal vessel disorder	2 (<0.1%)	0	2 (<0.1%)
Single functional kidney	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Stag horn calculus	0	2 (<0.1%)	2 (<0.1%)
Stress urinary incontinence	9 (0.2%)	4 (0.1%)	13 (0.2%)
Subcapsular renal haematoma	3 (<0.1%)	0	3 (<0.1%)
Terminal dribbling	1 (<0.1%)	0	1 (<0.1%)
Trigonitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tubulointerstitial nephritis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Urate nephropathy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Ureteral cyst	0	1 (<0.1%)	1 (<0.1%)
Ureteric stenosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ureterocele	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	20 (0.5%)	22 (0.6%)	42 (0.5%)
Urethral meatus stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral obstruction	0	1 (<0.1%)	1 (<0.1%)
Urethral stenosis	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Urge incontinence	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Urinary bladder polyp	3 (<0.1%)	0	3 (<0.1%)
Urinary hesitation	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Urinary incontinence	54 (1.4%)	55 (1.4%)	109 (1.4%)
Urinary retention	8 (0.2%)	13 (0.3%)	21 (0.3%)
Urinary tract disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary tract obstruction	1 (<0.1%)	5 (0.1%)	6 (<0.1%)
Urine abnormality	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Urine flow decreased	0	2 (<0.1%)	2 (<0.1%)
Urine odour abnormal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Reproductive system and breast disorders	863 (21.7%)	891 (22.4%)	1754 (22.0%)
Acquired phimosis	1 (<0.1%)	0	1 (<0.1%)
Amenorrhoea	1 (<0.1%)	0	1 (<0.1%)
Artificial menopause	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrophic vulvovaginitis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Balanoposthitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Bartholin's cyst	0	1 (<0.1%)	1 (<0.1%)
Benign prostatic hyperplasia	561 (14.1%)	584 (14.7%)	1145 (14.4%)
Breast calcifications	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast cyst	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Breast disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast fibrosis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Breast haematoma	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Breast hyperplasia	2 (<0.1%)	0	2 (<0.1%)
Breast mass	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Calculus prostatic	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Cervical cyst	0	1 (<0.1%)	1 (<0.1%)
Cervical dysplasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cervical polyp	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cystocele	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Dysfunctional uterine bleeding	1 (<0.1%)	0	1 (<0.1%)
Dysmenorrhoea	3 (<0.1%)	0	3 (<0.1%)
Endocervicosis	0	1 (<0.1%)	1 (<0.1%)
Endometrial hyperplasia	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Endometrial thickening	0	1 (<0.1%)	1 (<0.1%)
Endometriosis	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Epididymal cyst	0	2 (<0.1%)	2 (<0.1%)
Erectile dysfunction	191 (4.8%)	201 (5.0%)	392 (4.9%)
Female genital tract fistula	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Fibrocystic breast disease	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Genital prolapse	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gynaecomastia	8 (0.2%)	11 (0.3%)	19 (0.2%)
Haematospermia	1 (<0.1%)	0	1 (<0.1%)
Hydrometra	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrosalpinx	1 (<0.1%)	0	1 (<0.1%)
Infertility	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Mammary duct ectasia	0	1 (<0.1%)	1 (<0.1%)
Menometrorrhagia	1 (<0.1%)	0	1 (<0.1%)
Menopausal disorder	2 (<0.1%)	0	2 (<0.1%)
Menopausal symptoms	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Menorrhagia	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Metrorrhagia	2 (<0.1%)	0	2 (<0.1%)
Monorchidism	1 (<0.1%)	0	1 (<0.1%)
Organic erectile dysfunction	8 (0.2%)	7 (0.2%)	15 (0.2%)
Ovarian cyst	11 (0.3%)	14 (0.4%)	25 (0.3%)
Ovarian mass	0	1 (<0.1%)	1 (<0.1%)
Pelvic adhesions	0	1 (<0.1%)	1 (<0.1%)
Pelvic cyst	1 (<0.1%)	0	1 (<0.1%)
Pelvic fluid collection	1 (<0.1%)	0	1 (<0.1%)
Pelvic pain	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic prolapse	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penile rash	0	1 (<0.1%)	1 (<0.1%)
Perineal pain	1 (<0.1%)	0	1 (<0.1%)
Peyronie's disease	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Polycystic ovaries	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Postmenopausal haemorrhage	2 (<0.1%)	0	2 (<0.1%)
Prostatic calcification	9 (0.2%)	7 (0.2%)	16 (0.2%)
Prostatic cyst	0	1 (<0.1%)	1 (<0.1%)
Prostatic disorder	10 (0.3%)	8 (0.2%)	18 (0.2%)
Prostatic dysplasia	1 (<0.1%)	0	1 (<0.1%)
Prostatic mass	0	1 (<0.1%)	1 (<0.1%)
Prostatism	12 (0.3%)	13 (0.3%)	25 (0.3%)
Prostatitis	18 (0.5%)	32 (0.8%)	50 (0.6%)
Prostatomegaly	40 (1.0%)	33 (0.8%)	73 (0.9%)
Pruritus genital	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectocele	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Retrograde ejaculation	1 (<0.1%)	0	1 (<0.1%)
Scrotal mass	0	1 (<0.1%)	1 (<0.1%)
Seminal vesicular disorder	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Testicular pain	0	1 (<0.1%)	1 (<0.1%)
Testicular swelling	1 (<0.1%)	0	1 (<0.1%)
Testicular torsion	1 (<0.1%)	0	1 (<0.1%)
Uterine cervix stenosis	1 (<0.1%)	0	1 (<0.1%)
Uterine enlargement	0	1 (<0.1%)	1 (<0.1%)
Uterine fibrosis	1 (<0.1%)	0	1 (<0.1%)
Uterine haemorrhage	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine polyp	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Uterine prolapse	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Vaginal haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Vaginal polyp	0	1 (<0.1%)	1 (<0.1%)
Vaginal prolapse	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Varicocele	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Vulval disorder	0	1 (<0.1%)	1 (<0.1%)
Vulvar squamous cell hyperplasia	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal dryness	3 (<0.1%)	0	3 (<0.1%)
Vulvovaginal pruritus	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vulvovaginal rash	0	1 (<0.1%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	1022 (25.7%)	1042 (26.2%)	2064 (25.9%)
Acquired diaphragmatic eventration	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	3 (<0.1%)	7 (0.2%)	10 (0.1%)
Acute respiratory failure	0	2 (<0.1%)	2 (<0.1%)
Adenoidal hypertrophy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Allergic bronchitis	1 (<0.1%)	0	1 (<0.1%)
Allergic cough	0	1 (<0.1%)	1 (<0.1%)
Allergic pharyngitis	1 (<0.1%)	0	1 (<0.1%)
Allergic respiratory disease	1 (<0.1%)	0	1 (<0.1%)
Allergic sinusitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Apnoea	1 (<0.1%)	0	1 (<0.1%)
Asthma	176 (4.4%)	173 (4.3%)	349 (4.4%)
Asthma late onset	1 (<0.1%)	0	1 (<0.1%)
Asthma-chronic obstructive pulmonary disease overlap syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atelectasis	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Atopic cough	0	1 (<0.1%)	1 (<0.1%)
Bronchial disorder	0	2 (<0.1%)	2 (<0.1%)
Bronchial hyperreactivity	5 (0.1%)	7 (0.2%)	12 (0.2%)
Bronchial obstruction	1 (<0.1%)	0	1 (<0.1%)
Bronchiectasis	10 (0.3%)	4 (0.1%)	14 (0.2%)
Bronchitis chronic	41 (1.0%)	52 (1.3%)	93 (1.2%)
Bronchospasm	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Catarrh	0	2 (<0.1%)	2 (<0.1%)
Cheyne-Stokes respiration	0	1 (<0.1%)	1 (<0.1%)
Childhood asthma	0	1 (<0.1%)	1 (<0.1%)
Chronic obstructive pulmonary disease	252 (6.3%)	254 (6.4%)	506 (6.4%)
Chronic respiratory disease	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic respiratory failure	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Cough	42 (1.1%)	56 (1.4%)	98 (1.2%)
Cough variant asthma	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Cystic lung disease	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Diaphragmatic disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic paralysis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dysphonia	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Dyspnoea	45 (1.1%)	52 (1.3%)	97 (1.2%)
Dyspnoea exertional	30 (0.8%)	17 (0.4%)	47 (0.6%)
Emphysema	20 (0.5%)	20 (0.5%)	40 (0.5%)
Epistaxis	11 (0.3%)	18 (0.5%)	29 (0.4%)
Haemoptysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Haemothorax	0	1 (<0.1%)	1 (<0.1%)
Hydrothorax	0	1 (<0.1%)	1 (<0.1%)
Hypercapnia	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypersensitivity pneumonitis	1 (<0.1%)	0	1 (<0.1%)
Hyperventilation	1 (<0.1%)	0	1 (<0.1%)
Hypopnoea	0	1 (<0.1%)	1 (<0.1%)
Hypoventilation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Hypoxia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Increased upper airway secretion	0	1 (<0.1%)	1 (<0.1%)
Interstitial lung disease	11 (0.3%)	11 (0.3%)	22 (0.3%)
Laryngeal hypertrophy	1 (<0.1%)	0	1 (<0.1%)
Laryngeal leukoplakia	0	1 (<0.1%)	1 (<0.1%)
Laryngeal oedema	0	1 (<0.1%)	1 (<0.1%)
Laryngeal stenosis	1 (<0.1%)	0	1 (<0.1%)
Lung disorder	0	1 (<0.1%)	1 (<0.1%)
Lung hyperinflation	1 (<0.1%)	0	1 (<0.1%)
Lung induration	1 (<0.1%)	0	1 (<0.1%)
Lung infiltration	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung opacity	2 (<0.1%)	0	2 (<0.1%)
Nasal congestion	5 (0.1%)	4 (0.1%)	9 (0.1%)
Nasal discomfort	0	1 (<0.1%)	1 (<0.1%)
Nasal disorder	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nasal mucosal disorder	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Nasal polyps	5 (0.1%)	6 (0.2%)	11 (0.1%)
Nasal septum deviation	8 (0.2%)	10 (0.3%)	18 (0.2%)
Nasal septum perforation	1 (<0.1%)	0	1 (<0.1%)
Nasal turbinate hypertrophy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nocturnal dyspnoea	0	1 (<0.1%)	1 (<0.1%)
Obliterative bronchiolitis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Obstructive airways disorder	8 (0.2%)	2 (<0.1%)	10 (0.1%)
Oropharyngeal pain	7 (0.2%)	1 (<0.1%)	8 (0.1%)
Paranasal cyst	1 (<0.1%)	0	1 (<0.1%)
Paranasal sinus hypersecretion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Paranasal sinus inflammation	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal mass	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal polyp	0	1 (<0.1%)	1 (<0.1%)
Pickwickian syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pleural calcification	0	1 (<0.1%)	1 (<0.1%)
Pleural effusion	8 (0.2%)	14 (0.4%)	22 (0.3%)
Pleural fibrosis	1 (<0.1%)	0	1 (<0.1%)
Pleural thickening	1 (<0.1%)	0	1 (<0.1%)
Pleurisy	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Pneumonitis	4 (0.1%)	0	4 (<0.1%)
Pneumothorax	4 (0.1%)	4 (0.1%)	8 (0.1%)
Productive cough	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Pulmonary alveolar haemorrhage	1 (<0.1%)	0	1 (<0.1%)
Pulmonary arterial hypertension	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Pulmonary calcification	1 (<0.1%)	0	1 (<0.1%)
Pulmonary congestion	0	1 (<0.1%)	1 (<0.1%)
Pulmonary embolism	27 (0.7%)	23 (0.6%)	50 (0.6%)
Pulmonary fibrosis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Pulmonary granuloma	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Pulmonary hypertension	30 (0.8%)	31 (0.8%)	61 (0.8%)
Pulmonary infarction	0	1 (<0.1%)	1 (<0.1%)
Pulmonary mass	34 (0.9%)	27 (0.7%)	61 (0.8%)
Pulmonary oedema	5 (0.1%)	4 (0.1%)	9 (0.1%)
Pulmonary sarcoidosis	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Pulmonary thrombosis	1 (<0.1%)	0	1 (<0.1%)
Rales	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory acidosis	0	1 (<0.1%)	1 (<0.1%)
Respiratory arrest	0	1 (<0.1%)	1 (<0.1%)
Respiratory disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Respiratory failure	5 (0.1%)	8 (0.2%)	13 (0.2%)
Restrictive pulmonary disease	5 (0.1%)	6 (0.2%)	11 (0.1%)
Rhinitis allergic	96 (2.4%)	85 (2.1%)	181 (2.3%)
Rhinitis hypertrophic	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rhinitis perennial	0	1 (<0.1%)	1 (<0.1%)
Rhinorrhoea	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Sinus congestion	1 (<0.1%)	0	1 (<0.1%)
Sinus disorder	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Sinus perforation	0	1 (<0.1%)	1 (<0.1%)
Sinus polyp	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sleep apnoea syndrome	382 (9.6%)	377 (9.5%)	759 (9.5%)
Snoring	4 (0.1%)	3 (<0.1%)	7 (<0.1%)
Stridor	0	1 (<0.1%)	1 (<0.1%)
Throat irritation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tracheal stenosis	0	1 (<0.1%)	1 (<0.1%)
Upper respiratory tract inflammation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Upper-airway cough syndrome	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vasomotor rhinitis	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Vocal cord cyst	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord polyp	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vocal cord thickening	1 (<0.1%)	0	1 (<0.1%)
Wheezing	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Skin and subcutaneous tissue disorders	620 (15.6%)	643 (16.1%)	1263 (15.9%)
Acanthosis nigricans	4 (0.1%)	1 (<0.1%)	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Acne	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Actinic cheilitis	1 (<0.1%)	0	1 (<0.1%)
Actinic keratosis	38 (1.0%)	31 (0.8%)	69 (0.9%)
Alopecia	6 (0.2%)	7 (0.2%)	13 (0.2%)
Alopecia areata	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Alopecia scarring	0	1 (<0.1%)	1 (<0.1%)
Androgenetic alopecia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Angioedema	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Asteatosis	6 (0.2%)	7 (0.2%)	13 (0.2%)
Blister	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Blood blister	0	1 (<0.1%)	1 (<0.1%)
Chronic pigmented purpura	1 (<0.1%)	0	1 (<0.1%)
Chronic spontaneous urticaria	1 (<0.1%)	0	1 (<0.1%)
Cutaneous lupus erythematosus	1 (<0.1%)	0	1 (<0.1%)
Dandruff	0	2 (<0.1%)	2 (<0.1%)
Decubitus ulcer	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dermal cyst	6 (0.2%)	13 (0.3%)	19 (0.2%)
Dermatitis	39 (1.0%)	34 (0.9%)	73 (0.9%)
Dermatitis allergic	6 (0.2%)	10 (0.3%)	16 (0.2%)
Dermatitis atopic	8 (0.2%)	12 (0.3%)	20 (0.3%)
Dermatitis bullous	0	1 (<0.1%)	1 (<0.1%)
Dermatitis contact	15 (0.4%)	16 (0.4%)	31 (0.4%)
Dermatitis diaper	0	1 (<0.1%)	1 (<0.1%)
Dermatitis herpetiformis	1 (<0.1%)	0	1 (<0.1%)
Dermatitis psoriasiform	1 (<0.1%)	0	1 (<0.1%)
Diabetic bullosis	1 (<0.1%)	0	1 (<0.1%)
Diabetic cheiroarthropathy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetic dermopathy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Diabetic foot	73 (1.8%)	84 (2.1%)	157 (2.0%)
Diabetic neuropathic ulcer	1 (<0.1%)	0	1 (<0.1%)
Diabetic ulcer	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Drug eruption	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Dry skin	43 (1.1%)	42 (1.1%)	85 (1.1%)
Dyshidrotic eczema	2 (<0.1%)	0	2 (<0.1%)
Eczema	49 (1.2%)	55 (1.4%)	104 (1.3%)
Eczema asteatotic	7 (0.2%)	9 (0.2%)	16 (0.2%)
Eczema nummular	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Eosinophilic cellulitis	0	1 (<0.1%)	1 (<0.1%)
Erythema	8 (0.2%)	6 (0.2%)	14 (0.2%)
Erythema nodosum	3 (<0.1%)	0	3 (<0.1%)
Erythematotelangiectatic rosacea	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Granuloma annulare	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Granuloma skin	0	1 (<0.1%)	1 (<0.1%)
Hand dermatitis	3 (<0.1%)	0	3 (<0.1%)
Hidradenitis	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Hirsutism	0	3 (<0.1%)	3 (<0.1%)
Hyperhidrosis	0	2 (<0.1%)	2 (<0.1%)
Hyperkeratosis	25 (0.6%)	24 (0.6%)	49 (0.6%)
Hypersensitivity vasculitis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Idiopathic urticaria	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ingrowing nail	11 (0.3%)	7 (0.2%)	18 (0.2%)
Intertrigo	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Ischaemic skin ulcer	1 (<0.1%)	0	1 (<0.1%)
Keloid scar	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Keratosis pilaris	0	1 (<0.1%)	1 (<0.1%)
Leukoderma	1 (<0.1%)	0	1 (<0.1%)
Lichen planus	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lichen sclerosus	2 (<0.1%)	0	2 (<0.1%)
Lichenification	2 (<0.1%)	0	2 (<0.1%)
Lipodystrophy acquired	6 (0.2%)	4 (0.1%)	10 (0.1%)
Lipohypertrophy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Mechanical urticaria	0	1 (<0.1%)	1 (<0.1%)
Melanosis	1 (<0.1%)	0	1 (<0.1%)
Miliaria	0	1 (<0.1%)	1 (<0.1%)
Myxoid cyst	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nail disorder	0	1 (<0.1%)	1 (<0.1%)
Nail dystrophy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Nail hypertrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Necrobiosis lipoidica diabeticorum	0	2 (<0.1%)	2 (<0.1%)
Neurodermatitis	10 (0.3%)	6 (0.2%)	16 (0.2%)
Neuropathic ulcer	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neutrophilic dermatosis	0	1 (<0.1%)	1 (<0.1%)
Onychalgia	0	1 (<0.1%)	1 (<0.1%)
Onychogryphosis	3 (<0.1%)	0	3 (<0.1%)
Onycholysis	1 (<0.1%)	0	1 (<0.1%)
Palmoplantar keratoderma	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Panniculitis	1 (<0.1%)	0	1 (<0.1%)
Parapsoriasis	1 (<0.1%)	0	1 (<0.1%)
Peau d'orange	1 (<0.1%)	0	1 (<0.1%)
Pemphigoid	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pemphigus	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Petechiae	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Pigmentation disorder	3 (<0.1%)	0	3 (<0.1%)
Prurigo	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Pruritus	49 (1.2%)	55 (1.4%)	104 (1.3%)
Pruritus allergic	1 (<0.1%)	0	1 (<0.1%)
Pseudofolliculitis	0	2 (<0.1%)	2 (<0.1%)
Psoriasis	68 (1.7%)	78 (2.0%)	146 (1.8%)
Purpura	3 (<0.1%)	0	3 (<0.1%)
Purpura senile	0	1 (<0.1%)	1 (<0.1%)
Pustular psoriasis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pyoderma gangrenosum	1 (<0.1%)	0	1 (<0.1%)
Rash	20 (0.5%)	30 (0.8%)	50 (0.6%)
Rash erythematous	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rash pruritic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rosacea	8 (0.2%)	8 (0.2%)	16 (0.2%)
Scab	0	1 (<0.1%)	1 (<0.1%)
Scleroedema	0	1 (<0.1%)	1 (<0.1%)
Seborrhoea	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Seborrhoeic dermatitis	25 (0.6%)	16 (0.4%)	41 (0.5%)
Senile xerosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sensitive skin	2 (<0.1%)	0	2 (<0.1%)
Skin atrophy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin discolouration	0	2 (<0.1%)	2 (<0.1%)
Skin disorder	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Skin dystrophy	0	2 (<0.1%)	2 (<0.1%)
Skin exfoliation	0	2 (<0.1%)	2 (<0.1%)
Skin fissures	1 (<0.1%)	0	1 (<0.1%)
Skin hyperpigmentation	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Skin hypertrophy	2 (<0.1%)	0	2 (<0.1%)
Skin hypopigmentation	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	6 (0.2%)	11 (0.3%)	17 (0.2%)
Skin mass	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin necrosis	0	1 (<0.1%)	1 (<0.1%)
Skin plaque	1 (<0.1%)	0	1 (<0.1%)
Skin striae	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	49 (1.2%)	57 (1.4%)	106 (1.3%)
Skin wrinkling	0	1 (<0.1%)	1 (<0.1%)
Solar dermatitis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Solar lentigo	2 (<0.1%)	0	2 (<0.1%)
Stasis dermatitis	20 (0.5%)	20 (0.5%)	40 (0.5%)
Stevens-Johnson syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Telangiectasia	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Urticaria	28 (0.7%)	14 (0.4%)	42 (0.5%)
Urticaria chronic	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urticarial vasculitis	0	1 (<0.1%)	1 (<0.1%)
Vascular purpura	0	1 (<0.1%)	1 (<0.1%)
Vasculitic rash	0	1 (<0.1%)	1 (<0.1%)
Vasculitic ulcer	0	1 (<0.1%)	1 (<0.1%)
Vitiligo	8 (0.2%)	8 (0.2%)	16 (0.2%)
Xeroderma	5 (0.1%)	4 (0.1%)	9 (0.1%)
Social circumstances	232 (5.8%)	217 (5.4%)	449 (5.6%)
Alcohol use	1 (<0.1%)	0	1 (<0.1%)
Cardiac assistance device user	0	1 (<0.1%)	1 (<0.1%)
Corrective lens user	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Denture wearer	3 (<0.1%)	0	3 (<0.1%)
Diet noncompliance	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Edentulous	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Ex-tobacco user	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Limb prosthesis user	0	1 (<0.1%)	1 (<0.1%)
Loss of personal independence in daily activities	0	1 (<0.1%)	1 (<0.1%)
Menopause	149 (3.7%)	124 (3.1%)	273 (3.4%)
Organ donor	2 (<0.1%)	0	2 (<0.1%)
Orthosis user	1 (<0.1%)	0	1 (<0.1%)
Passive smoking	1 (<0.1%)	0	1 (<0.1%)
Postmenopause	52 (1.3%)	65 (1.6%)	117 (1.5%)
Social problem	0	1 (<0.1%)	1 (<0.1%)
Stress at work	0	1 (<0.1%)	1 (<0.1%)
Tobacco user	13 (0.3%)	13 (0.3%)	26 (0.3%)
Wheelchair user	1 (<0.1%)	0	1 (<0.1%)
Surgical and medical procedures	1656 (41.6%)	1642 (41.2%)	3298 (41.4%)
Abdominal hernia repair	6 (0.2%)	13 (0.3%)	19 (0.2%)
Abdominoplasty	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Abortion induced	0	1 (<0.1%)	1 (<0.1%)
Abscess drainage	6 (0.2%)	12 (0.3%)	18 (0.2%)
Acoustic neuroma removal	0	2 (<0.1%)	2 (<0.1%)
Acrochordon excision	1 (<0.1%)	0	1 (<0.1%)
Adenoidectomy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Adenotonsillectomy	3 (<0.1%)	0	3 (<0.1%)
Adrenalectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Amblyopia therapy	0	1 (<0.1%)	1 (<0.1%)
Amputation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Anal fissure excision	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Anal fistula repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aneurysm repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Angioplasty	21 (0.5%)	21 (0.5%)	42 (0.5%)
Ankle arthroplasty	1 (<0.1%)	0	1 (<0.1%)
Ankle operation	3 (<0.1%)	0	3 (<0.1%)
Anorectal operation	1 (<0.1%)	0	1 (<0.1%)
Anticoagulant therapy	0	3 (<0.1%)	3 (<0.1%)
Aortic anastomosis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Aortic aneurysm repair	6 (0.2%)	8 (0.2%)	14 (0.2%)
Aortic bypass	9 (0.2%)	7 (0.2%)	16 (0.2%)
Aortic stent insertion	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Aortic surgery	0	1 (<0.1%)	1 (<0.1%)
Aortic valve repair	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Aortic valve replacement	27 (0.7%)	28 (0.7%)	55 (0.7%)
Apicectomy	1 (<0.1%)	0	1 (<0.1%)
Appendicectomy	124 (3.1%)	172 (4.3%)	296 (3.7%)
Arterial repair	0	1 (<0.1%)	1 (<0.1%)
Arterial stent insertion	6 (0.2%)	7 (0.2%)	13 (0.2%)
Arterial therapeutic procedure	1 (<0.1%)	0	1 (<0.1%)
Arthrectomy	0	1 (<0.1%)	1 (<0.1%)
Arthrodesis	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Atrial appendage closure	0	1 (<0.1%)	1 (<0.1%)
Atrial septal defect repair	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Autonomic ganglionectomy	0	1 (<0.1%)	1 (<0.1%)
Axillary lymphadenectomy	0	1 (<0.1%)	1 (<0.1%)
Baker's cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bariatric gastric balloon insertion	1 (<0.1%)	0	1 (<0.1%)
Benign breast lump removal	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Benign tumour excision	1 (<0.1%)	0	1 (<0.1%)
Bentall procedure	1 (<0.1%)	0	1 (<0.1%)
Bile duct stent insertion	1 (<0.1%)	0	1 (<0.1%)
Biliary tract operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder calculus removal	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Bladder catheter permanent	1 (<0.1%)	0	1 (<0.1%)
Bladder catheterisation	0	2 (<0.1%)	2 (<0.1%)
Bladder neoplasm surgery	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Bladder operation	3 (<0.1%)	0	3 (<0.1%)
Bladder polypectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Bladder repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blepharoplasty	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Bone cyst excision	1 (<0.1%)	0	1 (<0.1%)
Bone debridement	1 (<0.1%)	0	1 (<0.1%)
Bone graft	2 (<0.1%)	0	2 (<0.1%)
Bone lesion excision	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Bone operation	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Bone prosthesis insertion	1 (<0.1%)	0	1 (<0.1%)
Bone trimming	0	1 (<0.1%)	1 (<0.1%)
Brachytherapy	1 (<0.1%)	0	1 (<0.1%)
Brachytherapy to prostate	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Breast conserving surgery	5 (0.1%)	9 (0.2%)	14 (0.2%)
Breast cyst excision	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Breast reconstruction	1 (<0.1%)	0	1 (<0.1%)
Breast tumour excision	0	1 (<0.1%)	1 (<0.1%)
Bunion operation	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Burn operation	0	1 (<0.1%)	1 (<0.1%)
Bursa removal	1 (<0.1%)	0	1 (<0.1%)
CSF shunt operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Caesarean section	29 (0.7%)	30 (0.8%)	59 (0.7%)
Cancer surgery	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Cardiac ablation	6 (0.2%)	6 (0.2%)	12 (0.2%)
Cardiac aneurysm repair	0	1 (<0.1%)	1 (<0.1%)
Cardiac operation	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac pacemaker insertion	76 (1.9%)	71 (1.8%)	147 (1.8%)
Cardiac pacemaker replacement	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac resynchronisation therapy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cardiopulmonary bypass	1 (<0.1%)	0	1 (<0.1%)
Cardiovascular event prophylaxis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardioversion	6 (0.2%)	4 (0.1%)	10 (0.1%)
Carotid artery bypass	0	2 (<0.1%)	2 (<0.1%)
Carotid artery stent insertion	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Carotid endarterectomy	55 (1.4%)	64 (1.6%)	119 (1.5%)
Carpal tunnel decompression	26 (0.7%)	25 (0.6%)	51 (0.6%)
Cartilage operation	1 (<0.1%)	0	1 (<0.1%)
Cataract operation	234 (5.9%)	222 (5.6%)	456 (5.7%)
Catheter placement	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Central venous catheterisation	1 (<0.1%)	0	1 (<0.1%)
Cerebral cyst excision	0	1 (<0.1%)	1 (<0.1%)
Cerebral endovascular aneurysm repair	0	2 (<0.1%)	2 (<0.1%)
Cervical conisation	2 (<0.1%)	0	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Cervical laser therapy	0	1 (<0.1%)	1 (<0.1%)
Cervical polypectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Chemotherapy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cholangiostomy	1 (<0.1%)	0	1 (<0.1%)
Cholecystectomy	236 (5.9%)	232 (5.8%)	468 (5.9%)
Cholecystostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholelithotomy	1 (<0.1%)	0	1 (<0.1%)
Cholelithotripsy	1 (<0.1%)	0	1 (<0.1%)
Circumcision	6 (0.2%)	8 (0.2%)	14 (0.2%)
Closed fracture manipulation	0	1 (<0.1%)	1 (<0.1%)
Colectomy	16 (0.4%)	16 (0.4%)	32 (0.4%)
Colectomy total	1 (<0.1%)	0	1 (<0.1%)
Colon operation	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Colostomy	0	5 (0.1%)	5 (<0.1%)
Continuous positive airway pressure	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Corneal lesion removal	0	1 (<0.1%)	1 (<0.1%)
Corneal transplant	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Coronary angioplasty	64 (1.6%)	67 (1.7%)	131 (1.6%)
Coronary arterial stent insertion	162 (4.1%)	133 (3.3%)	295 (3.7%)
Coronary artery bypass	203 (5.1%)	187 (4.7%)	390 (4.9%)
Coronary endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Coronary revascularisation	8 (0.2%)	5 (0.1%)	13 (0.2%)
Cox-Maze procedure	0	1 (<0.1%)	1 (<0.1%)
Cranial nerve decompression	1 (<0.1%)	0	1 (<0.1%)
Craniotomy	0	2 (<0.1%)	2 (<0.1%)
Cyst removal	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Cystocele repair	0	1 (<0.1%)	1 (<0.1%)
Cystoprostatectomy	0	1 (<0.1%)	1 (<0.1%)
Cystostomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dacryocystorhinostomy	0	2 (<0.1%)	2 (<0.1%)
Debridement	4 (0.1%)	5 (0.1%)	9 (0.1%)
Dental implantation	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Dental prosthesis placement	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dermatofibroma removal	1 (<0.1%)	0	1 (<0.1%)
Dialysis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Drug delivery device placement	0	1 (<0.1%)	1 (<0.1%)
Duodenal sphincterotomy	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer repair	2 (<0.1%)	0	2 (<0.1%)
Dupuytren's contracture operation	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Ear operation	1 (<0.1%)	0	1 (<0.1%)
Ear tube insertion	1 (<0.1%)	0	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Elbow operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Endarterectomy	0	1 (<0.1%)	1 (<0.1%)
Endodontic procedure	1 (<0.1%)	0	1 (<0.1%)
Endometrial ablation	0	1 (<0.1%)	1 (<0.1%)
Endoscopic sleeve gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Endovenous ablation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterostomy	2 (<0.1%)	0	2 (<0.1%)
Epidermoid cyst excision	0	2 (<0.1%)	2 (<0.1%)
Epididymal cyst removal	1 (<0.1%)	0	1 (<0.1%)
Ethmoid sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Eustachian tube operation	0	1 (<0.1%)	1 (<0.1%)
Eventration repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Excision of ampulla of Vater	1 (<0.1%)	0	1 (<0.1%)
Exeresis	0	1 (<0.1%)	1 (<0.1%)
Explorative laparotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Eye excision	0	3 (<0.1%)	3 (<0.1%)
Eye laser surgery	19 (0.5%)	15 (0.4%)	34 (0.4%)
Eye operation	6 (0.2%)	4 (0.1%)	10 (0.1%)
Eye prosthesis insertion	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Eyelid operation	1 (<0.1%)	0	1 (<0.1%)
Facetectomy	0	2 (<0.1%)	2 (<0.1%)
Fasciectomy	0	1 (<0.1%)	1 (<0.1%)
Fasciotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Female genital operation	1 (<0.1%)	0	1 (<0.1%)
Female sterilisation	32 (0.8%)	37 (0.9%)	69 (0.9%)
Finger amputation	8 (0.2%)	8 (0.2%)	16 (0.2%)
Fistula repair	1 (<0.1%)	0	1 (<0.1%)
Foot amputation	13 (0.3%)	17 (0.4%)	30 (0.4%)
Foot operation	0	1 (<0.1%)	1 (<0.1%)
Foraminotomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Functional endoscopic sinus surgery	1 (<0.1%)	0	1 (<0.1%)
Gallbladder operation	6 (0.2%)	4 (0.1%)	10 (0.1%)
Gastrectomy	4 (0.1%)	5 (0.1%)	9 (0.1%)
Gastric banding	10 (0.3%)	6 (0.2%)	16 (0.2%)
Gastric bypass	12 (0.3%)	10 (0.3%)	22 (0.3%)
Gastric operation	2 (<0.1%)	0	2 (<0.1%)
Gastric polypectomy	0	1 (<0.1%)	1 (<0.1%)
Gastric stapling	0	1 (<0.1%)	1 (<0.1%)
Gastroenterostomy	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorder prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal endoscopic therapy	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Gastroplasty	1 (<0.1%)	0	1 (<0.1%)
Glaucoma surgery	6 (0.2%)	5 (0.1%)	11 (0.1%)
Haemangioma removal	0	1 (<0.1%)	1 (<0.1%)
Haemodialysis	0	3 (<0.1%)	3 (<0.1%)
Haemorrhoid operation	15 (0.4%)	14 (0.4%)	29 (0.4%)
Hand repair operation	0	1 (<0.1%)	1 (<0.1%)
Hearing aid therapy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Heart transplant	0	1 (<0.1%)	1 (<0.1%)
Heart valve operation	1 (<0.1%)	0	1 (<0.1%)
Heart valve replacement	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Hepatectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hepatic embolisation	1 (<0.1%)	0	1 (<0.1%)
Hernia hiatus repair	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hernia repair	18 (0.5%)	15 (0.4%)	33 (0.4%)
High frequency ablation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hip arthroplasty	40 (1.0%)	44 (1.1%)	84 (1.1%)
Hip surgery	2 (<0.1%)	5 (0.1%)	7 (<0.1%)
Hormone therapy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hydrocele operation	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Hysterectomy	119 (3.0%)	136 (3.4%)	255 (3.2%)
Hysterosalpingo-oophorectomy	15 (0.4%)	9 (0.2%)	24 (0.3%)
Hysterotomy	1 (<0.1%)	0	1 (<0.1%)
Ileectomy	1 (<0.1%)	0	1 (<0.1%)
Ileocaecal resection	1 (<0.1%)	0	1 (<0.1%)
Ileocolectomy	0	1 (<0.1%)	1 (<0.1%)
Ileostomy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Ileostomy closure	4 (0.1%)	0	4 (<0.1%)
Implantable cardiac monitor insertion	1 (<0.1%)	0	1 (<0.1%)
Implantable defibrillator insertion	12 (0.3%)	12 (0.3%)	24 (0.3%)
Implantable defibrillator replacement	0	1 (<0.1%)	1 (<0.1%)
Incisional drainage	0	2 (<0.1%)	2 (<0.1%)
Incisional hernia repair	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Infection prophylaxis	1 (<0.1%)	0	1 (<0.1%)
Influenza immunisation	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	23 (0.6%)	39 (1.0%)	62 (0.8%)
Internal fixation of fracture	7 (0.2%)	5 (0.1%)	12 (0.2%)
Internal fixation of spine	1 (<0.1%)	0	1 (<0.1%)
Internal limiting membrane peeling	0	1 (<0.1%)	1 (<0.1%)
Intervertebral disc operation	26 (0.7%)	23 (0.6%)	49 (0.6%)
Intestinal anastomosis	1 (<0.1%)	0	1 (<0.1%)
Intestinal operation	0	3 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Intestinal polypectomy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Intestinal resection	0	1 (<0.1%)	1 (<0.1%)
Intra-aortic balloon placement	1 (<0.1%)	0	1 (<0.1%)
Intra-cerebral aneurysm operation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Intra-ocular injection	4 (0.1%)	6 (0.2%)	10 (0.1%)
Intra-thoracic aortic aneurysm repair	1 (<0.1%)	0	1 (<0.1%)
Intraocular lens implant	53 (1.3%)	58 (1.5%)	111 (1.4%)
Iridectomy	2 (<0.1%)	0	2 (<0.1%)
Iridotomy	3 (<0.1%)	0	3 (<0.1%)
Jaw operation	1 (<0.1%)	0	1 (<0.1%)
Jejunocolostomy	1 (<0.1%)	0	1 (<0.1%)
Joint arthroplasty	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Joint injection	0	1 (<0.1%)	1 (<0.1%)
Joint resurfacing surgery	1 (<0.1%)	0	1 (<0.1%)
Keratomileusis	0	1 (<0.1%)	1 (<0.1%)
Knee arthroplasty	49 (1.2%)	71 (1.8%)	120 (1.5%)
Knee operation	13 (0.3%)	21 (0.5%)	34 (0.4%)
Lacrimal duct procedure	0	1 (<0.1%)	1 (<0.1%)
Lacrimal gland operation	0	1 (<0.1%)	1 (<0.1%)
Laparotomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Large intestinal polypectomy	25 (0.6%)	24 (0.6%)	49 (0.6%)
Large intestine anastomosis	0	1 (<0.1%)	1 (<0.1%)
Laryngeal operation	1 (<0.1%)	0	1 (<0.1%)
Laryngeal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Laryngeal repair	1 (<0.1%)	0	1 (<0.1%)
Laser therapy	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Leg amputation	22 (0.6%)	33 (0.8%)	55 (0.7%)
Lens capsulotomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lens extraction	9 (0.2%)	9 (0.2%)	18 (0.2%)
Lenticular operation	0	1 (<0.1%)	1 (<0.1%)
Ligament operation	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Limb amputation	2 (<0.1%)	0	2 (<0.1%)
Limb operation	4 (0.1%)	6 (0.2%)	10 (0.1%)
Lip lesion excision	1 (<0.1%)	0	1 (<0.1%)
Lipectomy	1 (<0.1%)	0	1 (<0.1%)
Lipoma excision	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Lithotripsy	10 (0.3%)	11 (0.3%)	21 (0.3%)
Liver operation	0	1 (<0.1%)	1 (<0.1%)
Liver transplant	0	2 (<0.1%)	2 (<0.1%)
Lung lobectomy	6 (0.2%)	6 (0.2%)	12 (0.2%)
Lung operation	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Lymphadenectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mammoplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Mastectomy	11 (0.3%)	7 (0.2%)	18 (0.2%)
Mastoidectomy	2 (<0.1%)	0	2 (<0.1%)
Maxillary antrum operation	1 (<0.1%)	0	1 (<0.1%)
Maxillofacial operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Medical device implantation	1 (<0.1%)	0	1 (<0.1%)
Medical device removal	0	1 (<0.1%)	1 (<0.1%)
Medical diet	1 (<0.1%)	0	1 (<0.1%)
Meningeal repair	0	1 (<0.1%)	1 (<0.1%)
Meningioma surgery	0	1 (<0.1%)	1 (<0.1%)
Meniscus operation	11 (0.3%)	9 (0.2%)	20 (0.3%)
Meniscus removal	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Metabolic surgery	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Metatarsal excision	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mitral commissurotomy	0	1 (<0.1%)	1 (<0.1%)
Mitral valve repair	4 (0.1%)	5 (0.1%)	9 (0.1%)
Mitral valve replacement	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Mole excision	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Multiple drug therapy	0	2 (<0.1%)	2 (<0.1%)
Myomectomy	5 (0.1%)	8 (0.2%)	13 (0.2%)
Nail operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Nasal polypectomy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Nasal septal operation	10 (0.3%)	7 (0.2%)	17 (0.2%)
Nasopharyngeal surgery	0	1 (<0.1%)	1 (<0.1%)
Neck dissection	1 (<0.1%)	0	1 (<0.1%)
Neck surgery	0	2 (<0.1%)	2 (<0.1%)
Neobladder surgery	1 (<0.1%)	0	1 (<0.1%)
Nephrectomy	43 (1.1%)	40 (1.0%)	83 (1.0%)
Nephrostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephroureterectomy	3 (<0.1%)	0	3 (<0.1%)
Neurectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Neurolysis	0	1 (<0.1%)	1 (<0.1%)
Oesophageal operation	1 (<0.1%)	0	1 (<0.1%)
Oesophageal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Oesophagoenterostomy	0	1 (<0.1%)	1 (<0.1%)
Oophorectomy	14 (0.4%)	7 (0.2%)	21 (0.3%)
Oophorectomy bilateral	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Ophthalmic fluid-air exchange procedure	0	1 (<0.1%)	1 (<0.1%)
Orchidectomy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Orchidopexy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Orthopaedic procedure	1 (<0.1%)	0	1 (<0.1%)
Ostectomy	0	1 (<0.1%)	1 (<0.1%)
Osteotomy	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Otorhinolaryngological surgery	1 (<0.1%)	0	1 (<0.1%)
Ovarian cystectomy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Ovarian neoplasm surgery	0	3 (<0.1%)	3 (<0.1%)
Ovarian operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreas transplant	0	1 (<0.1%)	1 (<0.1%)
Pancreatectomy	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatic operation	1 (<0.1%)	0	1 (<0.1%)
Pancreaticoduodenectomy	0	1 (<0.1%)	1 (<0.1%)
Pancreaticogastrostomy	1 (<0.1%)	0	1 (<0.1%)
Pancreatobiliary sphincterotomy	1 (<0.1%)	0	1 (<0.1%)
Papilloma excision	0	1 (<0.1%)	1 (<0.1%)
Parathyroidectomy	12 (0.3%)	3 (<0.1%)	15 (0.2%)
Parotidectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Partial cystectomy	1 (<0.1%)	0	1 (<0.1%)
Penile prosthesis insertion	7 (0.2%)	5 (0.1%)	12 (0.2%)
Percutaneous coronary intervention	38 (1.0%)	45 (1.1%)	83 (1.0%)
Pericardial drainage	0	3 (<0.1%)	3 (<0.1%)
Perineoplasty	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral artery angioplasty	29 (0.7%)	22 (0.6%)	51 (0.6%)
Peripheral artery bypass	19 (0.5%)	24 (0.6%)	43 (0.5%)
Peripheral artery stent insertion	22 (0.6%)	13 (0.3%)	35 (0.4%)
Peripheral endarterectomy	5 (0.1%)	7 (0.2%)	12 (0.2%)
Peripheral nerve decompression	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral nerve destruction	1 (<0.1%)	0	1 (<0.1%)
Peripheral nerve neurostimulation	0	1 (<0.1%)	1 (<0.1%)
Peripheral nerve operation	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Peripheral nerve transposition	1 (<0.1%)	0	1 (<0.1%)
Peripheral revascularisation	0	3 (<0.1%)	3 (<0.1%)
Pharyngeal operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phlebectomy	11 (0.3%)	10 (0.3%)	21 (0.3%)
Phlebotomy	2 (<0.1%)	0	2 (<0.1%)
Photocoagulation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Plastic surgery to the face	0	1 (<0.1%)	1 (<0.1%)
Pleurectomy	0	1 (<0.1%)	1 (<0.1%)
Pneumocentesis	0	1 (<0.1%)	1 (<0.1%)
Polypectomy	6 (0.2%)	14 (0.4%)	20 (0.3%)
Posterior lens capsulotomy	1 (<0.1%)	0	1 (<0.1%)
Proctectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Proctocolectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Profundaplasty	0	1 (<0.1%)	1 (<0.1%)
Prophylaxis	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Prostate ablation	0	1 (<0.1%)	1 (<0.1%)
Prostatectomy	21 (0.5%)	33 (0.8%)	54 (0.7%)
Prostatic operation	1 (<0.1%)	10 (0.3%)	11 (0.1%)
Pterygium operation	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Ptosis repair	0	1 (<0.1%)	1 (<0.1%)
Pulmonary resection	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Pyelotomy	1 (<0.1%)	0	1 (<0.1%)
Pyloroplasty	1 (<0.1%)	0	1 (<0.1%)
Radical cystectomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radical hysterectomy	1 (<0.1%)	0	1 (<0.1%)
Radical mastectomy	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Radioactive iodine therapy	0	1 (<0.1%)	1 (<0.1%)
Radiotherapy	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Rectal polypectomy	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Rectal prolapse repair	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Removal of foreign body from eyelids	0	1 (<0.1%)	1 (<0.1%)
Renal artery angioplasty	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Renal artery stent placement	5 (0.1%)	6 (0.2%)	11 (0.1%)
Renal cyst aspiration	0	1 (<0.1%)	1 (<0.1%)
Renal cyst excision	0	1 (<0.1%)	1 (<0.1%)
Renal stone removal	27 (0.7%)	21 (0.5%)	48 (0.6%)
Renal surgery	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Renal sympathetic nerve ablation	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Renal transplant	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renal tumour excision	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Retinal laser coagulation	29 (0.7%)	20 (0.5%)	49 (0.6%)
Retinal operation	5 (0.1%)	2 (<0.1%)	7 (<0.1%)
Retinopexy	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Revascularisation procedure	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Rhinoplasty	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rotator cuff repair	8 (0.2%)	14 (0.4%)	22 (0.3%)
Routine health maintenance	1 (<0.1%)	0	1 (<0.1%)
Roux loop conversion	1 (<0.1%)	0	1 (<0.1%)
Salivary gland resection	0	1 (<0.1%)	1 (<0.1%)
Salpingectomy	0	2 (<0.1%)	2 (<0.1%)
Salpingo-oophorectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Salpingo-oophorectomy bilateral	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Salpingo-oophorectomy unilateral	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Scar excision	0	1 (<0.1%)	1 (<0.1%)
Sclerotherapy	1 (<0.1%)	0	1 (<0.1%)
Scrotal operation	1 (<0.1%)	0	1 (<0.1%)
Sebaceous cyst excision	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Shoulder arthroplasty	7 (0.2%)	5 (0.1%)	12 (0.2%)
Shoulder operation	9 (0.2%)	9 (0.2%)	18 (0.2%)
Sigmoidectomy	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Sinuplasty	1 (<0.1%)	0	1 (<0.1%)
Sinus operation	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Skin cryotherapy	1 (<0.1%)	0	1 (<0.1%)
Skin graft	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Skin lesion removal	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Skin neoplasm excision	13 (0.3%)	20 (0.5%)	33 (0.4%)
Small intestinal polypectomy	0	1 (<0.1%)	1 (<0.1%)
Small intestinal resection	0	1 (<0.1%)	1 (<0.1%)
Spinal corpectomy	1 (<0.1%)	0	1 (<0.1%)
Spinal decompression	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Spinal fusion surgery	10 (0.3%)	6 (0.2%)	16 (0.2%)
Spinal laminectomy	14 (0.4%)	17 (0.4%)	31 (0.4%)
Spinal nerve stimulator implantation	2 (<0.1%)	0	2 (<0.1%)
Spinal operation	14 (0.4%)	16 (0.4%)	30 (0.4%)
Splenectomy	6 (0.2%)	5 (0.1%)	11 (0.1%)
Stent placement	30 (0.8%)	16 (0.4%)	46 (0.6%)
Sterilisation	6 (0.2%)	0	6 (<0.1%)
Steroid therapy	0	1 (<0.1%)	1 (<0.1%)
Strabismus correction	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Subdural haematoma evacuation	1 (<0.1%)	0	1 (<0.1%)
Suprapubic prostatectomy	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Surgery	2 (<0.1%)	0	2 (<0.1%)
Sympathectomy	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Synovectomy	2 (<0.1%)	0	2 (<0.1%)
Synovial cyst removal	0	2 (<0.1%)	2 (<0.1%)
Tendon sheath incision	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Tenoplasty	1 (<0.1%)	7 (0.2%)	8 (0.1%)
Tenotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tetralogy of Fallot repair	0	1 (<0.1%)	1 (<0.1%)
Therapeutic embolisation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thoracic cavity drainage	0	1 (<0.1%)	1 (<0.1%)
Thoracotomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thrombectomy	0	1 (<0.1%)	1 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Thromboembolectomy	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Thrombolysis	0	1 (<0.1%)	1 (<0.1%)
Thymectomy	1 (<0.1%)	0	1 (<0.1%)
Thyroid adenoma removal	0	1 (<0.1%)	1 (<0.1%)
Thyroid nodule removal	2 (<0.1%)	0	2 (<0.1%)
Thyroid operation	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Thyroidectomy	39 (1.0%)	50 (1.3%)	89 (1.1%)
Toe amputation	79 (2.0%)	75 (1.9%)	154 (1.9%)
Toe operation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tongue operation	1 (<0.1%)	0	1 (<0.1%)
Tonsillectomy	48 (1.2%)	65 (1.6%)	113 (1.4%)
Tooth extraction	6 (0.2%)	6 (0.2%)	12 (0.2%)
Tooth repair	1 (<0.1%)	0	1 (<0.1%)
Trabeculectomy	2 (<0.1%)	0	2 (<0.1%)
Tracheostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Transcatheter aortic valve implantation	0	1 (<0.1%)	1 (<0.1%)
Transfusion	5 (0.1%)	1 (<0.1%)	6 (<0.1%)
Transmyocardial revascularisation	0	1 (<0.1%)	1 (<0.1%)
Transurethral bladder resection	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Transurethral incision of prostate	1 (<0.1%)	0	1 (<0.1%)
Transurethral prostatectomy	22 (0.6%)	23 (0.6%)	45 (0.6%)
Tricuspid valve repair	0	3 (<0.1%)	3 (<0.1%)
Tricuspid valve replacement	1 (<0.1%)	0	1 (<0.1%)
Tumour excision	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Turbinectomy	1 (<0.1%)	0	1 (<0.1%)
Turbinoplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tympanoplasty	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Umbilical hernia repair	21 (0.5%)	19 (0.5%)	40 (0.5%)
Umbilicoplasty	0	1 (<0.1%)	1 (<0.1%)
Ureter dilation procedure	1 (<0.1%)	0	1 (<0.1%)
Ureteral stent insertion	8 (0.2%)	4 (0.1%)	12 (0.2%)
Ureteric calculus removal	6 (0.2%)	5 (0.1%)	11 (0.1%)
Ureteric operation	1 (<0.1%)	0	1 (<0.1%)
Ureteric repair	0	1 (<0.1%)	1 (<0.1%)
Ureterolithotomy	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Urethral calculus removal	0	1 (<0.1%)	1 (<0.1%)
Urethral dilation procedure	2 (<0.1%)	0	2 (<0.1%)
Urethral meatotomy	0	1 (<0.1%)	1 (<0.1%)
Urethral operation	0	2 (<0.1%)	2 (<0.1%)
Urethral repair	2 (<0.1%)	0	2 (<0.1%)
Urethral stent insertion	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Urethrotomy	4 (0.1%)	0	4 (<0.1%)
Urinary bladder suspension	7 (0.2%)	4 (0.1%)	11 (0.1%)
Urinary control neurostimulator implantation	0	1 (<0.1%)	1 (<0.1%)
Urinary cystectomy	2 (<0.1%)	0	2 (<0.1%)
Urinary tract operation	0	1 (<0.1%)	1 (<0.1%)
Urostomy	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine dilation and curettage	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Uterine operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Uterine polypectomy	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Uterine repair	1 (<0.1%)	0	1 (<0.1%)
Uterine tumour excision	1 (<0.1%)	0	1 (<0.1%)
Uvulectomy	0	1 (<0.1%)	1 (<0.1%)
Uvulopalatopharyngoplasty	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Uvuloplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vaginoperineoplasty	1 (<0.1%)	0	1 (<0.1%)
Vagotomy	3 (<0.1%)	0	3 (<0.1%)
Varicocele repair	1 (<0.1%)	0	1 (<0.1%)
Varicose vein operation	10 (0.3%)	8 (0.2%)	18 (0.2%)
Vascular anastomosis	1 (<0.1%)	0	1 (<0.1%)
Vascular graft	15 (0.4%)	8 (0.2%)	23 (0.3%)
Vascular operation	2 (<0.1%)	0	2 (<0.1%)
Vascular stent insertion	12 (0.3%)	9 (0.2%)	21 (0.3%)
Vasectomy	9 (0.2%)	13 (0.3%)	22 (0.3%)
Vena cava filter insertion	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Venous angioplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Venous operation	0	1 (<0.1%)	1 (<0.1%)
Venous stent insertion	0	1 (<0.1%)	1 (<0.1%)
Ventriculo-peritoneal shunt	0	1 (<0.1%)	1 (<0.1%)
Vertebroplasty	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitamin supplementation	0	1 (<0.1%)	1 (<0.1%)
Vitrectomy	35 (0.9%)	36 (0.9%)	71 (0.9%)
Vocal cord operation	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vocal cord polypectomy	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Volvulus repair	0	1 (<0.1%)	1 (<0.1%)
Wrist surgery	1 (<0.1%)	0	1 (<0.1%)
Vascular disorders	3902 (98.0%)	3917 (98.4%)	7819 (98.2%)
Accelerated hypertension	0	1 (<0.1%)	1 (<0.1%)
Aneurysm	1 (<0.1%)	0	1 (<0.1%)
Angiopathy	2 (<0.1%)	6 (0.2%)	8 (0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Angiosclerosis	0	1 (<0.1%)	1 (<0.1%)
Aortic aneurysm	33 (0.8%)	39 (1.0%)	72 (0.9%)
Aortic arteriosclerosis	57 (1.4%)	52 (1.3%)	109 (1.4%)
Aortic dilatation	7 (0.2%)	9 (0.2%)	16 (0.2%)
Aortic disorder	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Aortic dissection	1 (<0.1%)	0	1 (<0.1%)
Aortic stenosis	40 (1.0%)	30 (0.8%)	70 (0.9%)
Aortic thrombosis	0	1 (<0.1%)	1 (<0.1%)
Arterial disorder	2 (<0.1%)	0	2 (<0.1%)
Arterial insufficiency	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial occlusive disease	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Arteriosclerosis	73 (1.8%)	74 (1.9%)	147 (1.8%)
Arteriosclerosis Moenckeberg-type	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Arteritis	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Atheroembolism	0	1 (<0.1%)	1 (<0.1%)
Brachiocephalic arteriosclerosis	6 (0.2%)	4 (0.1%)	10 (0.1%)
Brachiocephalic artery stenosis	3 (<0.1%)	0	3 (<0.1%)
Circulatory collapse	1 (<0.1%)	0	1 (<0.1%)
Cryoglobulinaemia	2 (<0.1%)	0	2 (<0.1%)
Cyanosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Deep vein thrombosis	39 (1.0%)	37 (0.9%)	76 (1.0%)
Diabetic macroangiopathy	15 (0.4%)	13 (0.3%)	28 (0.4%)
Diabetic microangiopathy	6 (0.2%)	6 (0.2%)	12 (0.2%)
Diabetic vascular disorder	66 (1.7%)	49 (1.2%)	115 (1.4%)
Diastolic hypertension	1 (<0.1%)	0	1 (<0.1%)
Dry gangrene	2 (<0.1%)	0	2 (<0.1%)
Embolism	0	1 (<0.1%)	1 (<0.1%)
Embolism venous	0	2 (<0.1%)	2 (<0.1%)
Essential hypertension	135 (3.4%)	140 (3.5%)	275 (3.5%)
Extremity necrosis	2 (<0.1%)	0	2 (<0.1%)
Giant cell arteritis	0	1 (<0.1%)	1 (<0.1%)
Granulomatosis with polyangiitis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Haematoma	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hot flush	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hyperaemia	3 (<0.1%)	0	3 (<0.1%)
Hypertension	3721 (93.5%)	3743 (94.0%)	7464 (93.7%)
Hypertensive angiopathy	10 (0.3%)	8 (0.2%)	18 (0.2%)
Hypertensive crisis	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hypertensive end-organ damage	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hypertensive urgency	2 (<0.1%)	0	2 (<0.1%)
Hypotension	6 (0.2%)	12 (0.3%)	18 (0.2%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Hypovolaemic shock	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	0	1 (<0.1%)	1 (<0.1%)
Iliac artery stenosis	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infarction	0	2 (<0.1%)	2 (<0.1%)
Intermittent claudication	37 (0.9%)	54 (1.4%)	91 (1.1%)
Labile hypertension	2 (<0.1%)	0	2 (<0.1%)
Leriche syndrome	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphocele	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lymphoedema	11 (0.3%)	13 (0.3%)	24 (0.3%)
Lymphostasis	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Macroangiopathy	4 (0.1%)	4 (0.1%)	8 (0.1%)
Malignant hypertension	1 (<0.1%)	0	1 (<0.1%)
Microangiopathy	5 (0.1%)	4 (0.1%)	9 (0.1%)
Neovascularisation	0	1 (<0.1%)	1 (<0.1%)
Obstructive shock	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	13 (0.3%)	10 (0.3%)	23 (0.3%)
Pallor	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pelvic venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Peripheral arterial occlusive disease	718 (18.0%)	704 (17.7%)	1422 (17.9%)
Peripheral artery aneurysm	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Peripheral artery occlusion	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Peripheral artery stenosis	6 (0.2%)	8 (0.2%)	14 (0.2%)
Peripheral artery thrombosis	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Peripheral coldness	0	2 (<0.1%)	2 (<0.1%)
Peripheral embolism	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Peripheral ischaemia	8 (0.2%)	7 (0.2%)	15 (0.2%)
Peripheral vascular disorder	28 (0.7%)	44 (1.1%)	72 (0.9%)
Peripheral venous disease	97 (2.4%)	88 (2.2%)	185 (2.3%)
Phlebitis	5 (0.1%)	3 (<0.1%)	8 (0.1%)
Phlebitis deep	1 (<0.1%)	0	1 (<0.1%)
Poor peripheral circulation	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Post thrombotic syndrome	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Postpartum venous thrombosis	1 (<0.1%)	0	1 (<0.1%)
Raynaud's phenomenon	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Renovascular hypertension	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Secondary hypertension	0	1 (<0.1%)	1 (<0.1%)
Subclavian artery occlusion	0	2 (<0.1%)	2 (<0.1%)
Subclavian artery stenosis	7 (0.2%)	3 (<0.1%)	10 (0.1%)
Subclavian steal syndrome	2 (<0.1%)	0	2 (<0.1%)
Supra-aortic trunk sclerosis	0	1 (<0.1%)	1 (<0.1%)
Thromboangiitis obliterans	0	2 (<0.1%)	2 (<0.1%)

Table 4.5 / 1: Number of subjects with medical history findings by primary system organ class and preferred term (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Primary system organ class Preferred term MedDRA version 23.1	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Thrombophlebitis	10 (0.3%)	14 (0.4%)	24 (0.3%)
Thrombophlebitis superficial	1 (<0.1%)	0	1 (<0.1%)
Thrombosis	3 (<0.1%)	5 (0.1%)	8 (0.1%)
Varicose ulceration	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Varicose vein	123 (3.1%)	95 (2.4%)	218 (2.7%)
Vascular stenosis	1 (<0.1%)	0	1 (<0.1%)
Vasoconstriction	0	1 (<0.1%)	1 (<0.1%)
Vasodilatation	0	2 (<0.1%)	2 (<0.1%)
Vein disorder	3 (<0.1%)	0	3 (<0.1%)
Vena cava thrombosis	0	1 (<0.1%)	1 (<0.1%)
Venous hypertension	1 (<0.1%)	0	1 (<0.1%)
Venous thrombosis	3 (<0.1%)	4 (0.1%)	7 (<0.1%)
Venous thrombosis in pregnancy	0	1 (<0.1%)	1 (<0.1%)
Venous thrombosis limb	0	5 (0.1%)	5 (<0.1%)
White coat hypertension	8 (0.2%)	11 (0.3%)	19 (0.2%)

Medical history findings are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_admh.sas 26JAN2023 15:29
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4.6 Concomitant medication

Table 4.6 / 1: Number of subjects who took at least one new non anti-diabetic concomitant medication of interest (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	3260 (81.9%)	3290 (82.6%)	6550 (82.3%)
ACEI	606 (15.2%)	629 (15.8%)	1235 (15.5%)
ARB	1048 (26.3%)	1137 (28.6%)	2185 (27.4%)
RAS-inhibitors	1525 (38.3%)	1596 (40.1%)	3121 (39.2%)
Beta-blocker	1110 (27.9%)	1207 (30.3%)	2317 (29.1%)
Diuretics	1683 (42.3%)	1785 (44.8%)	3468 (43.6%)
Loop diuretics	1257 (31.6%)	1342 (33.7%)	2599 (32.6%)
Thiazide diuretics	403 (10.1%)	454 (11.4%)	857 (10.8%)
Potassium supplements	278 (7.0%)	356 (8.9%)	634 (8.0%)
Potassium lowering agents (including binders)	391 (9.8%)	237 (6.0%)	628 (7.9%)
Alpha blocking agents	1114 (28.0%)	1200 (30.1%)	2314 (29.1%)
Calcium channel blockers	1331 (33.4%)	1555 (39.1%)	2886 (36.2%)
Centrally acting antihypertensives	259 (6.5%)	322 (8.1%)	581 (7.3%)
Strong CYP3A4 inhibitors	231 (5.8%)	208 (5.2%)	439 (5.5%)
Moderate CYP3A4 inhibitors	551 (13.8%)	538 (13.5%)	1089 (13.7%)
Weak CYP3A4 inhibitors	1578 (39.6%)	1663 (41.8%)	3241 (40.7%)
Unclassified CYP3A4 inhibitors	191 (4.8%)	195 (4.9%)	386 (4.8%)
Strong CYP3A4 inducers	51 (1.3%)	51 (1.3%)	102 (1.3%)
Moderate CYP3A4 inducers	266 (6.7%)	304 (7.6%)	570 (7.2%)
Weak CYP3A4 inducers	294 (7.4%)	312 (7.8%)	606 (7.6%)
Unclassified CYP3A4 inducers	190 (4.8%)	167 (4.2%)	357 (4.5%)
Oral anticoagulants	364 (9.1%)	370 (9.3%)	734 (9.2%)
Acetylsalycylic acid and its salts	638 (16.0%)	686 (17.2%)	1324 (16.6%)
Statins	1168 (29.3%)	1210 (30.4%)	2378 (29.9%)
Erythropoeitin stimulating agents	205 (5.1%)	225 (5.7%)	430 (5.4%)
NSAIDS (excluding acetylsalicylic acid)	1115 (28.0%)	1108 (27.8%)	2223 (27.9%)
ARNIs	8 (0.2%)	12 (0.3%)	20 (0.3%)
Potassium-sparing diuretics	202 (5.1%)	236 (5.9%)	438 (5.5%)
Platelet aggregation inhibitors (excluding heparin)	968 (24.3%)	976 (24.5%)	1944 (24.4%)
Trimethoprim and derivatives	126 (3.2%)	123 (3.1%)	249 (3.1%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:31
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Table 4.6 / 2: Number of subjects who took at least one new anti-diabetic concomitant medication of interest (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Drug grouping	BAY 94-8862 N=3981 (100%)	Placebo N=3982 (100%)	Total N=7963 (100%)
Number (%) of subjects with at least one new concomitant medication of interest	2553 (64.1%)	2583 (64.9%)	5136 (64.5%)
Insulins and analogues	1863 (46.8%)	1875 (47.1%)	3738 (46.9%)
Dipeptidyl peptidase 4 inhibitors	689 (17.3%)	685 (17.2%)	1374 (17.3%)
Glucagon-like peptide-1(GLP1) agonists	404 (10.1%)	412 (10.3%)	816 (10.2%)
SGLT-2 inhibitors	334 (8.4%)	343 (8.6%)	677 (8.5%)
Biguanides	772 (19.4%)	749 (18.8%)	1521 (19.1%)
Sulfonylureas	461 (11.6%)	487 (12.2%)	948 (11.9%)
Alpha glucosidase inhibitors	153 (3.8%)	142 (3.6%)	295 (3.7%)
Meglitinides	167 (4.2%)	192 (4.8%)	359 (4.5%)
Thiazolidinediones	121 (3.0%)	127 (3.2%)	248 (3.1%)

Medications that began after the start of study drug, and those that were started after end of study drug, are included in this table.
Multiple drug groups per drug are possible. Therefore, the same drug may be counted in more than one category for the same subject.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adcm.sas 26JAN2023 15:31
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1.2.1 Time-to-event analyses

Table 1.2.1 / 1: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	369 (9.3%)	389 (9.8%)
Number (%) of subjects censored	3612 (90.7%)	3593 (90.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.82; 1.09]	
two-sided p-value from stratified logrank test	0.4210	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	185 (10.8%)	200 (11.7%)
Number (%) of subjects censored	1533 (89.2%)	1503 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.75; 1.12]	
two-sided p-value from stratified logrank test	0.4045	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	72 (10.4%)	63 (8.9%)
Number (%) of subjects censored	620 (89.6%)	645 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.18 [0.84; 1.65]	
two-sided p-value from stratified logrank test	0.3490	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	47 (4.5%)	74 (7.1%)
Number (%) of subjects censored	992 (95.5%)	966 (92.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.42; 0.88]	
two-sided p-value from stratified logrank test	0.0078	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	36 (9.6%)	42 (11.2%)
Number (%) of subjects censored	340 (90.4%)	333 (88.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.54; 1.33]	
two-sided p-value from stratified logrank test	0.4699	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	29 (18.6%)	10 (6.4%)
Number (%) of subjects censored	127 (81.4%)	146 (93.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	2.94 [1.43; 6.07]	
two-sided p-value from stratified logrank test	0.0022	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 3: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0022

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	235 (10.7%)	227 (10.4%)
Number (%) of subjects censored	1962 (89.3%)	1948 (89.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.85; 1.22]	
two-sided p-value from stratified logrank test	0.8661	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	133 (7.5%)	161 (8.9%)
Number (%) of subjects censored	1649 (92.5%)	1641 (91.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.67; 1.05]	
two-sided p-value from stratified logrank test	0.1315	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 5: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.2005

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	176 (11.3%)	177 (11.3%)
Number (%) of subjects censored	1385 (88.7%)	1388 (88.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.83; 1.26]	
two-sided p-value from stratified logrank test	0.8563	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	192 (8.0%)	212 (8.8%)
Number (%) of subjects censored	2218 (92.0%)	2197 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.73; 1.08]	
two-sided p-value from stratified logrank test	0.2294	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 7: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.4323

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	225 (10.8%)	260 (12.6%)
Number (%) of subjects censored	1855 (89.2%)	1804 (87.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.71; 1.01]	
two-sided p-value from stratified logrank test	0.0677	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	144 (7.6%)	129 (6.7%)
Number (%) of subjects censored	1757 (92.4%)	1789 (93.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.14 [0.90; 1.45]	
two-sided p-value from stratified logrank test	0.2741	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 9: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.0491

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	237 (8.9%)	243 (9.2%)
Number (%) of subjects censored	2424 (91.1%)	2392 (90.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.80; 1.14]	
two-sided p-value from stratified logrank test	0.6175	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	131 (9.9%)	145 (10.8%)
Number (%) of subjects censored	1188 (90.1%)	1200 (89.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.74; 1.19]	
two-sided p-value from stratified logrank test	0.6059	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 11: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.9282

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	101 (8.3%)	118 (9.7%)
Number (%) of subjects censored	1117 (91.7%)	1103 (90.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.64; 1.10]	
two-sided p-value from stratified logrank test	0.1958	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	248 (9.6%)	255 (9.8%)
Number (%) of subjects censored	2345 (90.4%)	2341 (90.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.82; 1.16]	
two-sided p-value from stratified logrank test	0.7655	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 12: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	18 (10.8%)	16 (9.8%)
Number (%) of subjects censored	149 (89.2%)	147 (90.2%)
Median Time to event (month) [95 % CI]	59.000 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.49; 2.21]	
two-sided p-value from stratified logrank test	0.9212	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 13: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.5831

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	288 (10.9%)	298 (11.2%)
Number (%) of subjects censored	2362 (89.1%)	2357 (88.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.82; 1.13]	
two-sided p-value from stratified logrank test	0.6430	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	18 (10.4%)	13 (7.0%)
Number (%) of subjects censored	155 (89.6%)	173 (93.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.16 [0.53; 2.53]	
two-sided p-value from stratified logrank test	0.7092	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	40 (4.3%)	61 (6.5%)
Number (%) of subjects censored	889 (95.7%)	871 (93.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.40; 0.91]	
two-sided p-value from stratified logrank test	0.0152	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 14: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	23 (10.0%)	17 (8.1%)
Number (%) of subjects censored	206 (90.0%)	192 (91.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.14 [0.59; 2.21]	
two-sided p-value from stratified logrank test	0.6943	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 15: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.1073

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	244 (9.0%)	290 (10.3%)
Number (%) of subjects censored	2473 (91.0%)	2523 (89.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.72; 1.01]	
two-sided p-value from stratified logrank test	0.0650	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 16: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	125 (9.9%)	99 (8.5%)
Number (%) of subjects censored	1139 (90.1%)	1070 (91.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.20 [0.91; 1.57]	
two-sided p-value from stratified logrank test	0.1900	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 17: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.0304

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 18: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	99 (6.9%)	90 (6.4%)
Number (%) of subjects censored	1344 (93.1%)	1324 (93.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.08 [0.81; 1.45]	
two-sided p-value from stratified logrank test	0.5809	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 18: Time to all-cause mortality (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	270 (10.6%)	299 (11.6%)
Number (%) of subjects censored	2268 (89.4%)	2269 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.76; 1.06]	
two-sided p-value from stratified logrank test	0.1923	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 19: Time to all-cause mortality (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.2408

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 20: Time to all-cause mortality (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	369 (9.3%)	389 (9.8%)
Number (%) of subjects censored	3612 (90.7%)	3593 (90.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.82; 1.09]	
two-sided p-value from unstratified logrank test	0.4660	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
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Table 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	603 (15.1%)	678 (17.0%)
Number (%) of subjects censored	3378 (84.9%)	3304 (83.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.79; 0.98]	
two-sided p-value from stratified logrank test	0.0232	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 22: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	280 (7.0%)	341 (8.6%)
Number (%) of subjects censored	3701 (93.0%)	3641 (91.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.70; 0.96]	
two-sided p-value from stratified logrank test	0.0144	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	76 (4.4%)	107 (6.3%)
Number (%) of subjects censored	1642 (95.6%)	1596 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.71 [0.53; 0.95]	
two-sided p-value from stratified logrank test	0.0211	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	62 (9.0%)	70 (9.9%)
Number (%) of subjects censored	630 (91.0%)	638 (90.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.63; 1.25]	
two-sided p-value from stratified logrank test	0.4977	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	93 (9.0%)	123 (11.8%)
Number (%) of subjects censored	946 (91.0%)	917 (88.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.57; 0.98]	
two-sided p-value from stratified logrank test	0.0317	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	36 (9.6%)	32 (8.5%)
Number (%) of subjects censored	340 (90.4%)	343 (91.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.69; 1.78]	
two-sided p-value from stratified logrank test	0.6761	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 23: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	13 (8.3%)	9 (5.8%)
Number (%) of subjects censored	143 (91.7%)	147 (94.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.83 [0.75; 4.45]	
two-sided p-value from stratified logrank test	0.1763	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 24: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.1775

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	209 (9.5%)	252 (11.6%)
Number (%) of subjects censored	1988 (90.5%)	1923 (88.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.97]	
two-sided p-value from stratified logrank test	0.0237	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 25: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	71 (4.0%)	89 (4.9%)
Number (%) of subjects censored	1711 (96.0%)	1713 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.62; 1.17]	
two-sided p-value from stratified logrank test	0.3146	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 26: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.7873

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	37 (2.4%)	36 (2.3%)
Number (%) of subjects censored	1524 (97.6%)	1529 (97.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.05 [0.66; 1.66]	
two-sided p-value from stratified logrank test	0.8452	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 27: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	243 (10.1%)	305 (12.7%)
Number (%) of subjects censored	2167 (89.9%)	2104 (87.3%)
Median Time to event (month) [95 % CI]	n.c.	57.833 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.67; 0.94]	
two-sided p-value from stratified logrank test	0.0077	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 28: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.2672

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	112 (5.4%)	147 (7.1%)
Number (%) of subjects censored	1968 (94.6%)	1917 (92.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.57; 0.93]	
two-sided p-value from stratified logrank test	0.0109	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 29: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	168 (8.8%)	194 (10.1%)
Number (%) of subjects censored	1733 (91.2%)	1724 (89.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.73; 1.10]	
two-sided p-value from stratified logrank test	0.2908	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 30: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.2060

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	194 (7.3%)	233 (8.8%)
Number (%) of subjects censored	2467 (92.7%)	2402 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.98]	
two-sided p-value from stratified logrank test	0.0276	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 31: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	86 (6.5%)	108 (8.0%)
Number (%) of subjects censored	1233 (93.5%)	1237 (92.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.64; 1.13]	
two-sided p-value from stratified logrank test	0.2706	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 32: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.8298

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	59 (4.8%)	64 (5.2%)
Number (%) of subjects censored	1159 (95.2%)	1157 (94.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.64; 1.31]	
two-sided p-value from stratified logrank test	0.6268	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	201 (7.8%)	247 (9.5%)
Number (%) of subjects censored	2392 (92.2%)	2349 (90.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.68; 0.99]	
two-sided p-value from stratified logrank test	0.0351	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 33: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	19 (11.4%)	30 (18.4%)
Number (%) of subjects censored	148 (88.6%)	133 (81.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.48 [0.25; 0.92]	
two-sided p-value from stratified logrank test	0.0252	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 34: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.1644

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	130 (4.9%)	164 (6.2%)
Number (%) of subjects censored	2520 (95.1%)	2491 (93.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.64; 1.01]	
two-sided p-value from stratified logrank test	0.0642	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	31 (17.9%)	34 (18.3%)
Number (%) of subjects censored	142 (82.1%)	152 (81.7%)
Median Time to event (month) [95 % CI]	n.c.	57.833 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.40; 1.15]	
two-sided p-value from stratified logrank test	0.1471	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	86 (9.3%)	118 (12.7%)
Number (%) of subjects censored	843 (90.7%)	814 (87.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.56; 0.98]	
two-sided p-value from stratified logrank test	0.0333	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 35: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	33 (14.4%)	25 (12.0%)
Number (%) of subjects censored	196 (85.6%)	184 (88.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.31 [0.76; 2.25]	
two-sided p-value from stratified logrank test	0.3276	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 36: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.2638

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 37: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	190 (7.0%)	248 (8.8%)
Number (%) of subjects censored	2527 (93.0%)	2565 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.64; 0.93]	
two-sided p-value from stratified logrank test	0.0065	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 37: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	90 (7.1%)	93 (8.0%)
Number (%) of subjects censored	1174 (92.9%)	1076 (92.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.71; 1.27]	
two-sided p-value from stratified logrank test	0.7094	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 38: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.2310

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 39: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	142 (9.8%)	171 (12.1%)
Number (%) of subjects censored	1301 (90.2%)	1243 (87.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.66; 1.03]	
two-sided p-value from stratified logrank test	0.0917	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 39: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	138 (5.4%)	170 (6.6%)
Number (%) of subjects censored	2400 (94.6%)	2398 (93.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.65; 1.02]	
two-sided p-value from stratified logrank test	0.0675	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 40: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.9717

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 41: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	280 (7.0%)	341 (8.6%)
Number (%) of subjects censored	3701 (93.0%)	3641 (91.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.82 [0.70; 0.95]	
two-sided p-value from unstratified logrank test	0.0111	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 42: Time to onset of kidney failure, a sustained decrease of eGFR >= 57% from baseline over at least 4 weeks or renal death (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	169 (4.2%)	236 (5.9%)
Number (%) of subjects censored	3812 (95.8%)	3746 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.60; 0.89]	
two-sided p-value from stratified logrank test	0.0017	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 43: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	230 (5.8%)	251 (6.3%)
Number (%) of subjects censored	3751 (94.2%)	3731 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.75; 1.07]	
two-sided p-value from stratified logrank test	0.2327	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	60 (3.5%)	81 (4.8%)
Number (%) of subjects censored	1658 (96.5%)	1622 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.74 [0.53; 1.03]	
two-sided p-value from stratified logrank test	0.0703	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	55 (7.9%)	48 (6.8%)
Number (%) of subjects censored	637 (92.1%)	660 (93.2%)
Median Time to event (month) [95 % CI]	59.933 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.11 [0.75; 1.64]	
two-sided p-value from stratified logrank test	0.6006	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	77 (7.4%)	94 (9.0%)
Number (%) of subjects censored	962 (92.6%)	946 (91.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.58; 1.07]	
two-sided p-value from stratified logrank test	0.1221	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	27 (7.2%)	21 (5.6%)
Number (%) of subjects censored	349 (92.8%)	354 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.26 [0.71; 2.23]	
two-sided p-value from stratified logrank test	0.4244	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 44: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	11 (7.1%)	7 (4.5%)
Number (%) of subjects censored	145 (92.9%)	149 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.72 [0.66; 4.48]	
two-sided p-value from stratified logrank test	0.2581	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 45: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.1732

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	199 (9.1%)	218 (10.0%)
Number (%) of subjects censored	1998 (90.9%)	1957 (90.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.73; 1.08]	
two-sided p-value from stratified logrank test	0.2319	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 46: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	31 (1.7%)	33 (1.8%)
Number (%) of subjects censored	1751 (98.3%)	1769 (98.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.57; 1.54]	
two-sided p-value from stratified logrank test	0.7964	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 47: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.8477

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	25 (1.6%)	27 (1.7%)
Number (%) of subjects censored	1536 (98.4%)	1538 (98.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.51; 1.52]	
two-sided p-value from stratified logrank test	0.6448	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 48: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	205 (8.5%)	224 (9.3%)
Number (%) of subjects censored	2205 (91.5%)	2185 (90.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.74; 1.09]	
two-sided p-value from stratified logrank test	0.2647	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 49: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9324

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	90 (4.3%)	110 (5.3%)
Number (%) of subjects censored	1990 (95.7%)	1954 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.58; 1.01]	
two-sided p-value from stratified logrank test	0.0584	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 50: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	140 (7.4%)	141 (7.4%)
Number (%) of subjects censored	1761 (92.6%)	1777 (92.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.79; 1.27]	
two-sided p-value from stratified logrank test	0.9720	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 51: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.1428

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	157 (5.9%)	165 (6.3%)
Number (%) of subjects censored	2504 (94.1%)	2470 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.73; 1.13]	
two-sided p-value from stratified logrank test	0.3662	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 52: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	73 (5.5%)	86 (6.4%)
Number (%) of subjects censored	1246 (94.5%)	1259 (93.6%)
Median Time to event (month) [95 % CI]	59.933 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.63; 1.19]	
two-sided p-value from stratified logrank test	0.3622	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 53: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.7589

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	50 (4.1%)	50 (4.1%)
Number (%) of subjects censored	1168 (95.9%)	1171 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.64; 1.41]	
two-sided p-value from stratified logrank test	0.8106	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	166 (6.4%)	176 (6.8%)
Number (%) of subjects censored	2427 (93.6%)	2420 (93.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.75; 1.15]	
two-sided p-value from stratified logrank test	0.4993	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 54: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	13 (7.8%)	25 (15.3%)
Number (%) of subjects censored	154 (92.2%)	138 (84.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.42 [0.20; 0.89]	
two-sided p-value from stratified logrank test	0.0205	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 55: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.0430

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	109 (4.1%)	122 (4.6%)
Number (%) of subjects censored	2541 (95.9%)	2533 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.68; 1.15]	
two-sided p-value from stratified logrank test	0.3671	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	26 (15.0%)	20 (10.8%)
Number (%) of subjects censored	147 (85.0%)	166 (89.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.45; 1.63]	
two-sided p-value from stratified logrank test	0.6309	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	71 (7.6%)	92 (9.9%)
Number (%) of subjects censored	858 (92.4%)	840 (90.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.55; 1.02]	
two-sided p-value from stratified logrank test	0.0664	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 56: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	24 (10.5%)	17 (8.1%)
Number (%) of subjects censored	205 (89.5%)	192 (91.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.49 [0.78; 2.85]	
two-sided p-value from stratified logrank test	0.2221	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 57: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.2964

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 58: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	153 (5.6%)	183 (6.5%)
Number (%) of subjects censored	2564 (94.4%)	2630 (93.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.65; 1.01]	
two-sided p-value from stratified logrank test	0.0607	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 58: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	77 (6.1%)	68 (5.8%)
Number (%) of subjects censored	1187 (93.9%)	1101 (94.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.79; 1.54]	
two-sided p-value from stratified logrank test	0.5570	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 59: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1287

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 60: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	122 (8.5%)	124 (8.8%)
Number (%) of subjects censored	1321 (91.5%)	1290 (91.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.73; 1.22]	
two-sided p-value from stratified logrank test	0.6659	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 60: Time to onset of kidney failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	108 (4.3%)	127 (4.9%)
Number (%) of subjects censored	2430 (95.7%)	2441 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.64; 1.07]	
two-sided p-value from stratified logrank test	0.1522	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 61: Time to onset of kidney failure (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.5203

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 62: Time to onset of kidney failure (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	230 (5.8%)	251 (6.3%)
Number (%) of subjects censored	3751 (94.2%)	3731 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.76; 1.09]	
two-sided p-value from unstratified logrank test	0.3113	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 63: Time to onset of kidney failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	130 (3.3%)	161 (4.0%)
Number (%) of subjects censored	3851 (96.7%)	3821 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.64; 1.02]	
two-sided p-value from stratified logrank test	0.0728	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 64: Time to onset of ESRD (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	133 (3.3%)	149 (3.7%)
Number (%) of subjects censored	3848 (96.7%)	3833 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.70; 1.12]	
two-sided p-value from stratified logrank test	0.3252	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 65: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	182 (4.6%)	210 (5.3%)
Number (%) of subjects censored	3799 (95.4%)	3772 (94.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.70; 1.04]	
two-sided p-value from stratified logrank test	0.1052	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 66: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	182 (4.6%)	248 (6.2%)
Number (%) of subjects censored	3799 (95.4%)	3734 (93.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.60; 0.89]	
two-sided p-value from stratified logrank test	0.0014	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 67: Time to renal death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	2 (<0.1%)	3 (<0.1%)
Number (%) of subjects censored	3979 (>99.9%)	3979 (>99.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.69 [0.12; 4.14]	
two-sided p-value from stratified logrank test	0.6849	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 68: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	490 (12.3%)	526 (13.2%)
Number (%) of subjects censored	3491 (87.7%)	3456 (86.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.82; 1.05]	
two-sided p-value from stratified logrank test	0.2151	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 69: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	528 (13.3%)	615 (15.4%)
Number (%) of subjects censored	3453 (86.7%)	3367 (84.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.74; 0.94]	
two-sided p-value from stratified logrank test	0.0026	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	251 (14.6%)	282 (16.6%)
Number (%) of subjects censored	1467 (85.4%)	1421 (83.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.73; 1.03]	
two-sided p-value from stratified logrank test	0.1090	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	104 (15.0%)	141 (19.9%)
Number (%) of subjects censored	588 (85.0%)	567 (80.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.75 [0.58; 0.96]	
two-sided p-value from stratified logrank test	0.0238	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	106 (10.2%)	122 (11.7%)
Number (%) of subjects censored	933 (89.8%)	918 (88.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.62; 1.04]	
two-sided p-value from stratified logrank test	0.0960	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	38 (10.1%)	51 (13.6%)
Number (%) of subjects censored	338 (89.9%)	324 (86.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.48; 1.11]	
two-sided p-value from stratified logrank test	0.1387	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 70: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	29 (18.6%)	19 (12.2%)
Number (%) of subjects censored	127 (81.4%)	137 (87.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.52 [0.85; 2.73]	
two-sided p-value from stratified logrank test	0.1537	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 71: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.2352

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	325 (14.8%)	359 (16.5%)
Number (%) of subjects censored	1872 (85.2%)	1816 (83.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.75; 1.01]	
two-sided p-value from stratified logrank test	0.0686	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 72: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	202 (11.3%)	255 (14.2%)
Number (%) of subjects censored	1580 (88.7%)	1547 (85.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.65; 0.95]	
two-sided p-value from stratified logrank test	0.0106	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 73: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.4051

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	216 (13.8%)	252 (16.1%)
Number (%) of subjects censored	1345 (86.2%)	1313 (83.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.70; 1.02]	
two-sided p-value from stratified logrank test	0.0719	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 74: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	310 (12.9%)	362 (15.0%)
Number (%) of subjects censored	2100 (87.1%)	2047 (85.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.72; 0.97]	
two-sided p-value from stratified logrank test	0.0188	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 75: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.9711

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	344 (16.5%)	406 (19.7%)
Number (%) of subjects censored	1736 (83.5%)	1658 (80.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.70; 0.94]	
two-sided p-value from stratified logrank test	0.0048	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 76: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	184 (9.7%)	209 (10.9%)
Number (%) of subjects censored	1717 (90.3%)	1709 (89.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.72; 1.08]	
two-sided p-value from stratified logrank test	0.2167	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 77: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.5154

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	359 (13.5%)	396 (15.0%)
Number (%) of subjects censored	2302 (86.5%)	2239 (85.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.75; <1.00]	
two-sided p-value from stratified logrank test	0.0472	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 78: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	168 (12.7%)	218 (16.2%)
Number (%) of subjects censored	1151 (87.3%)	1127 (83.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.64; 0.97]	
two-sided p-value from stratified logrank test	0.0225	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 79: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.4195

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	136 (11.2%)	167 (13.7%)
Number (%) of subjects censored	1082 (88.8%)	1054 (86.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.63; 0.99]	
two-sided p-value from stratified logrank test	0.0428	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	360 (13.9%)	420 (16.2%)
Number (%) of subjects censored	2233 (86.1%)	2176 (83.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.72; 0.96]	
two-sided p-value from stratified logrank test	0.0103	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 80: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	30 (18.0%)	27 (16.6%)
Number (%) of subjects censored	137 (82.0%)	136 (83.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.20 [0.68; 2.10]	
two-sided p-value from stratified logrank test	0.5265	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 81: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.4736

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	396 (14.9%)	461 (17.4%)
Number (%) of subjects censored	2254 (85.1%)	2194 (82.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.73; 0.96]	
two-sided p-value from stratified logrank test	0.0109	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	28 (16.2%)	40 (21.5%)
Number (%) of subjects censored	145 (83.8%)	146 (78.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.40; 1.12]	
two-sided p-value from stratified logrank test	0.1244	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	78 (8.4%)	88 (9.4%)
Number (%) of subjects censored	851 (91.6%)	844 (90.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.62; 1.16]	
two-sided p-value from stratified logrank test	0.2985	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 82: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	26 (11.4%)	26 (12.4%)
Number (%) of subjects censored	203 (88.6%)	183 (87.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.52; 1.67]	
two-sided p-value from stratified logrank test	0.8071	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 83: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8249

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 84: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	365 (13.4%)	434 (15.4%)
Number (%) of subjects censored	2352 (86.6%)	2379 (84.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.72; 0.96]	
two-sided p-value from stratified logrank test	0.0099	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 84: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	163 (12.9%)	181 (15.5%)
Number (%) of subjects censored	1101 (87.1%)	988 (84.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.68; 1.04]	
two-sided p-value from stratified logrank test	0.1060	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 85: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.9989

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 86: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	161 (11.2%)	162 (11.5%)
Number (%) of subjects censored	1282 (88.8%)	1252 (88.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.78; 1.22]	
two-sided p-value from stratified logrank test	0.8334	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 86: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	367 (14.5%)	453 (17.6%)
Number (%) of subjects censored	2171 (85.5%)	2115 (82.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.69; 0.91]	
two-sided p-value from stratified logrank test	0.0010	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 87: Time to first occurrence of CV death or non-fatal CV event (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.1315

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 88: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	528 (13.3%)	615 (15.4%)
Number (%) of subjects censored	3453 (86.7%)	3367 (84.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.75; 0.95]	
two-sided p-value from unstratified logrank test	0.0048	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 89: Time to CV death, non-fatal MI, non-fatal stroke or hospitalization for Heart Failure (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	376 (9.4%)	489 (12.3%)
Number (%) of subjects censored	3605 (90.6%)	3493 (87.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.77 [0.67; 0.88]	
two-sided p-value from stratified logrank test	0.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 90: Time to CV death (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	204 (5.1%)	228 (5.7%)
Number (%) of subjects censored	3777 (94.9%)	3754 (94.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.74; 1.08]	
two-sided p-value from stratified logrank test	0.2339	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 91: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	110 (2.8%)	131 (3.3%)
Number (%) of subjects censored	3871 (97.2%)	3851 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.64; 1.06]	
two-sided p-value from stratified logrank test	0.1384	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 92: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	114 (2.9%)	122 (3.1%)
Number (%) of subjects censored	3867 (97.1%)	3860 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.71; 1.19]	
two-sided p-value from stratified logrank test	0.5313	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 93: Time to hospitalization due to heart failure (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	188 (4.7%)	221 (5.5%)
Number (%) of subjects censored	3793 (95.3%)	3761 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.69; 1.02]	
two-sided p-value from stratified logrank test	0.0848	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 94: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	121 (3.0%)	141 (3.5%)
Number (%) of subjects censored	3860 (97.0%)	3841 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.66; 1.08]	
two-sided p-value from stratified logrank test	0.1696	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	60 (3.5%)	57 (3.3%)
Number (%) of subjects censored	1658 (96.5%)	1646 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.72; 1.49]	
two-sided p-value from stratified logrank test	0.8473	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	20 (2.9%)	38 (5.4%)
Number (%) of subjects censored	672 (97.1%)	670 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.54 [0.31; 0.93]	
two-sided p-value from stratified logrank test	0.0233	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	28 (2.7%)	30 (2.9%)
Number (%) of subjects censored	1011 (97.3%)	1010 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.87 [0.52; 1.46]	
two-sided p-value from stratified logrank test	0.6040	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	5 (1.3%)	10 (2.7%)
Number (%) of subjects censored	371 (98.7%)	365 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.51 [0.17; 1.50]	
two-sided p-value from stratified logrank test	0.2136	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 95: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	8 (5.1%)	6 (3.8%)
Number (%) of subjects censored	148 (94.9%)	150 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.28 [0.44; 3.75]	
two-sided p-value from stratified logrank test	0.6453	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 96: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.2587

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	63 (2.9%)	92 (4.2%)
Number (%) of subjects censored	2134 (97.1%)	2083 (95.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.48; 0.91]	
two-sided p-value from stratified logrank test	0.0118	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 97: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	57 (3.2%)	49 (2.7%)
Number (%) of subjects censored	1725 (96.8%)	1753 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.16 [0.79; 1.71]	
two-sided p-value from stratified logrank test	0.4366	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 98: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.0275

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	56 (3.6%)	62 (4.0%)
Number (%) of subjects censored	1505 (96.4%)	1503 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.61; 1.26]	
two-sided p-value from stratified logrank test	0.4724	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 99: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	64 (2.7%)	79 (3.3%)
Number (%) of subjects censored	2346 (97.3%)	2330 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.58; 1.12]	
two-sided p-value from stratified logrank test	0.2021	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 100: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.7472

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	89 (4.3%)	95 (4.6%)
Number (%) of subjects censored	1991 (95.7%)	1969 (95.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.69; 1.23]	
two-sided p-value from stratified logrank test	0.5739	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 101: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	32 (1.7%)	46 (2.4%)
Number (%) of subjects censored	1869 (98.3%)	1872 (97.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.44; 1.08]	
two-sided p-value from stratified logrank test	0.0982	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 102: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.2798

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 103: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	83 (3.1%)	90 (3.4%)
Number (%) of subjects censored	2578 (96.9%)	2545 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.66; 1.21]	
two-sided p-value from stratified logrank test	0.4624	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 103: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	37 (2.8%)	51 (3.8%)
Number (%) of subjects censored	1282 (97.2%)	1294 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.73 [0.48; 1.12]	
two-sided p-value from stratified logrank test	0.1525	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 104: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.4135

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	25 (2.1%)	40 (3.3%)
Number (%) of subjects censored	1193 (97.9%)	1181 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.61 [0.37; >1.00]	
two-sided p-value from stratified logrank test	0.0488	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	92 (3.5%)	94 (3.6%)
Number (%) of subjects censored	2501 (96.5%)	2502 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.72; 1.28]	
two-sided p-value from stratified logrank test	0.7975	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 105: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	3 (1.8%)	7 (4.3%)
Number (%) of subjects censored	164 (98.2%)	156 (95.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.49 [0.12; 1.90]	
two-sided p-value from stratified logrank test	0.2907	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 106: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.1804

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	95 (3.6%)	108 (4.1%)
Number (%) of subjects censored	2555 (96.4%)	2547 (95.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.67; 1.16]	
two-sided p-value from stratified logrank test	0.3568	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	4 (2.3%)	7 (3.8%)
Number (%) of subjects censored	169 (97.7%)	179 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.52 [0.15; 1.84]	
two-sided p-value from stratified logrank test	0.3043	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	17 (1.8%)	19 (2.0%)
Number (%) of subjects censored	912 (98.2%)	913 (98.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.47; 1.80]	
two-sided p-value from stratified logrank test	0.8091	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 107: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	5 (2.2%)	7 (3.3%)
Number (%) of subjects censored	224 (97.8%)	202 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.19; 2.51]	
two-sided p-value from stratified logrank test	0.5791	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 108: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8657

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 109: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	92 (3.4%)	110 (3.9%)
Number (%) of subjects censored	2625 (96.6%)	2703 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.63; 1.11]	
two-sided p-value from stratified logrank test	0.2107	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 109: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	29 (2.3%)	31 (2.7%)
Number (%) of subjects censored	1235 (97.7%)	1138 (97.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.52; 1.44]	
two-sided p-value from stratified logrank test	0.5774	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 110: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.9705

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 111: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	32 (2.2%)	39 (2.8%)
Number (%) of subjects censored	1411 (97.8%)	1375 (97.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.52; 1.34]	
two-sided p-value from stratified logrank test	0.4459	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 111: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	89 (3.5%)	102 (4.0%)
Number (%) of subjects censored	2449 (96.5%)	2466 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.65; 1.15]	
two-sided p-value from stratified logrank test	0.3022	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 112: Time to fatal or non-fatal myocardial infarction (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.8252

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 113: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	121 (3.0%)	141 (3.5%)
Number (%) of subjects censored	3860 (97.0%)	3841 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.67; 1.09]	
two-sided p-value from unstratified logrank test	0.1992	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 114: Time to fatal or non-fatal myocardial infarction (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	98 (2.5%)	118 (3.0%)
Number (%) of subjects censored	3883 (97.5%)	3864 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.64; 1.09]	
two-sided p-value from stratified logrank test	0.1921	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 115: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	128 (3.2%)	141 (3.5%)
Number (%) of subjects censored	3853 (96.8%)	3841 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.70; 1.14]	
two-sided p-value from stratified logrank test	0.3586	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	61 (3.6%)	59 (3.5%)
Number (%) of subjects censored	1657 (96.4%)	1644 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.71; 1.46]	
two-sided p-value from stratified logrank test	0.9247	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	15 (2.2%)	36 (5.1%)
Number (%) of subjects censored	677 (97.8%)	672 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.43 [0.24; 0.79]	
two-sided p-value from stratified logrank test	0.0050	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	32 (3.1%)	31 (3.0%)
Number (%) of subjects censored	1007 (96.9%)	1009 (97.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.59; 1.60]	
two-sided p-value from stratified logrank test	0.9204	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	9 (2.4%)	12 (3.2%)
Number (%) of subjects censored	367 (97.6%)	363 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.32; 1.80]	
two-sided p-value from stratified logrank test	0.5267	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 116: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	11 (7.1%)	3 (1.9%)
Number (%) of subjects censored	145 (92.9%)	153 (98.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	3.50 [0.97; 12.55]	
two-sided p-value from stratified logrank test	0.0406	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 117: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.0297

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	72 (3.3%)	70 (3.2%)
Number (%) of subjects censored	2125 (96.7%)	2105 (96.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.71; 1.38]	
two-sided p-value from stratified logrank test	0.9705	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 118: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	56 (3.1%)	71 (3.9%)
Number (%) of subjects censored	1726 (96.9%)	1731 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.79 [0.56; 1.12]	
two-sided p-value from stratified logrank test	0.1893	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 119: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.3524

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	46 (2.9%)	61 (3.9%)
Number (%) of subjects censored	1515 (97.1%)	1504 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.52; 1.12]	
two-sided p-value from stratified logrank test	0.1655	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 120: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	82 (3.4%)	80 (3.3%)
Number (%) of subjects censored	2328 (96.6%)	2329 (96.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.74; 1.37]	
two-sided p-value from stratified logrank test	0.9859	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 121: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.2488

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 122: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	76 (3.7%)	92 (4.5%)
Number (%) of subjects censored	2004 (96.3%)	1972 (95.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.59; 1.09]	
two-sided p-value from stratified logrank test	0.1629	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 122: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	52 (2.7%)	49 (2.6%)
Number (%) of subjects censored	1849 (97.3%)	1869 (97.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.72; 1.57]	
two-sided p-value from stratified logrank test	0.7639	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 123: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.2753

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 124: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	93 (3.5%)	91 (3.5%)
Number (%) of subjects censored	2568 (96.5%)	2544 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.73; 1.31]	
two-sided p-value from stratified logrank test	0.8756	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 124: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	35 (2.7%)	50 (3.7%)
Number (%) of subjects censored	1284 (97.3%)	1295 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.72 [0.46; 1.11]	
two-sided p-value from stratified logrank test	0.1375	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 125: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.2481

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	26 (2.1%)	30 (2.5%)
Number (%) of subjects censored	1192 (97.9%)	1191 (97.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.86 [0.50; 1.45]	
two-sided p-value from stratified logrank test	0.5604	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	96 (3.7%)	105 (4.0%)
Number (%) of subjects censored	2497 (96.3%)	2491 (96.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.68; 1.18]	
two-sided p-value from stratified logrank test	0.4185	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 126: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	6 (3.6%)	5 (3.1%)
Number (%) of subjects censored	161 (96.4%)	158 (96.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.17 [0.35; 3.93]	
two-sided p-value from stratified logrank test	0.8011	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 127: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.9140

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	90 (3.4%)	99 (3.7%)
Number (%) of subjects censored	2560 (96.6%)	2556 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.68; 1.20]	
two-sided p-value from stratified logrank test	0.4718	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	5 (2.9%)	13 (7.0%)
Number (%) of subjects censored	168 (97.1%)	173 (93.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.54 [0.18; 1.57]	
two-sided p-value from stratified logrank test	0.2482	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	26 (2.8%)	27 (2.9%)
Number (%) of subjects censored	903 (97.2%)	905 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.55; 1.62]	
two-sided p-value from stratified logrank test	0.8295	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 128: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	7 (3.1%)	2 (1.0%)
Number (%) of subjects censored	222 (96.9%)	207 (99.0%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	2.79 [0.56; 13.99]	
two-sided p-value from stratified logrank test	0.1951	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 129: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.2015

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 130: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	99 (3.6%)	99 (3.5%)
Number (%) of subjects censored	2618 (96.4%)	2714 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.01 [0.76; 1.34]	
two-sided p-value from stratified logrank test	0.9344	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 130: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	29 (2.3%)	42 (3.6%)
Number (%) of subjects censored	1235 (97.7%)	1127 (96.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.66 [0.41; 1.07]	
two-sided p-value from stratified logrank test	0.0876	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 131: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.1031

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 132: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	45 (3.1%)	41 (2.9%)
Number (%) of subjects censored	1398 (96.9%)	1373 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.12 [0.73; 1.73]	
two-sided p-value from stratified logrank test	0.6112	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 132: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	83 (3.3%)	100 (3.9%)
Number (%) of subjects censored	2455 (96.7%)	2468 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.83 [0.62; 1.11]	
two-sided p-value from stratified logrank test	0.2046	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 133: Time to fatal or non-fatal stroke (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.3391

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 134: Time to fatal or non-fatal stroke (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	128 (3.2%)	141 (3.5%)
Number (%) of subjects censored	3853 (96.8%)	3841 (96.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.90 [0.71; 1.15]	
two-sided p-value from unstratified logrank test	0.3961	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 135: Time to fatal or non-fatal stroke (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	103 (2.6%)	117 (2.9%)
Number (%) of subjects censored	3878 (97.4%)	3865 (97.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.89 [0.68; 1.16]	
two-sided p-value from stratified logrank test	0.3947	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 136: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	190 (4.8%)	233 (5.9%)
Number (%) of subjects censored	3791 (95.2%)	3749 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.98]	
two-sided p-value from stratified logrank test	0.0299	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	84 (4.9%)	107 (6.3%)
Number (%) of subjects censored	1634 (95.1%)	1596 (93.7%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.58; 1.03]	
two-sided p-value from stratified logrank test	0.0808	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	50 (7.2%)	54 (7.6%)
Number (%) of subjects censored	642 (92.8%)	654 (92.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.66; 1.43]	
two-sided p-value from stratified logrank test	0.8948	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	37 (3.6%)	50 (4.8%)
Number (%) of subjects censored	1002 (96.4%)	990 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.68 [0.44; 1.04]	
two-sided p-value from stratified logrank test	0.0706	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	11 (2.9%)	14 (3.7%)
Number (%) of subjects censored	365 (97.1%)	361 (96.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.36; 1.76]	
two-sided p-value from stratified logrank test	0.5771	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 137: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	8 (5.1%)	8 (5.1%)
Number (%) of subjects censored	148 (94.9%)	148 (94.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.39; 2.88]	
two-sided p-value from stratified logrank test	0.9017	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 138: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.7458

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	123 (5.6%)	132 (6.1%)
Number (%) of subjects censored	2074 (94.4%)	2043 (93.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.71; 1.17]	
two-sided p-value from stratified logrank test	0.4585	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 139: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	67 (3.8%)	101 (5.6%)
Number (%) of subjects censored	1715 (96.2%)	1701 (94.4%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.67 [0.49; 0.91]	
two-sided p-value from stratified logrank test	0.0107	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 140: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.1276

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 141: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	64 (4.1%)	82 (5.2%)
Number (%) of subjects censored	1497 (95.9%)	1483 (94.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.55; 1.06]	
two-sided p-value from stratified logrank test	0.1037	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 141: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	125 (5.2%)	150 (6.2%)
Number (%) of subjects censored	2285 (94.8%)	2259 (93.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.84 [0.66; 1.06]	
two-sided p-value from stratified logrank test	0.1397	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 142: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.6448

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 143: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	124 (6.0%)	161 (7.8%)
Number (%) of subjects censored	1956 (94.0%)	1903 (92.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.60; 0.96]	
two-sided p-value from stratified logrank test	0.0201	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 143: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	66 (3.5%)	72 (3.8%)
Number (%) of subjects censored	1835 (96.5%)	1846 (96.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.66; 1.29]	
two-sided p-value from stratified logrank test	0.6444	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 144: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3406

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 145: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	134 (5.0%)	161 (6.1%)
Number (%) of subjects censored	2527 (95.0%)	2474 (93.9%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.80 [0.64; 1.01]	
two-sided p-value from stratified logrank test	0.0595	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 145: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	56 (4.2%)	72 (5.4%)
Number (%) of subjects censored	1263 (95.8%)	1273 (94.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.57; 1.16]	
two-sided p-value from stratified logrank test	0.2507	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 146: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.9737

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	52 (4.3%)	64 (5.2%)
Number (%) of subjects censored	1166 (95.7%)	1157 (94.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.56; 1.17]	
two-sided p-value from stratified logrank test	0.2619	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	124 (4.8%)	160 (6.2%)
Number (%) of subjects censored	2469 (95.2%)	2436 (93.8%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.60; 0.96]	
two-sided p-value from stratified logrank test	0.0224	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 147: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	13 (7.8%)	9 (5.5%)
Number (%) of subjects censored	154 (92.2%)	154 (94.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.47 [0.57; 3.76]	
two-sided p-value from stratified logrank test	0.4218	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 148: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.3340

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	139 (5.2%)	177 (6.7%)
Number (%) of subjects censored	2511 (94.8%)	2478 (93.3%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.78 [0.62; 0.97]	
two-sided p-value from stratified logrank test	0.0269	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	15 (8.7%)	14 (7.5%)
Number (%) of subjects censored	158 (91.3%)	172 (92.5%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.10 [0.52; 2.36]	
two-sided p-value from stratified logrank test	0.8007	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	26 (2.8%)	32 (3.4%)
Number (%) of subjects censored	903 (97.2%)	900 (96.6%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.45; 1.28]	
two-sided p-value from stratified logrank test	0.2964	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 149: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	10 (4.4%)	10 (4.8%)
Number (%) of subjects censored	219 (95.6%)	199 (95.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.04 [0.41; 2.63]	
two-sided p-value from stratified logrank test	0.9349	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 150: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.8709

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 151: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	117 (4.3%)	164 (5.8%)
Number (%) of subjects censored	2600 (95.7%)	2649 (94.2%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.70 [0.55; 0.89]	
two-sided p-value from stratified logrank test	0.0035	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 151: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	73 (5.8%)	69 (5.9%)
Number (%) of subjects censored	1191 (94.2%)	1100 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.69; 1.35]	
two-sided p-value from stratified logrank test	0.8425	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
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Table 1.2.1 / 152: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.0871

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 153: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	54 (3.7%)	55 (3.9%)
Number (%) of subjects censored	1389 (96.3%)	1359 (96.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.66; 1.41]	
two-sided p-value from stratified logrank test	0.8592	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 153: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	136 (5.4%)	178 (6.9%)
Number (%) of subjects censored	2402 (94.6%)	2390 (93.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.76 [0.61; 0.95]	
two-sided p-value from stratified logrank test	0.0165	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 154: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.2852

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 155: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	190 (4.8%)	233 (5.9%)
Number (%) of subjects censored	3791 (95.2%)	3749 (94.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.81 [0.67; 0.98]	
two-sided p-value from unstratified logrank test	0.0302	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 156: Time to CV death for HF or hospitalization for HF (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	126 (3.2%)	197 (4.9%)
Number (%) of subjects censored	3855 (96.8%)	3785 (95.1%)
Median Time to event (month) [95 % CI]	n.c.	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.64 [0.51; 0.80]	
two-sided p-value from stratified logrank test	0.0001	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 157: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	1846 (46.4%)	1914 (48.1%)
Number (%) of subjects censored	2135 (53.6%)	2068 (51.9%)
Median Time to event (month) [95 % CI]	40.533 [38.500;42.700]	37.467 [34.933;39.267]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.89; 1.01]	
two-sided p-value from stratified logrank test	0.1162	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

Statistics	BAY 94-8862	Placebo
N	1718 (100.0%)	1703 (100.0%)
Number (%) of subjects with event	806 (46.9%)	816 (47.9%)
Number (%) of subjects censored	912 (53.1%)	887 (52.1%)
Median Time to event (month) [95 % CI]	39.667 [36.467;43.000]	38.100 [34.300;40.433]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.87; 1.06]	
two-sided p-value from stratified logrank test	0.4232	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

Statistics	BAY 94-8862	Placebo
N	692 (100.0%)	708 (100.0%)
Number (%) of subjects with event	325 (47.0%)	344 (48.6%)
Number (%) of subjects censored	367 (53.0%)	364 (51.4%)
Median Time to event (month) [95 % CI]	41.500 [36.500;47.000]	38.400 [32.467;47.433]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.99 [0.85; 1.16]	
two-sided p-value from stratified logrank test	0.9449	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

Statistics	BAY 94-8862	Placebo
N	1039 (100.0%)	1040 (100.0%)
Number (%) of subjects with event	502 (48.3%)	543 (52.2%)
Number (%) of subjects censored	537 (51.7%)	497 (47.8%)
Median Time to event (month) [95 % CI]	38.400 [32.933;45.167]	32.933 [30.600;38.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.88 [0.78; 0.99]	
two-sided p-value from stratified logrank test	0.0384	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

Statistics	BAY 94-8862	Placebo
N	376 (100.0%)	375 (100.0%)
Number (%) of subjects with event	125 (33.2%)	126 (33.6%)
Number (%) of subjects censored	251 (66.8%)	249 (66.4%)
Median Time to event (month) [95 % CI]	42.600 [n.c.]	n.c.
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.00 [0.78; 1.28]	
two-sided p-value from stratified logrank test	0.9853	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 158: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

Statistics	BAY 94-8862	Placebo
N	156 (100.0%)	156 (100.0%)
Number (%) of subjects with event	88 (56.4%)	85 (54.5%)
Number (%) of subjects censored	68 (43.6%)	71 (45.5%)
Median Time to event (month) [95 % CI]	27.433 [18.933;40.333]	29.800 [24.633;39.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.78; 1.44]	
two-sided p-value from stratified logrank test	0.6956	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 159: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Region	0.6215

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	2197 (100.0%)	2175 (100.0%)
Number (%) of subjects with event	1059 (48.2%)	1079 (49.6%)
Number (%) of subjects censored	1138 (51.8%)	1096 (50.4%)
Median Time to event (month) [95 % CI]	37.933 [34.900;40.100]	35.000 [32.233;38.033]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.88; 1.05]	
two-sided p-value from stratified logrank test	0.3816	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 160: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Statistics	BAY 94-8862	Placebo
N	1782 (100.0%)	1802 (100.0%)
Number (%) of subjects with event	786 (44.1%)	832 (46.2%)
Number (%) of subjects censored	996 (55.9%)	970 (53.8%)
Median Time to event (month) [95 % CI]	44.367 [41.233;50.100]	40.333 [36.967;44.667]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.85; 1.03]	
two-sided p-value from stratified logrank test	0.1718	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 161: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening eGFR (mL/min/1.73m2) category	0.6484

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 162: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	1561 (100.0%)	1565 (100.0%)
Number (%) of subjects with event	766 (49.1%)	790 (50.5%)
Number (%) of subjects censored	795 (50.9%)	775 (49.5%)
Median Time to event (month) [95 % CI]	43.533 [40.367;48.600]	40.767 [37.733;45.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.87; 1.06]	
two-sided p-value from stratified logrank test	0.4292	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 162: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Statistics	BAY 94-8862	Placebo
N	2410 (100.0%)	2409 (100.0%)
Number (%) of subjects with event	1074 (44.6%)	1119 (46.5%)
Number (%) of subjects censored	1336 (55.4%)	1290 (53.5%)
Median Time to event (month) [95 % CI]	38.067 [35.800;40.133]	34.667 [32.333;37.433]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.87; 1.03]	
two-sided p-value from stratified logrank test	0.1739	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 163: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Screening albuminuria (mg/g) category	0.8213

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 164: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

Statistics	BAY 94-8862	Placebo
N	2080 (100.0%)	2064 (100.0%)
Number (%) of subjects with event	1044 (50.2%)	1082 (52.4%)
Number (%) of subjects censored	1036 (49.8%)	982 (47.6%)
Median Time to event (month) [95 % CI]	35.533 [31.967;38.233]	30.067 [27.700;32.367]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.85; 1.01]	
two-sided p-value from stratified logrank test	0.0750	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 164: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

Statistics	BAY 94-8862	Placebo
N	1901 (100.0%)	1918 (100.0%)
Number (%) of subjects with event	802 (42.2%)	832 (43.4%)
Number (%) of subjects censored	1099 (57.8%)	1086 (56.6%)
Median Time to event (month) [95 % CI]	49.133 [43.300;54.500]	43.833 [40.333;48.767]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.89; 1.08]	
two-sided p-value from stratified logrank test	0.7238	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 165: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
History of CVD (Medical history)	0.3627

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 166: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	2661 (100.0%)	2635 (100.0%)
Number (%) of subjects with event	1248 (46.9%)	1258 (47.7%)
Number (%) of subjects censored	1413 (53.1%)	1377 (52.3%)
Median Time to event (month) [95 % CI]	40.067 [37.933;42.700]	38.100 [35.633;40.367]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.89; 1.04]	
two-sided p-value from stratified logrank test	0.3688	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 166: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Statistics	BAY 94-8862	Placebo
N	1319 (100.0%)	1345 (100.0%)
Number (%) of subjects with event	597 (45.3%)	655 (48.7%)
Number (%) of subjects censored	722 (54.7%)	690 (51.3%)
Median Time to event (month) [95 % CI]	41.300 [36.433;46.067]	35.100 [31.200;39.900]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.93 [0.83; 1.04]	
two-sided p-value from stratified logrank test	0.2179	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 167: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline serum potassium (mmol/L) category	0.5393

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

Statistics	BAY 94-8862	Placebo
N	1218 (100.0%)	1221 (100.0%)
Number (%) of subjects with event	538 (44.2%)	566 (46.4%)
Number (%) of subjects censored	680 (55.8%)	655 (53.6%)
Median Time to event (month) [95 % CI]	43.700 [40.867;54.333]	41.800 [36.600;46.600]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.84; 1.07]	
two-sided p-value from stratified logrank test	0.4261	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Statistics	BAY 94-8862	Placebo
N	2593 (100.0%)	2596 (100.0%)
Number (%) of subjects with event	1231 (47.5%)	1264 (48.7%)
Number (%) of subjects censored	1362 (52.5%)	1332 (51.3%)
Median Time to event (month) [95 % CI]	39.233 [36.433;41.567]	35.967 [32.967;38.400]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.88; 1.03]	
two-sided p-value from stratified logrank test	0.2243	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 168: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

Statistics	BAY 94-8862	Placebo
N	167 (100.0%)	163 (100.0%)
Number (%) of subjects with event	75 (44.9%)	82 (50.3%)
Number (%) of subjects censored	92 (55.1%)	81 (49.7%)
Median Time to event (month) [95 % CI]	37.733 [n.c.]	36.133 [24.233;39.767]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.02 [0.72; 1.45]	
two-sided p-value from stratified logrank test	0.8951	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 169: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Baseline systolic blood pressure (mmHg) category	0.8756

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

Statistics	BAY 94-8862	Placebo
N	2650 (100.0%)	2655 (100.0%)
Number (%) of subjects with event	1231 (46.5%)	1277 (48.1%)
Number (%) of subjects censored	1419 (53.5%)	1378 (51.9%)
Median Time to event (month) [95 % CI]	40.133 [37.667;43.000]	36.767 [34.300;39.033]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.89; 1.04]	
two-sided p-value from stratified logrank test	0.3565	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

Statistics	BAY 94-8862	Placebo
N	173 (100.0%)	186 (100.0%)
Number (%) of subjects with event	81 (46.8%)	95 (51.1%)
Number (%) of subjects censored	92 (53.2%)	91 (48.9%)
Median Time to event (month) [95 % CI]	38.933 [n.c.]	32.700 [26.433;41.767]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.85 [0.62; 1.17]	
two-sided p-value from stratified logrank test	0.3244	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

Statistics	BAY 94-8862	Placebo
N	929 (100.0%)	932 (100.0%)
Number (%) of subjects with event	443 (47.7%)	463 (49.7%)
Number (%) of subjects censored	486 (52.3%)	469 (50.3%)
Median Time to event (month) [95 % CI]	40.533 [34.000;49.133]	37.467 [31.667;42.633]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.92 [0.80; 1.05]	
two-sided p-value from stratified logrank test	0.2023	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 170: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

Statistics	BAY 94-8862	Placebo
N	229 (100.0%)	209 (100.0%)
Number (%) of subjects with event	91 (39.7%)	79 (37.8%)
Number (%) of subjects censored	138 (60.3%)	130 (62.2%)
Median Time to event (month) [95 % CI]	41.100 [39.300;48.633]	47.567 [n.c.]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	1.06 [0.76; 1.48]	
two-sided p-value from stratified logrank test	0.7435	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 171: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Race (4 categories)	0.7454

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 172: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

Statistics	BAY 94-8862	Placebo
N	2717 (100.0%)	2813 (100.0%)
Number (%) of subjects with event	1308 (48.1%)	1372 (48.8%)
Number (%) of subjects censored	1409 (51.9%)	1441 (51.2%)
Median Time to event (month) [95 % CI]	39.233 [36.233;41.500]	36.067 [33.233;39.000]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.97 [0.90; 1.05]	
two-sided p-value from stratified logrank test	0.4424	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 172: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

Statistics	BAY 94-8862	Placebo
N	1264 (100.0%)	1169 (100.0%)
Number (%) of subjects with event	538 (42.6%)	542 (46.4%)
Number (%) of subjects censored	726 (57.4%)	627 (53.6%)
Median Time to event (month) [95 % CI]	48.600 [n.c.]	38.967 [35.967;44.467]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.91 [0.81; 1.03]	
two-sided p-value from stratified logrank test	0.1530	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
End of table

Table 1.2.1 / 173: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Sex	0.3172

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
End of table

Table 1.2.1 / 174: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

Statistics	BAY 94-8862	Placebo
N	1443 (100.0%)	1414 (100.0%)
Number (%) of subjects with event	629 (43.6%)	626 (44.3%)
Number (%) of subjects censored	814 (56.4%)	788 (55.7%)
Median Time to event (month) [95 % CI]	43.000 [39.300;48.633]	42.467 [36.667;45.700]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.98 [0.87; 1.10]	
two-sided p-value from stratified logrank test	0.7136	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18

Table 1.2.1 / 174: Time to all-cause hospitalization (months): Kaplan-Meier summary, stratified logrank test and Hazard Ratio by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

Statistics	BAY 94-8862	Placebo
N	2538 (100.0%)	2568 (100.0%)
Number (%) of subjects with event	1217 (48.0%)	1288 (50.2%)
Number (%) of subjects censored	1321 (52.0%)	1280 (49.8%)
Median Time to event (month) [95 % CI]	39.267 [36.067;41.667]	35.000 [32.200;38.333]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.94 [0.87; 1.02]	
two-sided p-value from stratified logrank test	0.1370	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
End of table

Table 1.2.1 / 175: Time to all-cause hospitalization (months): Wald chi-square p-values from stratified model for subgroup Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Subgroup-Variable	Treatment and Subgroup interaction p-value
Age group (years) 3rd category	0.6808

Wald chi-square p-value from stratified model including treatment, subgroup, and treatment x subgroup interaction.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
End of table

Table 1.2.1 / 176: Time to all-cause hospitalization (months): Kaplan-Meier summary, unstratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	1846 (46.4%)	1914 (48.1%)
Number (%) of subjects censored	2135 (53.6%)	2068 (51.9%)
Median Time to event (month) [95 % CI]	40.533 [38.500;42.700]	37.467 [34.933;39.267]
Hazard ratio from unstratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.90; 1.02]	
two-sided p-value from unstratified logrank test	0.1603	

Hazard ratio from unstratified cox proportional hazard model including treatment as factor.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
End of table

Table 1.2.1 / 177: Time to all-cause hospitalization (months) for on-treatment FAS: Kaplan-Meier summary, stratified logrank test and Hazard Ratio (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistics	BAY 94-8862	Placebo
N	3981 (100.0%)	3982 (100.0%)
Number (%) of subjects with event	1639 (41.2%)	1726 (43.3%)
Number (%) of subjects censored	2342 (58.8%)	2256 (56.7%)
Median Time to event (month) [95 % CI]	41.600 [39.300;44.367]	38.367 [35.967;40.700]
Hazard ratio from stratified Cox proportional hazards model (BAY 94-8862/Placebo) [95 % CI]	0.95 [0.89; 1.02]	
two-sided p-value from stratified logrank test	0.1707	

Hazard ratio from stratified cox proportional hazard model including treatment as factor.
Stratification factors: Region / eGFR category at screening / type of albuminuria at screening / history of CV disease
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_ipd_s1.sas 06FEB2023 17:18
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Table 1.2.1 / 178: Time to all-cause hospitalization (months): Rate Ratio from stratified Andersen-Gill model with robust estimation of standard errors (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Statistic	Value
Rate ratio from stratified Andersen-Gill model with robust estimation of standard errors (BAY 94-8862/Placebo) [95 % CI]	0.96 [0.84; 1.09]
two-sided p-value from stratified Andersen-Gill model with robust estimation of standard errors	0.5384

Andersen-Gill model accounting for recurrent events.
If multiple events occured on the same day, only a single event is counted for the analysis.
Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/t_adtte_cox_prophaz_sens3_s.sas 06FEB2023 17:44
End of table

Figure 1.2.1 / 1: Time to all-cause mortality (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

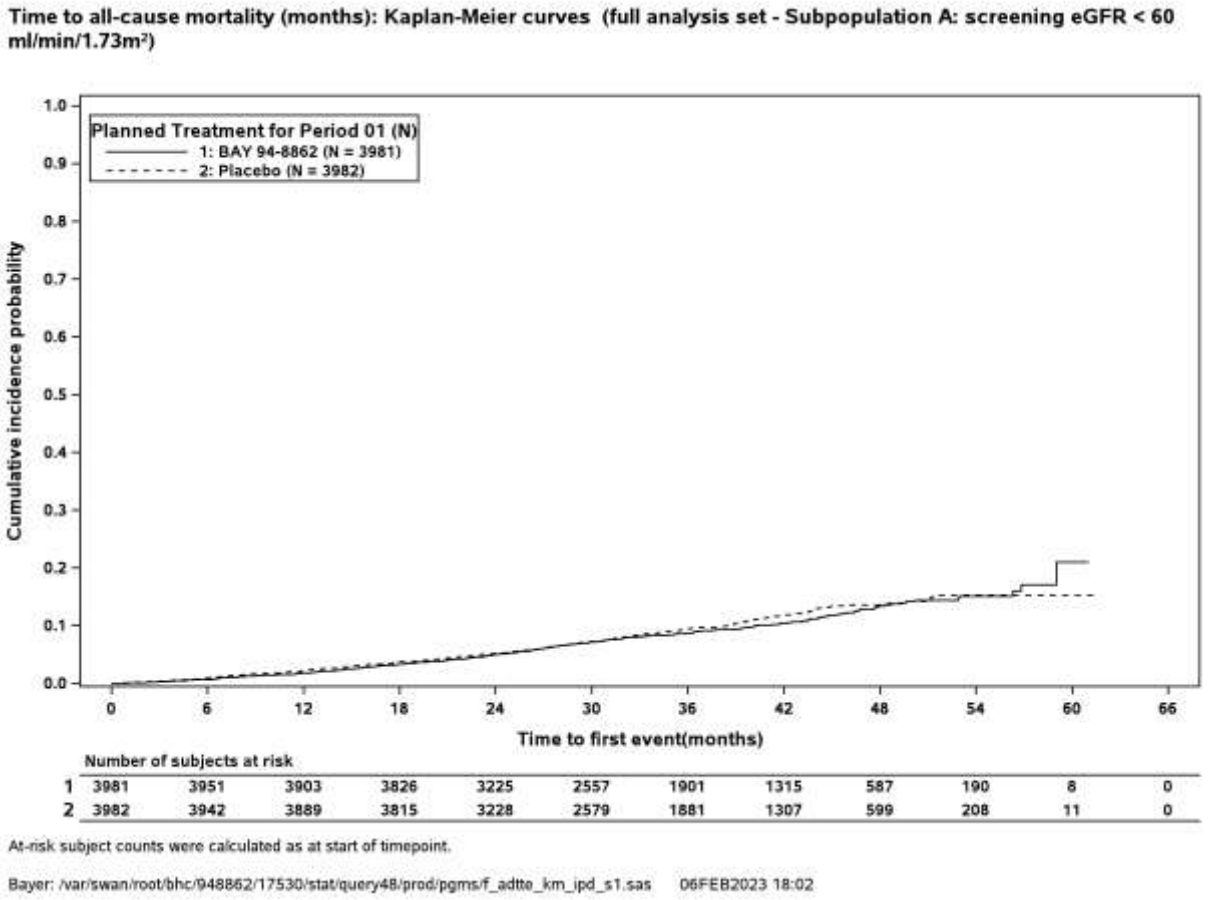


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

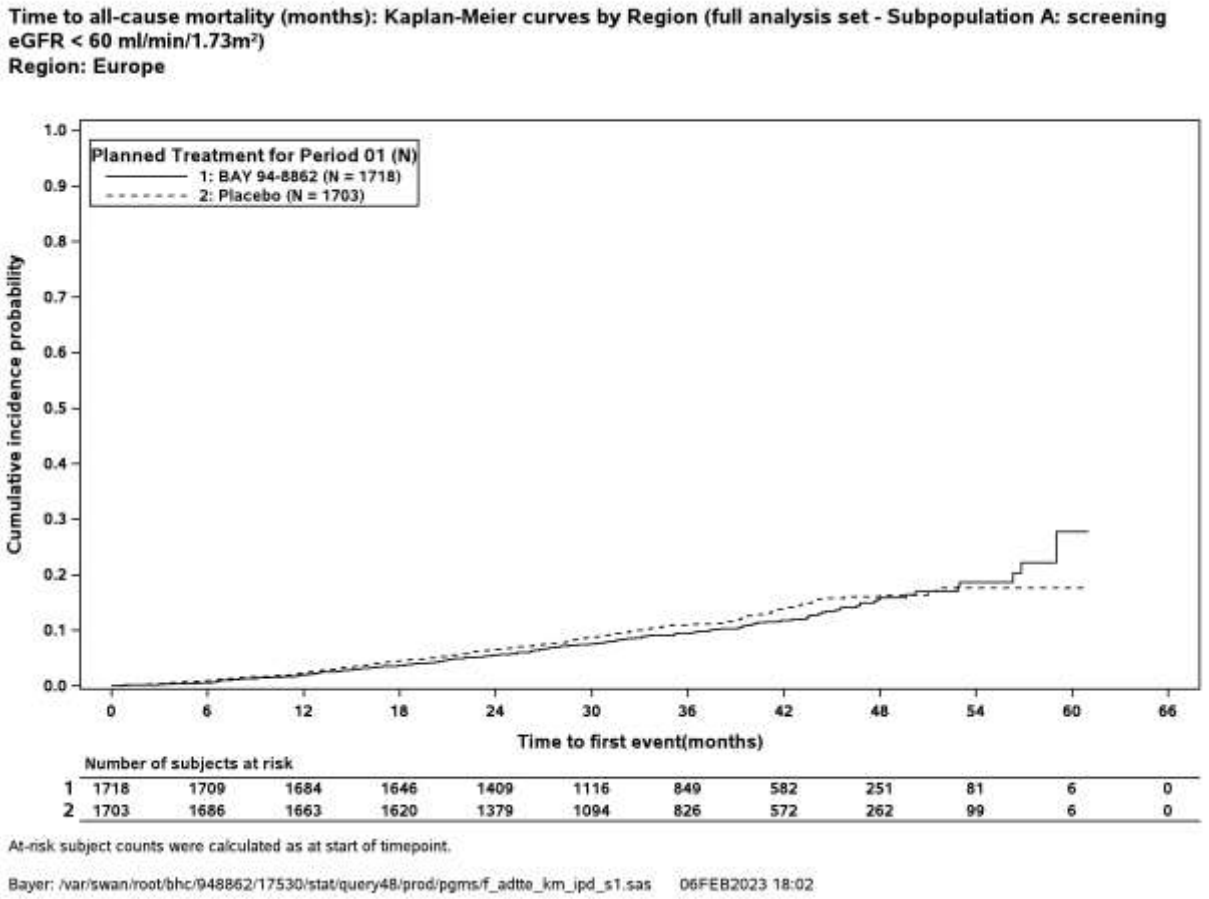


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

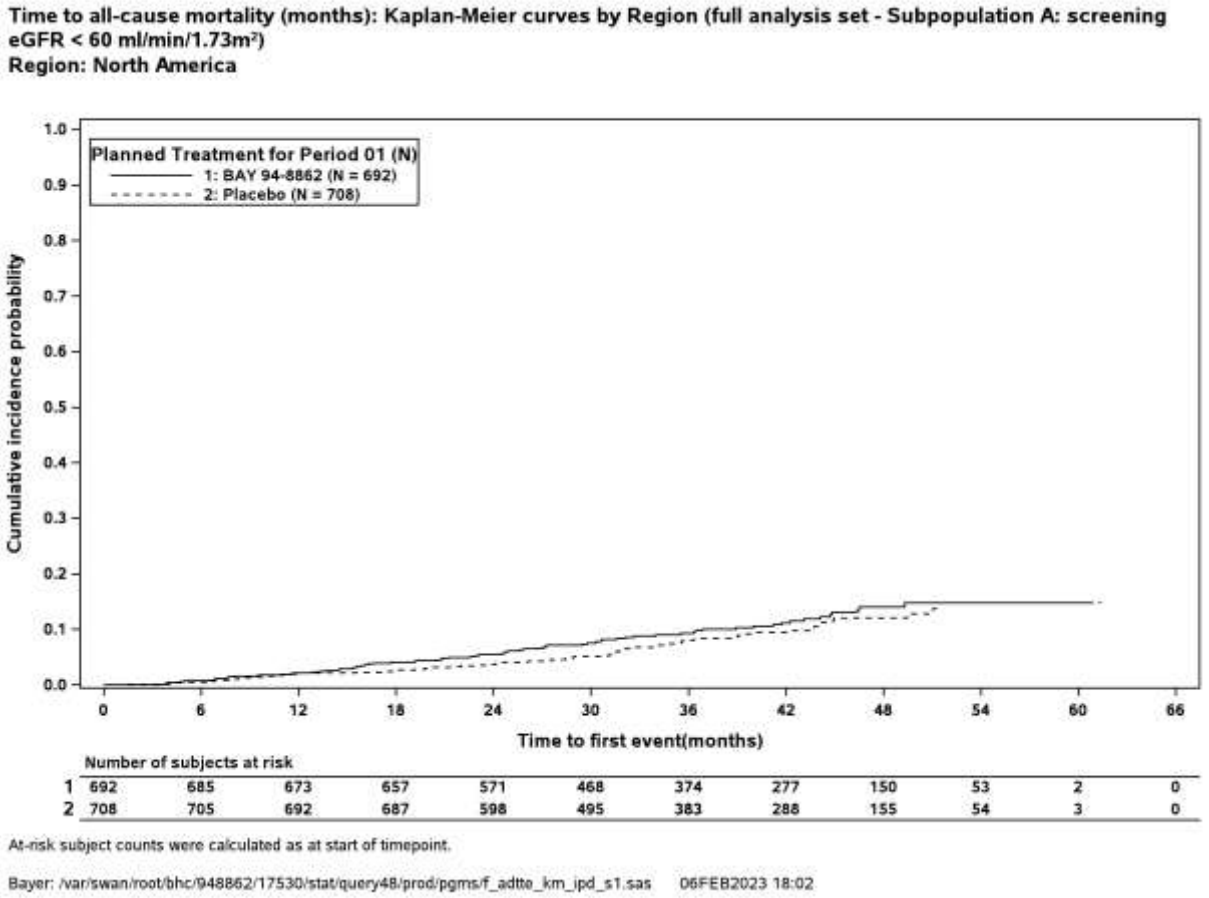


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

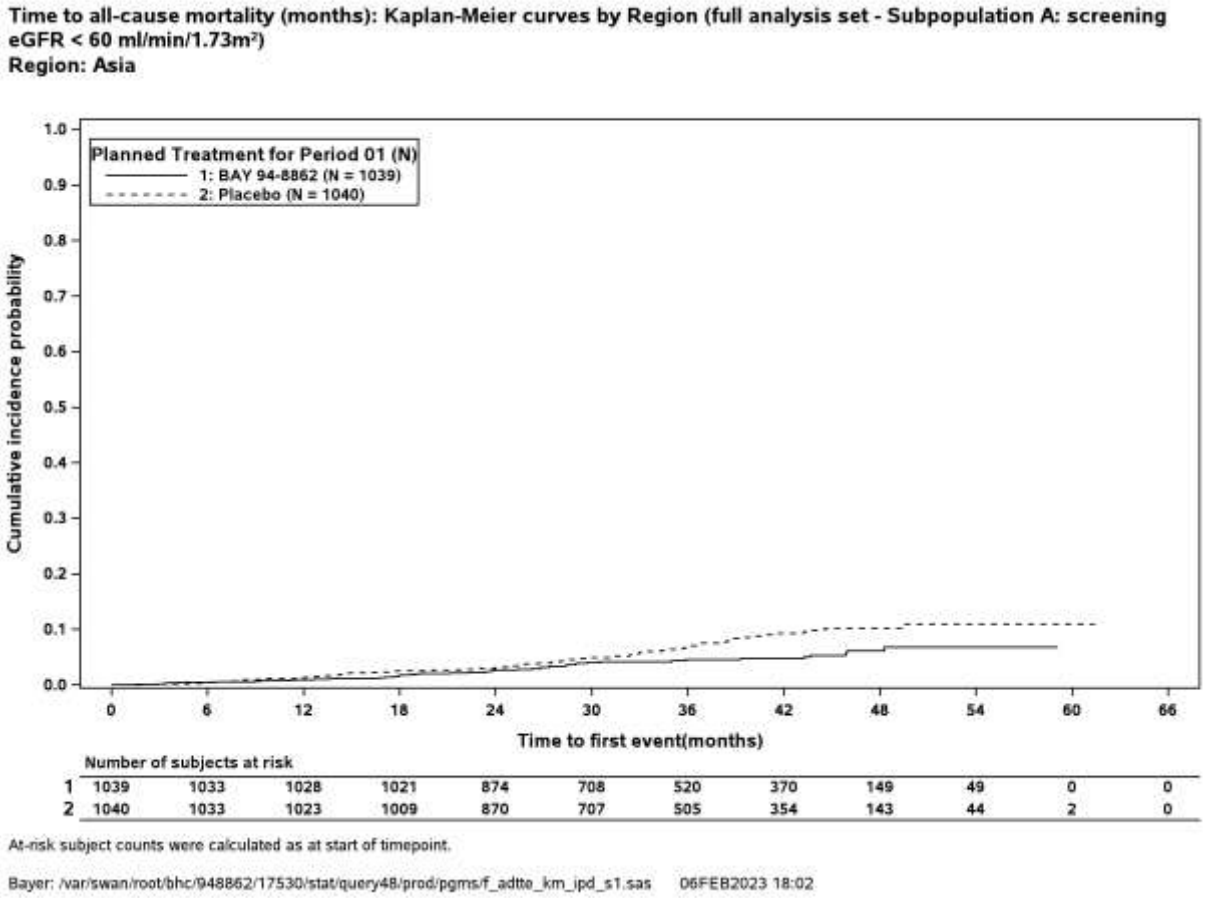


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

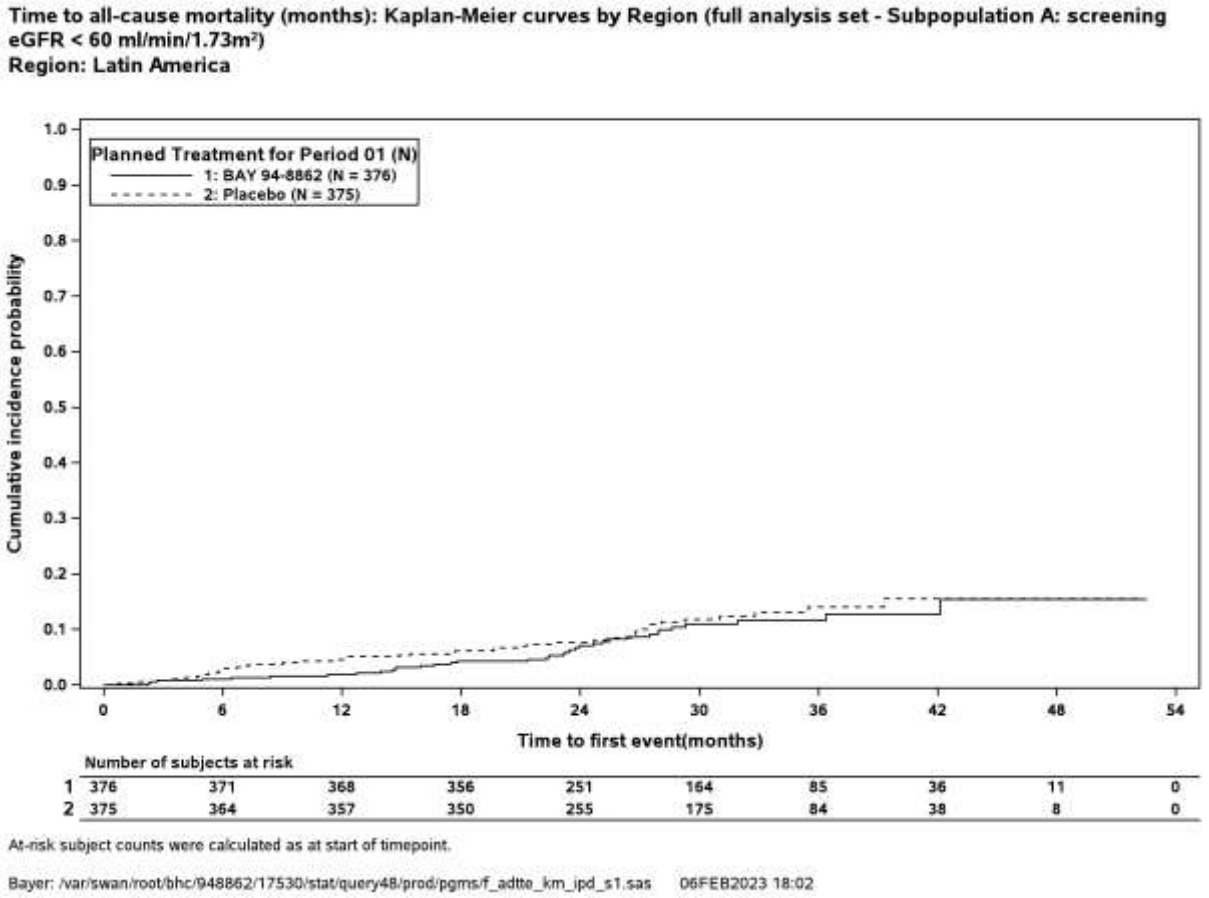


Figure 1.2.1 / 2: Time to all-cause mortality (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

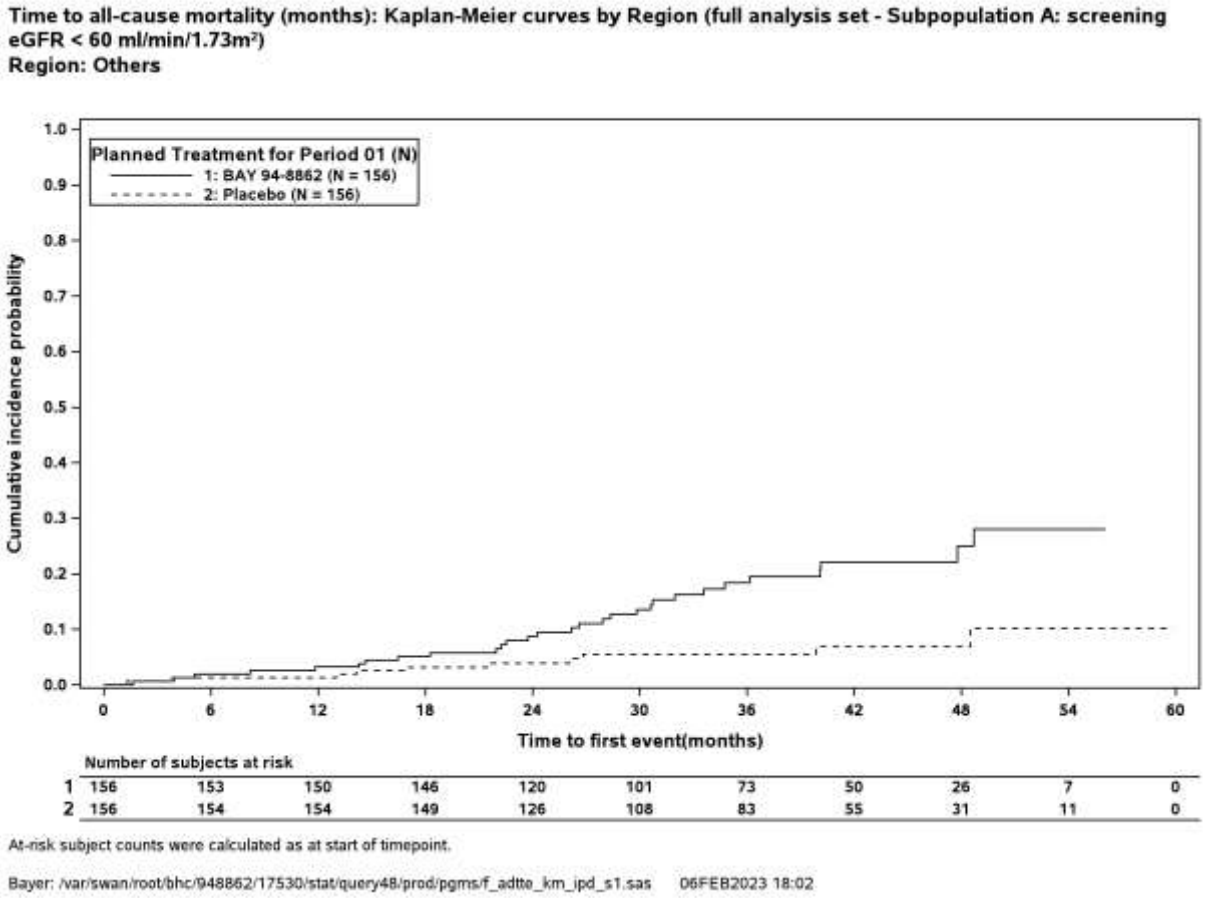


Figure 1.2.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

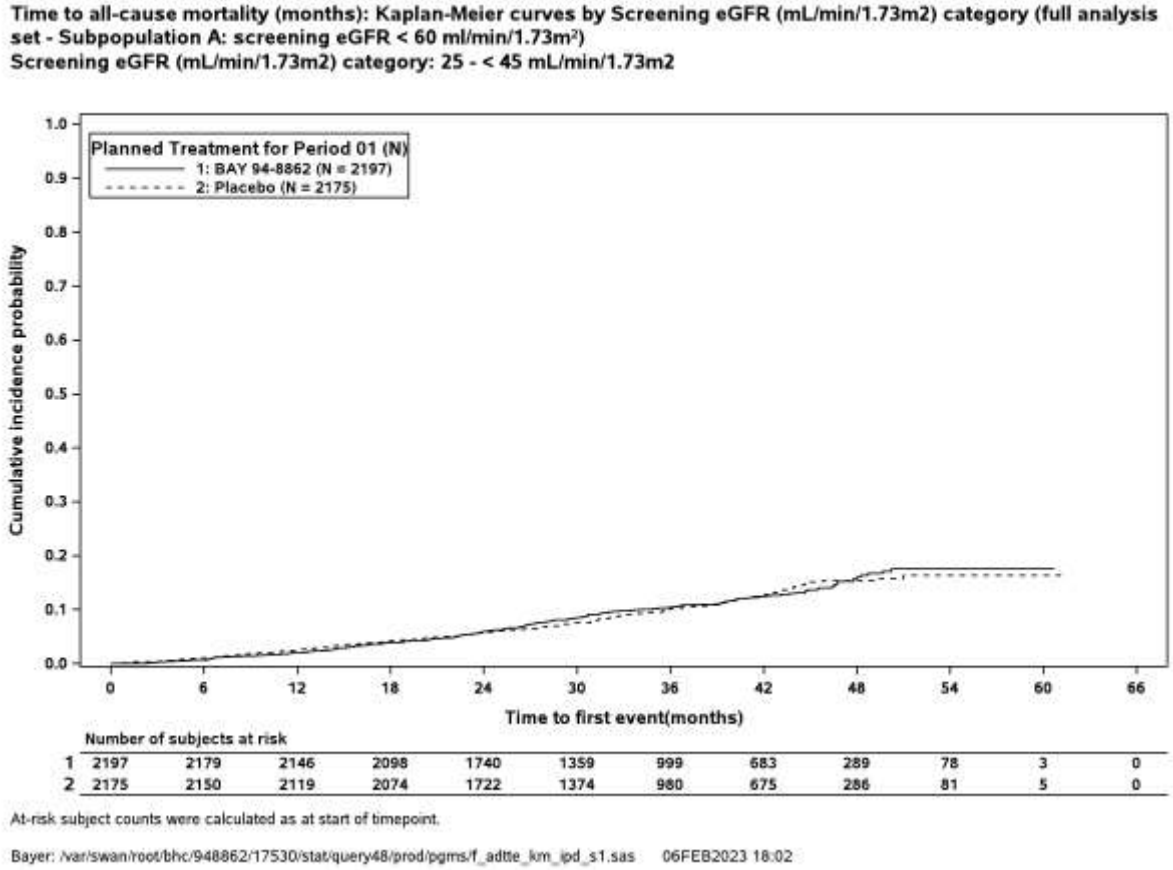


Figure 1.2.1 / 3: Time to all-cause mortality (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

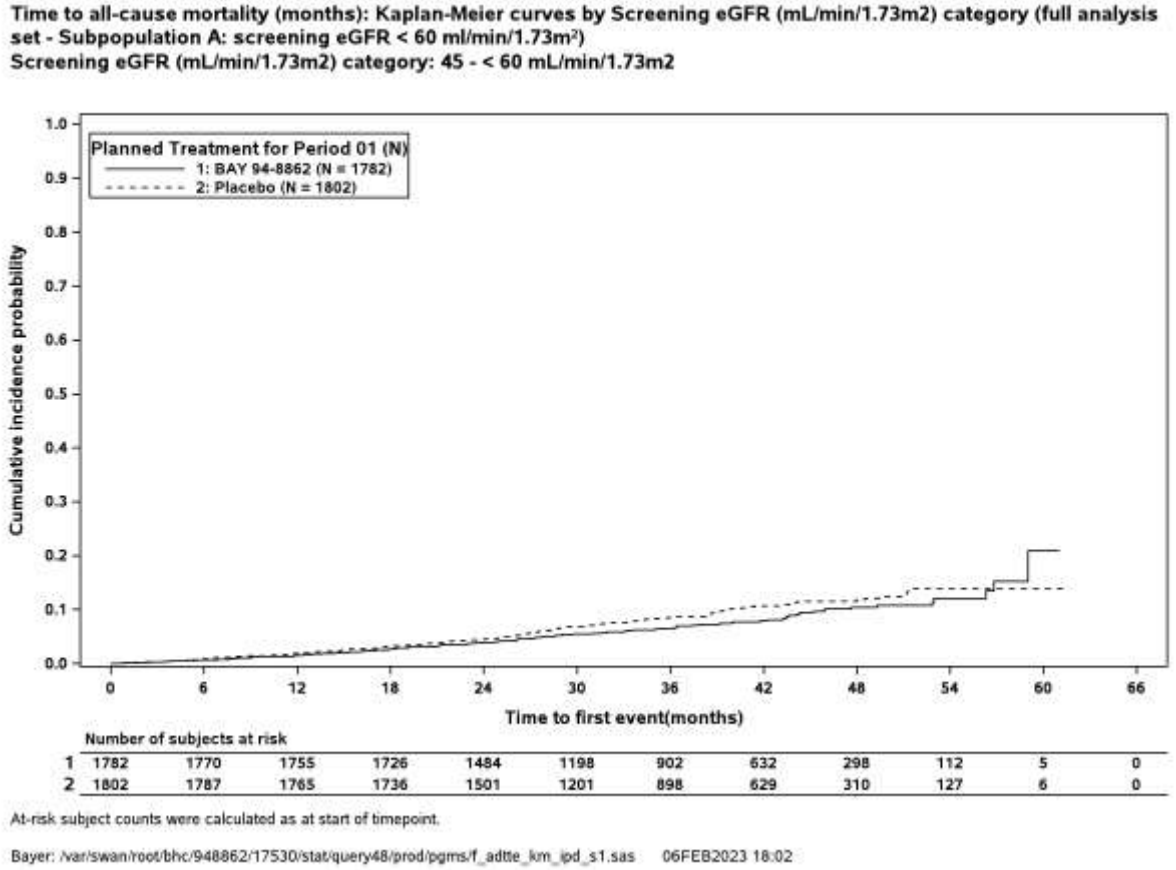


Figure 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

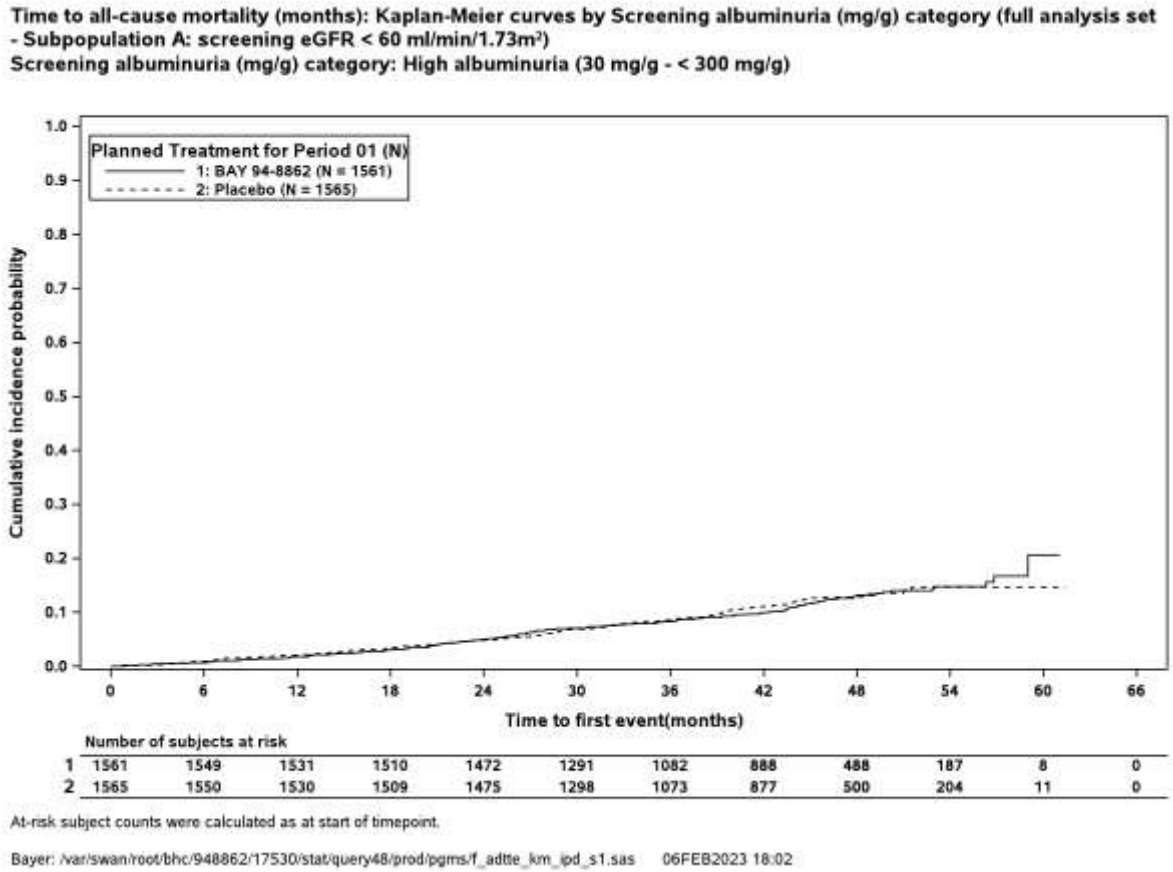


Figure 1.2.1 / 4: Time to all-cause mortality (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

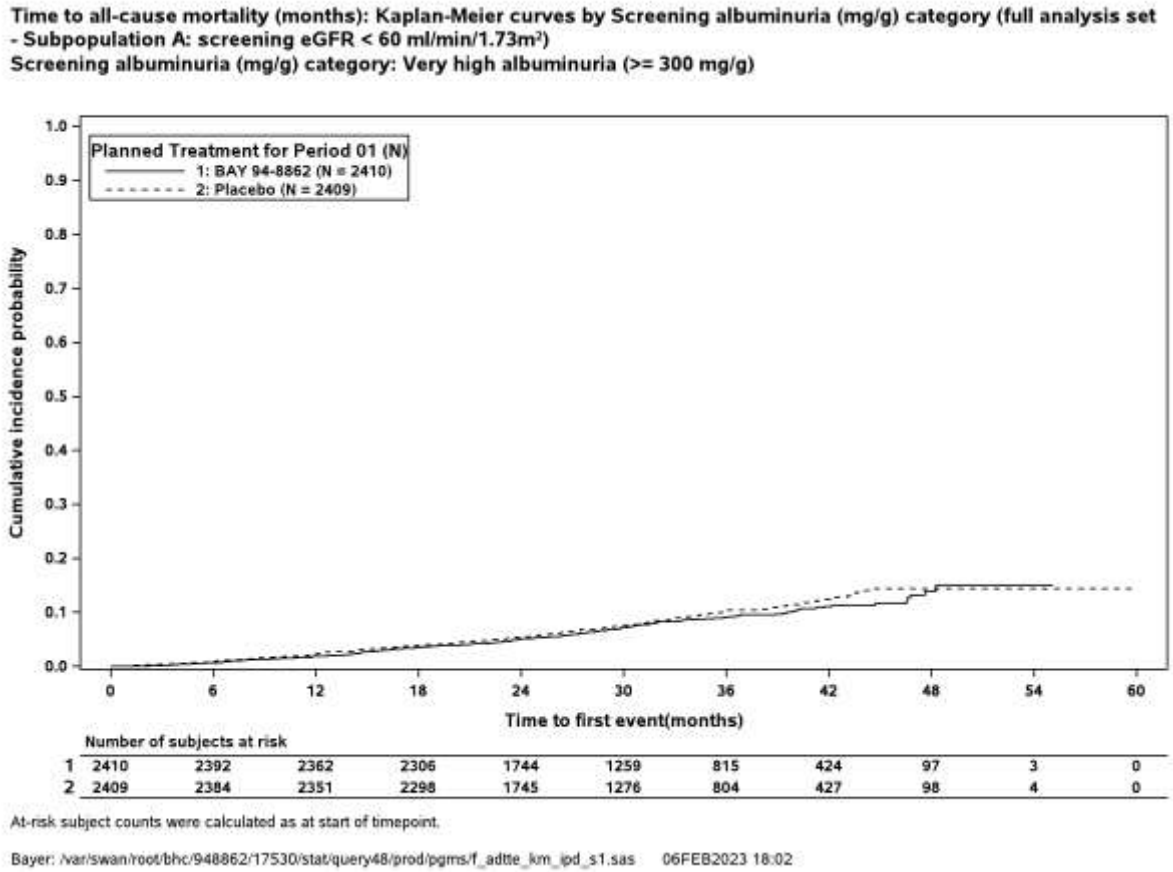


Figure 1.2.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

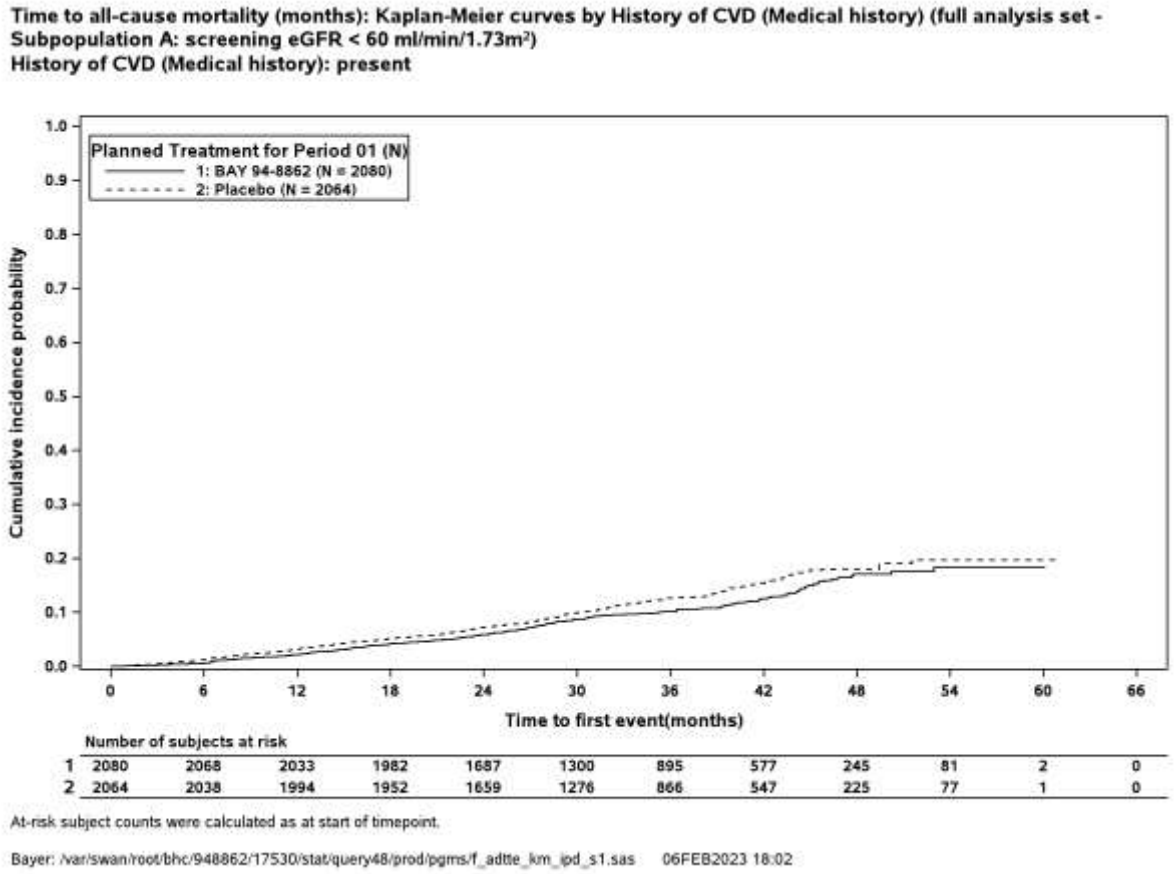


Figure 1.2.1 / 5: Time to all-cause mortality (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

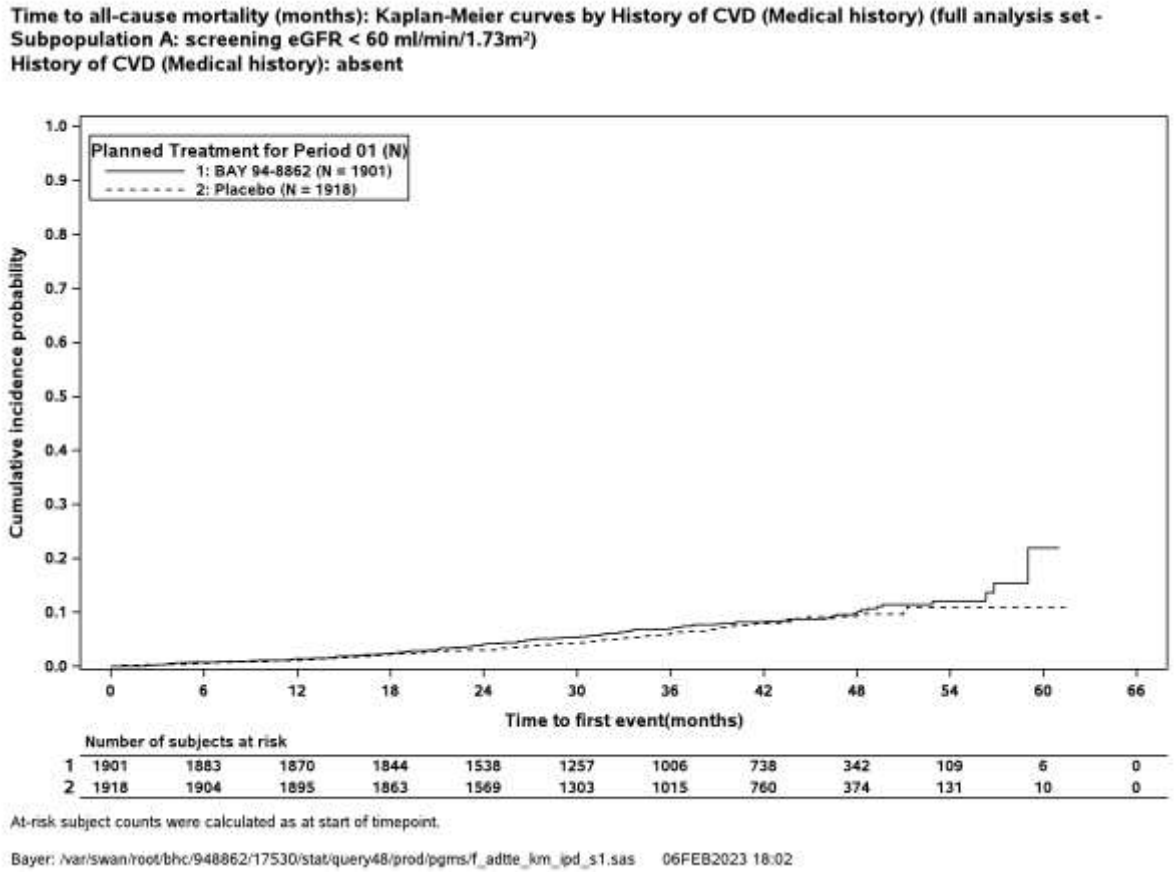


Figure 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

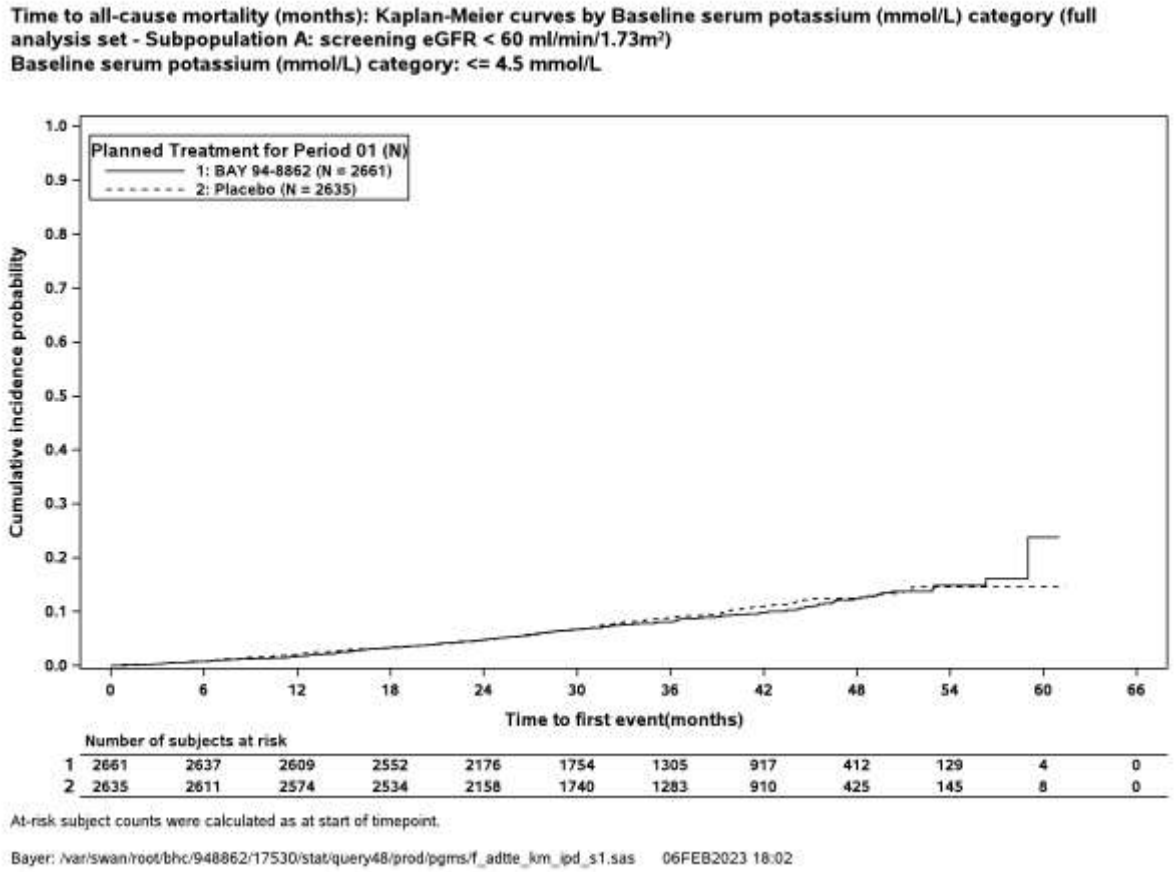


Figure 1.2.1 / 6: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

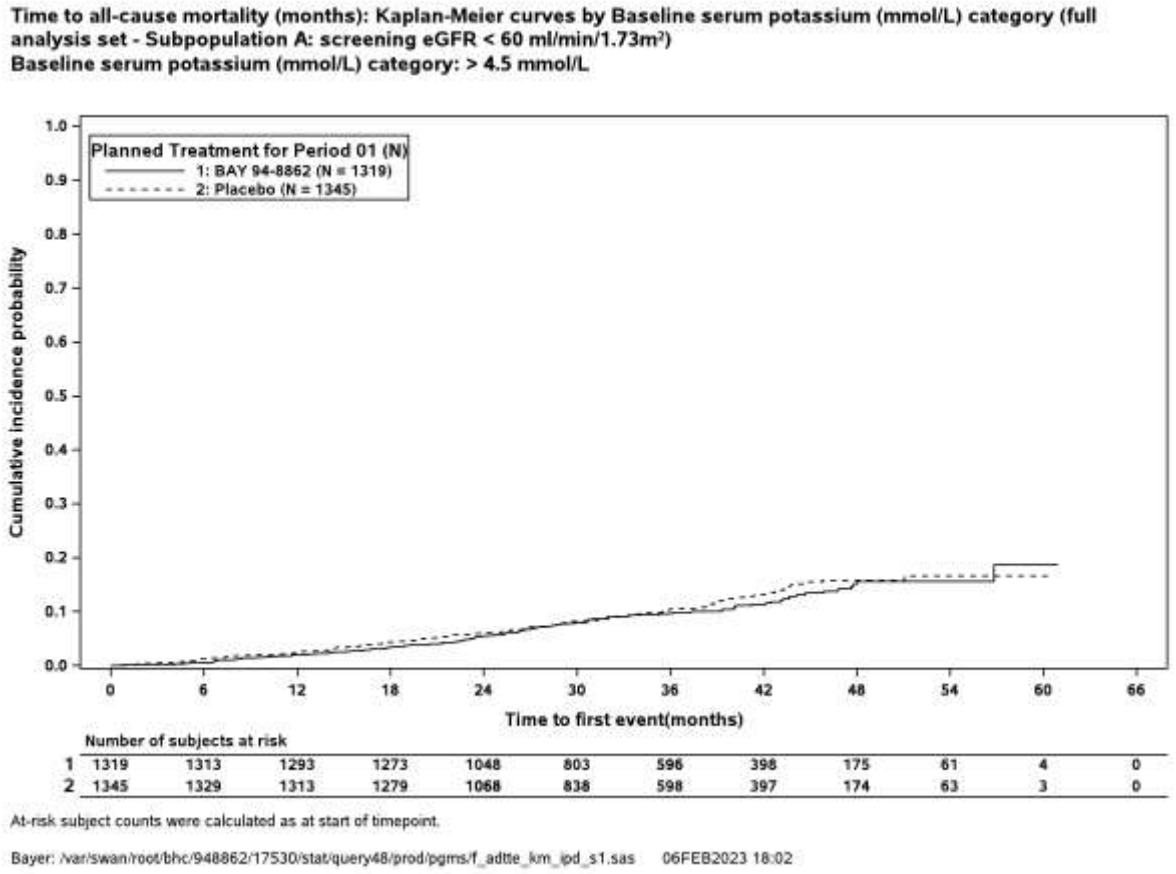


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

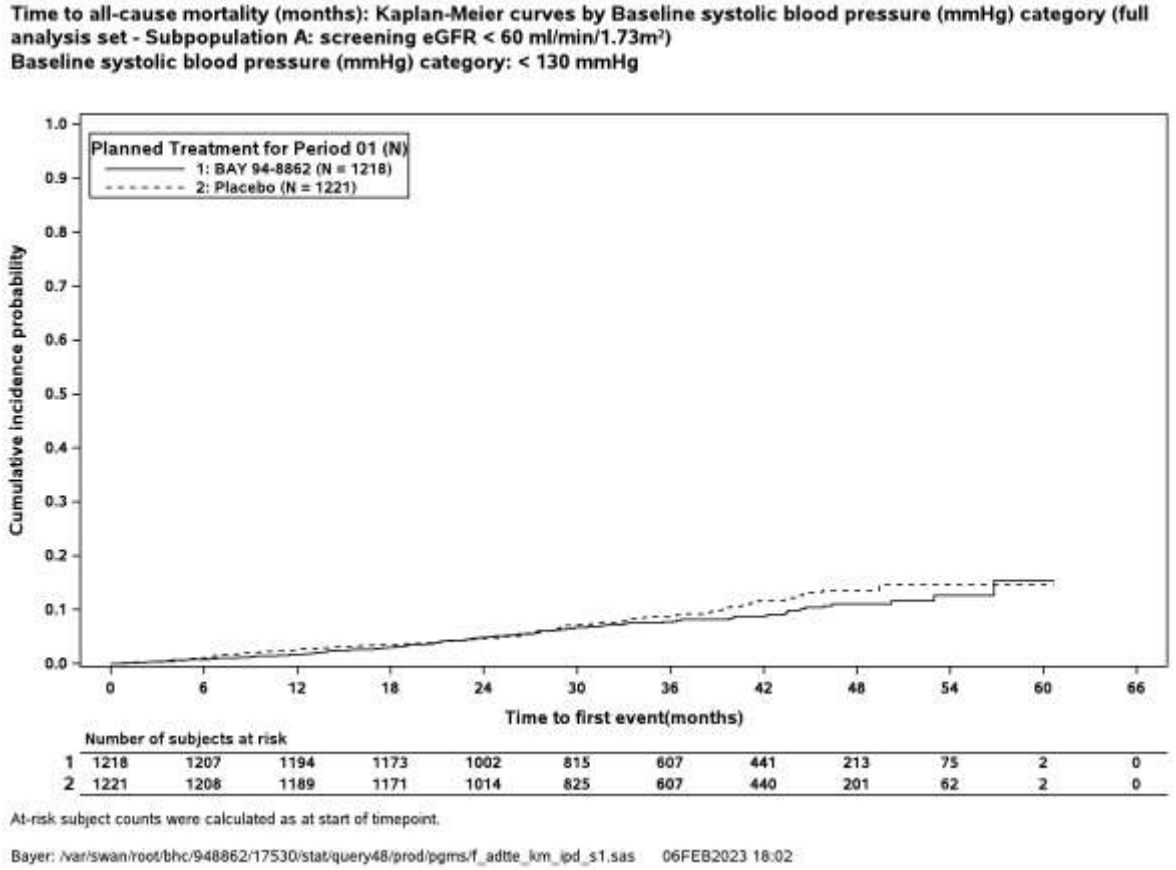


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

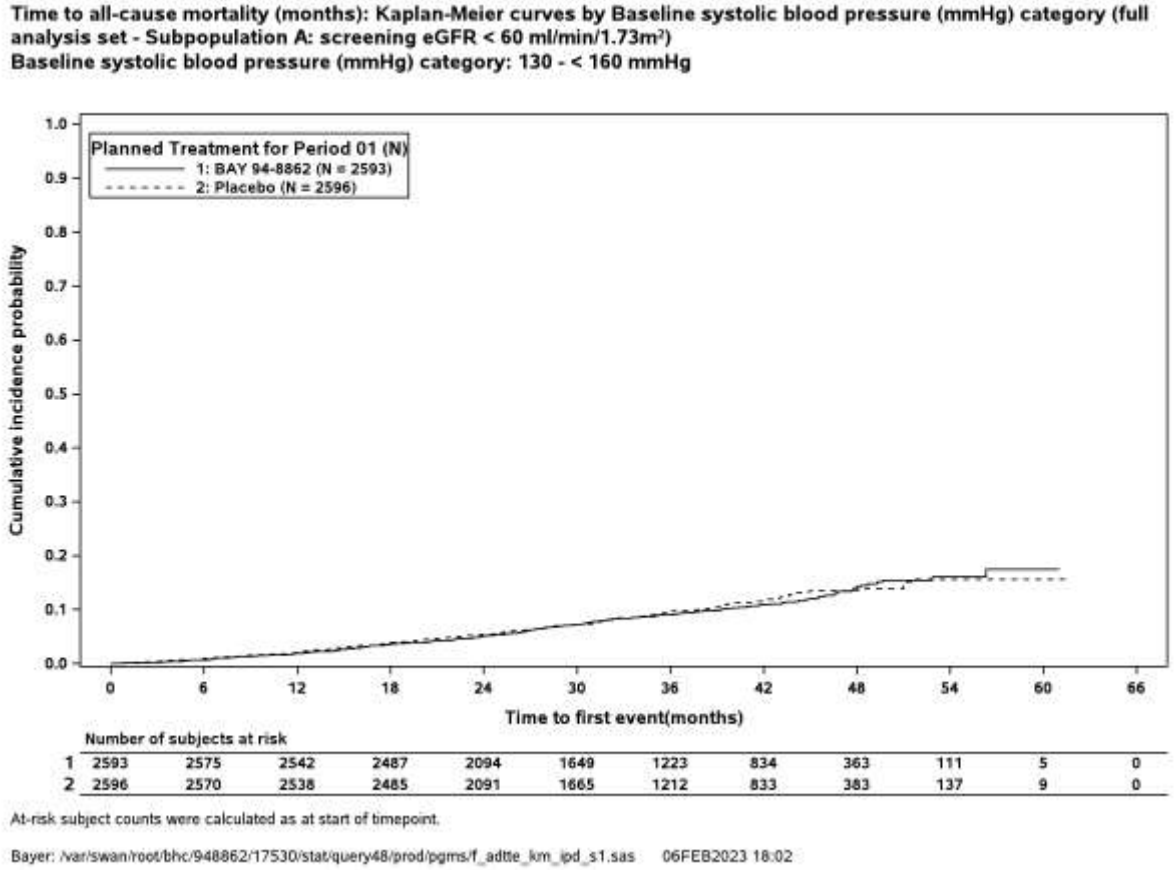


Figure 1.2.1 / 7: Time to all-cause mortality (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

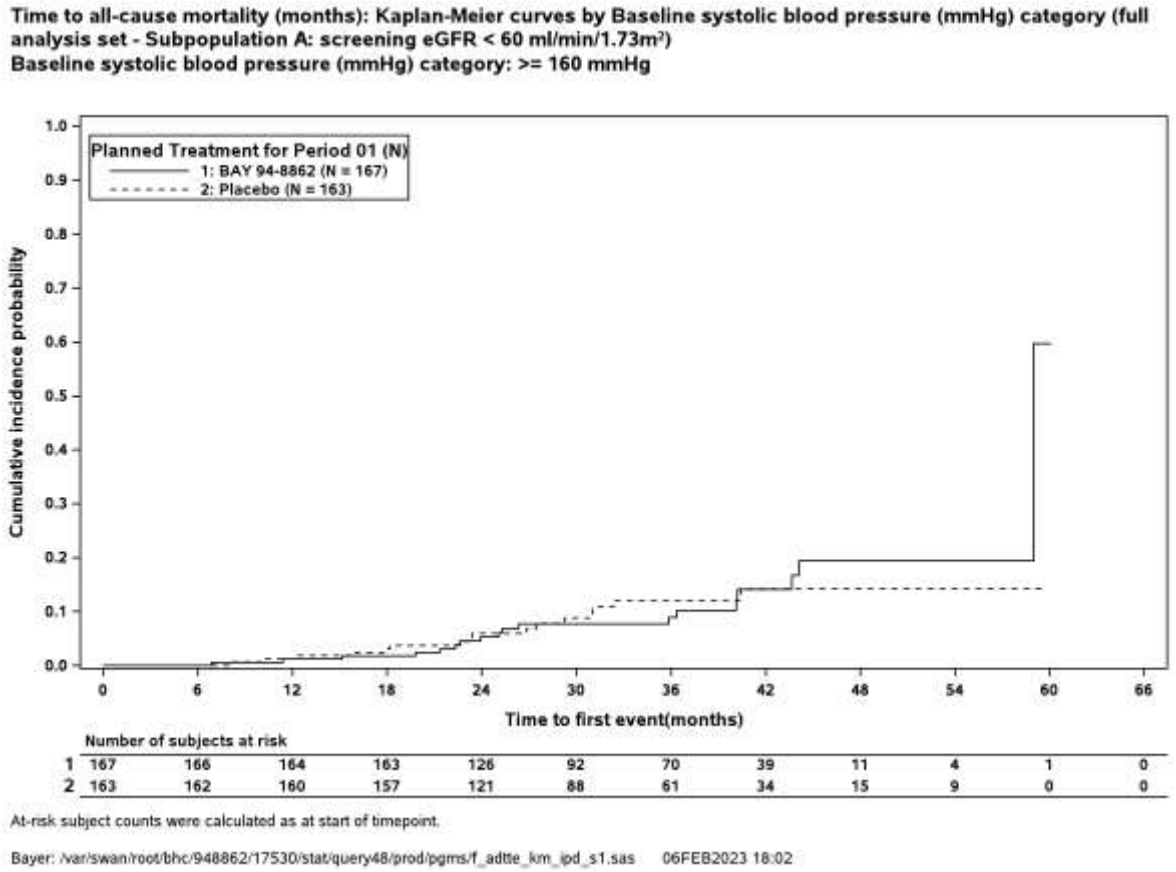


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

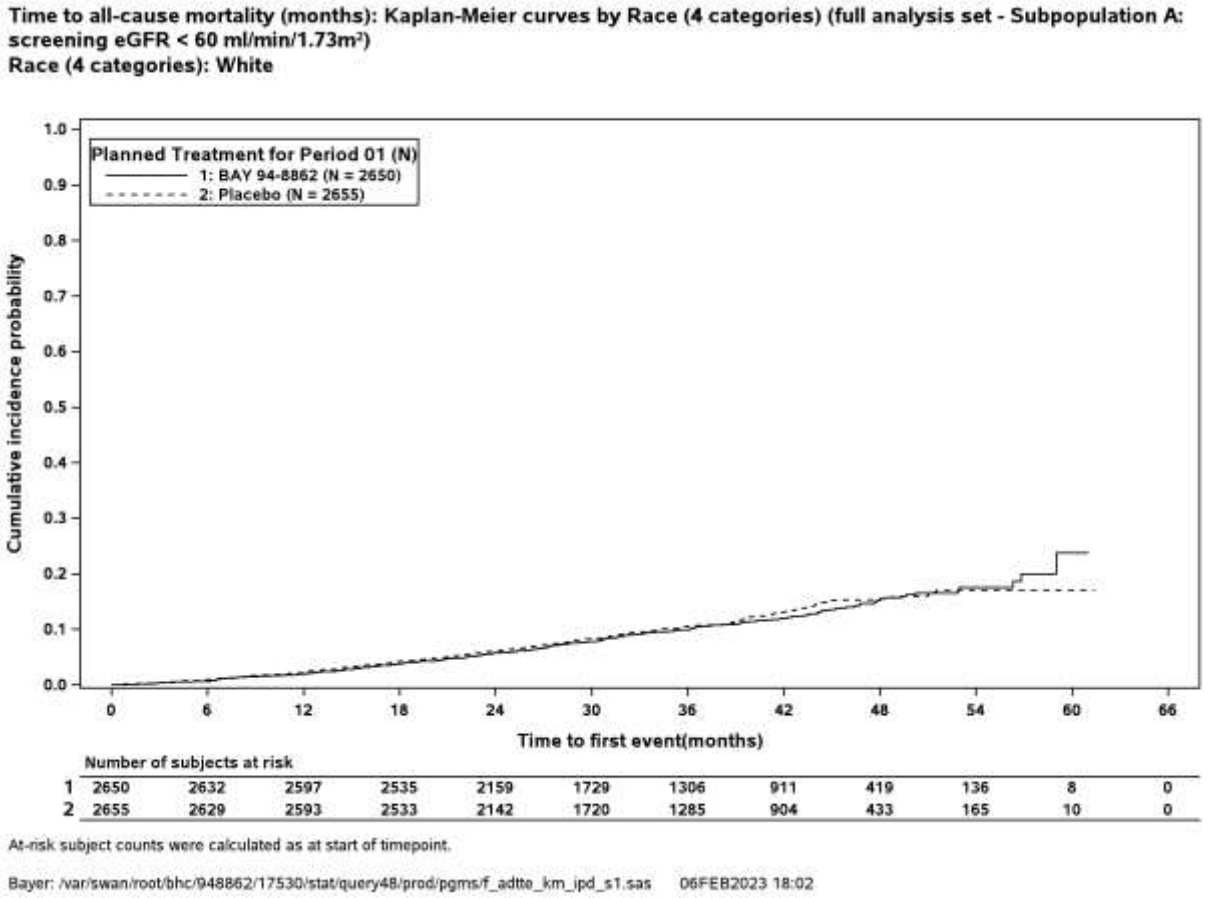


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

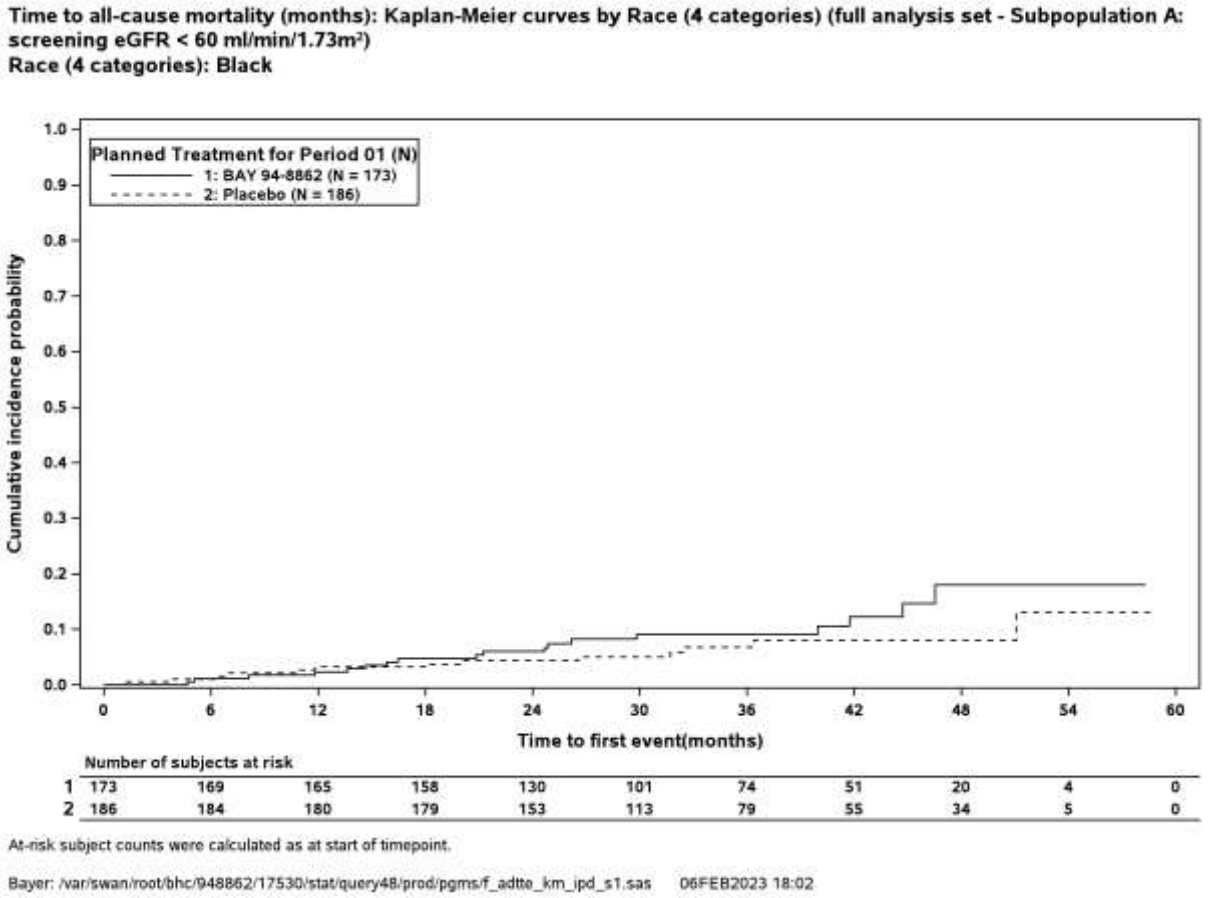


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

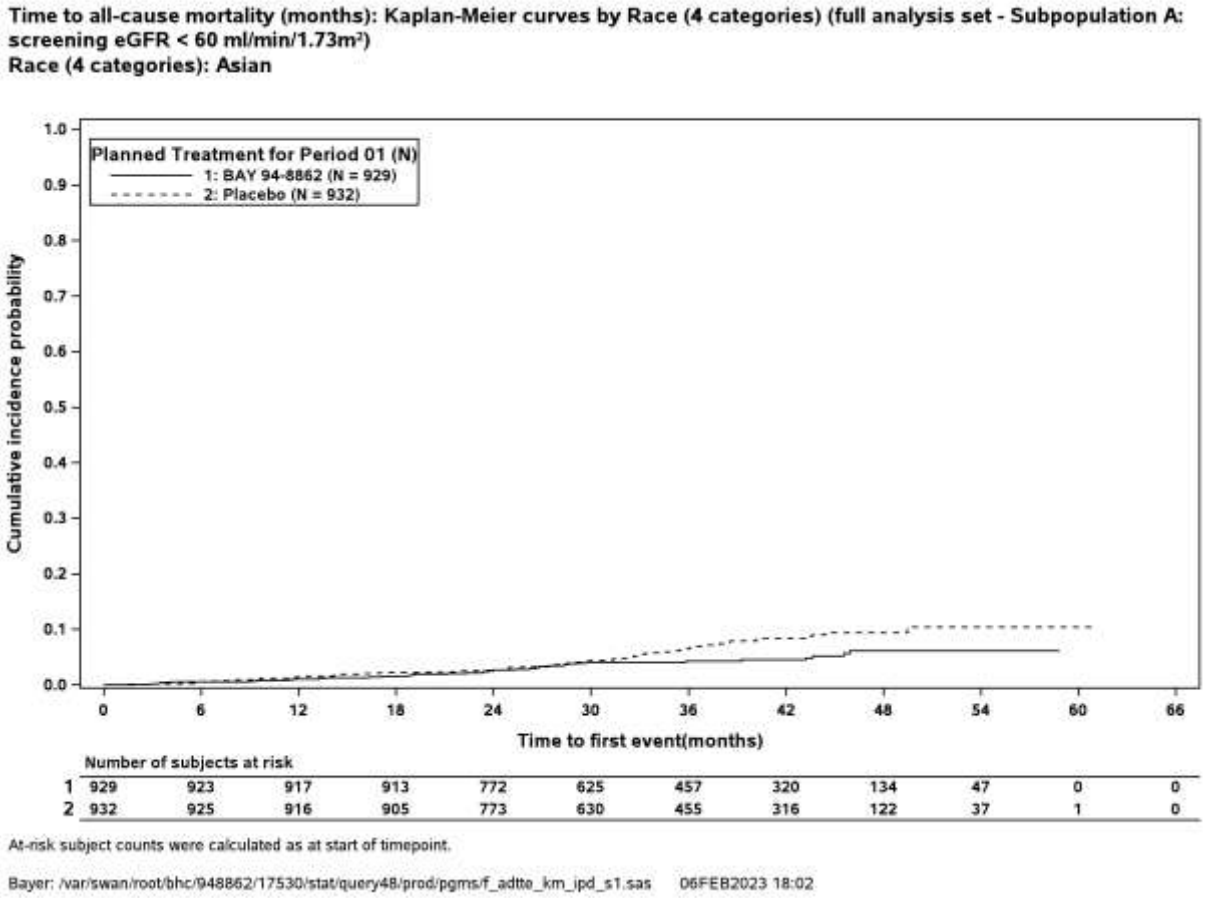


Figure 1.2.1 / 8: Time to all-cause mortality (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

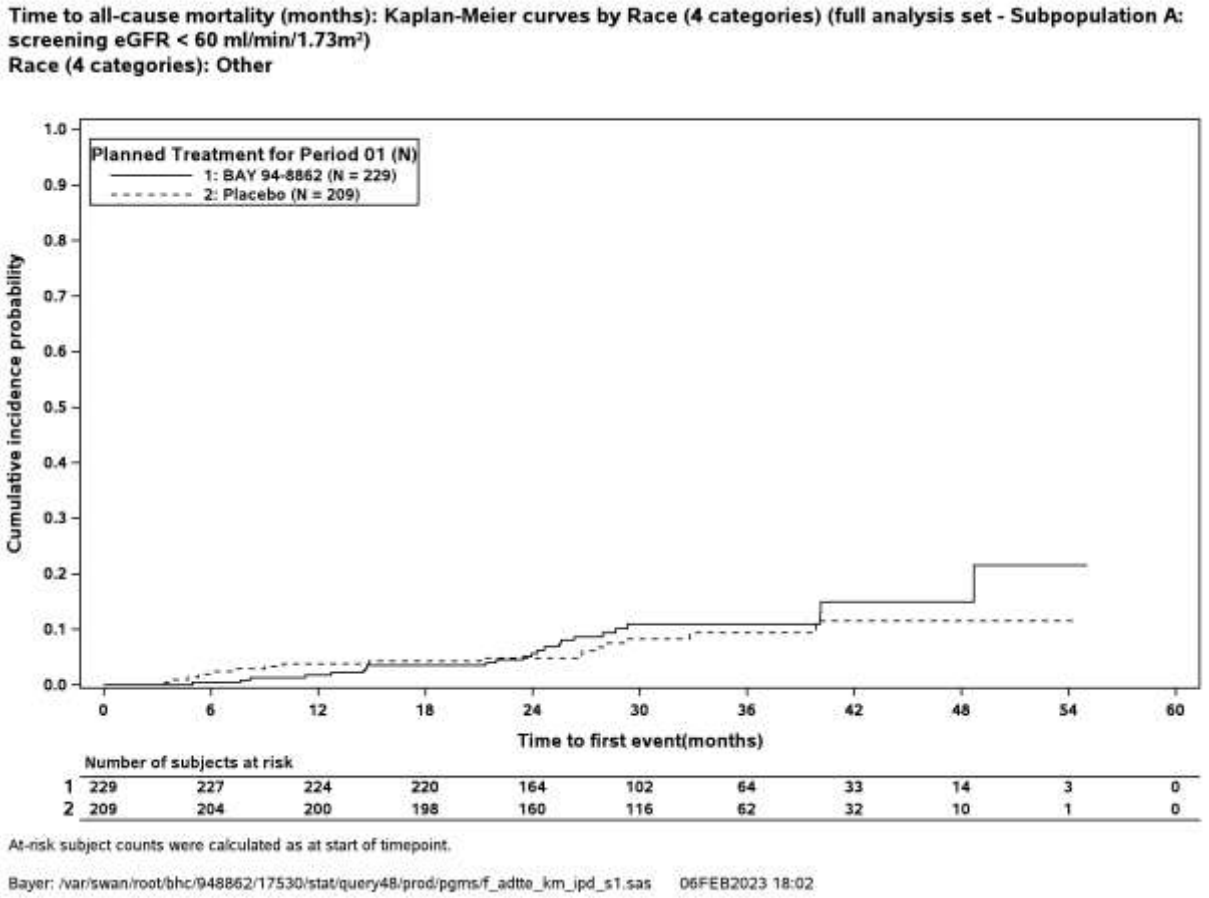


Figure 1.2.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

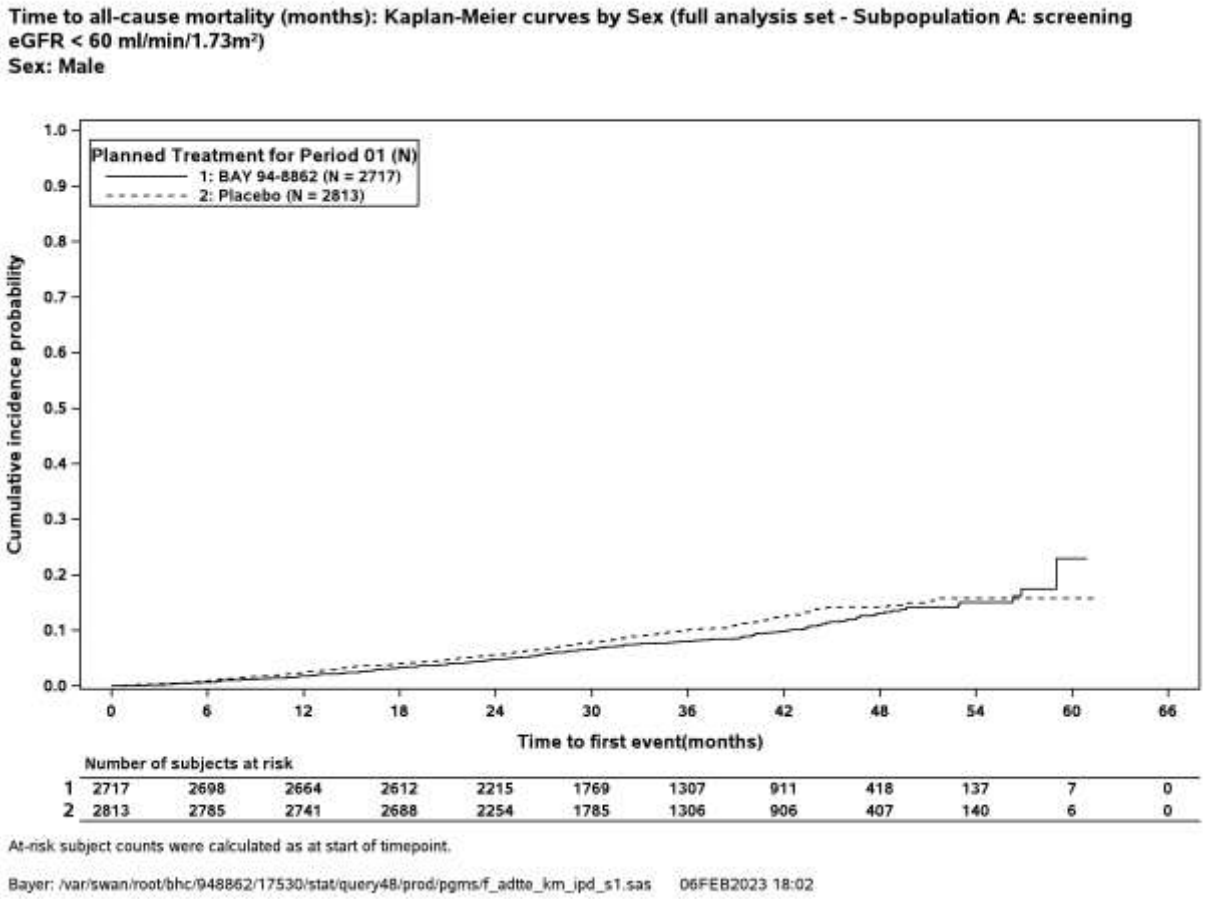


Figure 1.2.1 / 9: Time to all-cause mortality (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

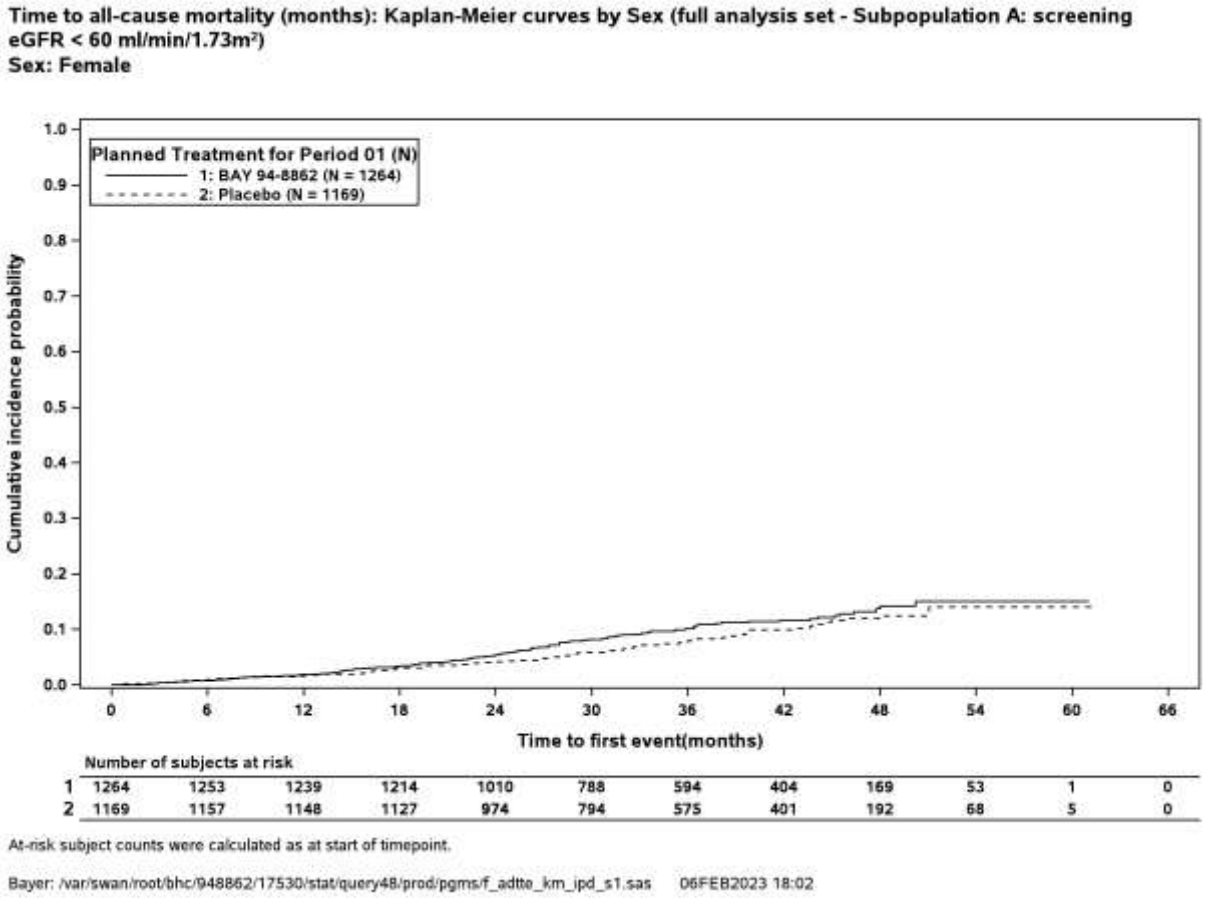


Figure 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

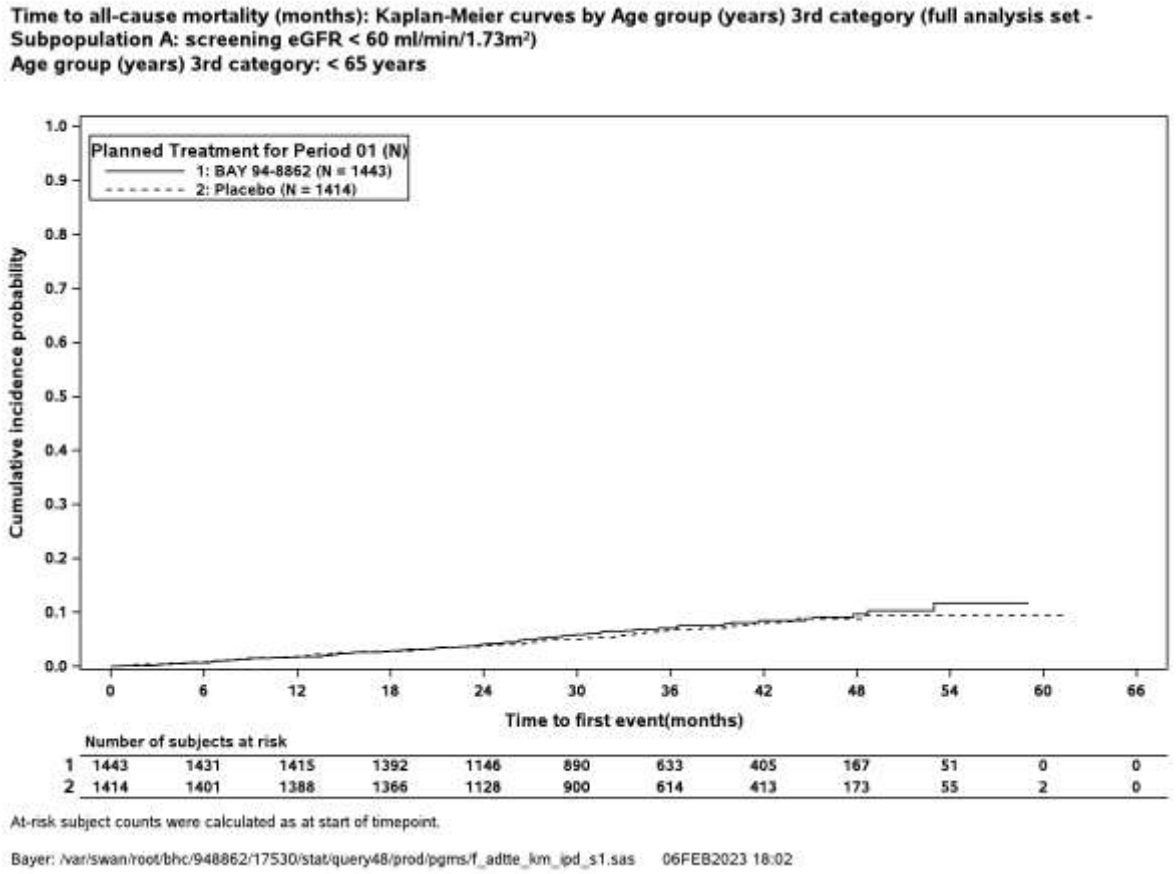


Figure 1.2.1 / 10: Time to all-cause mortality (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

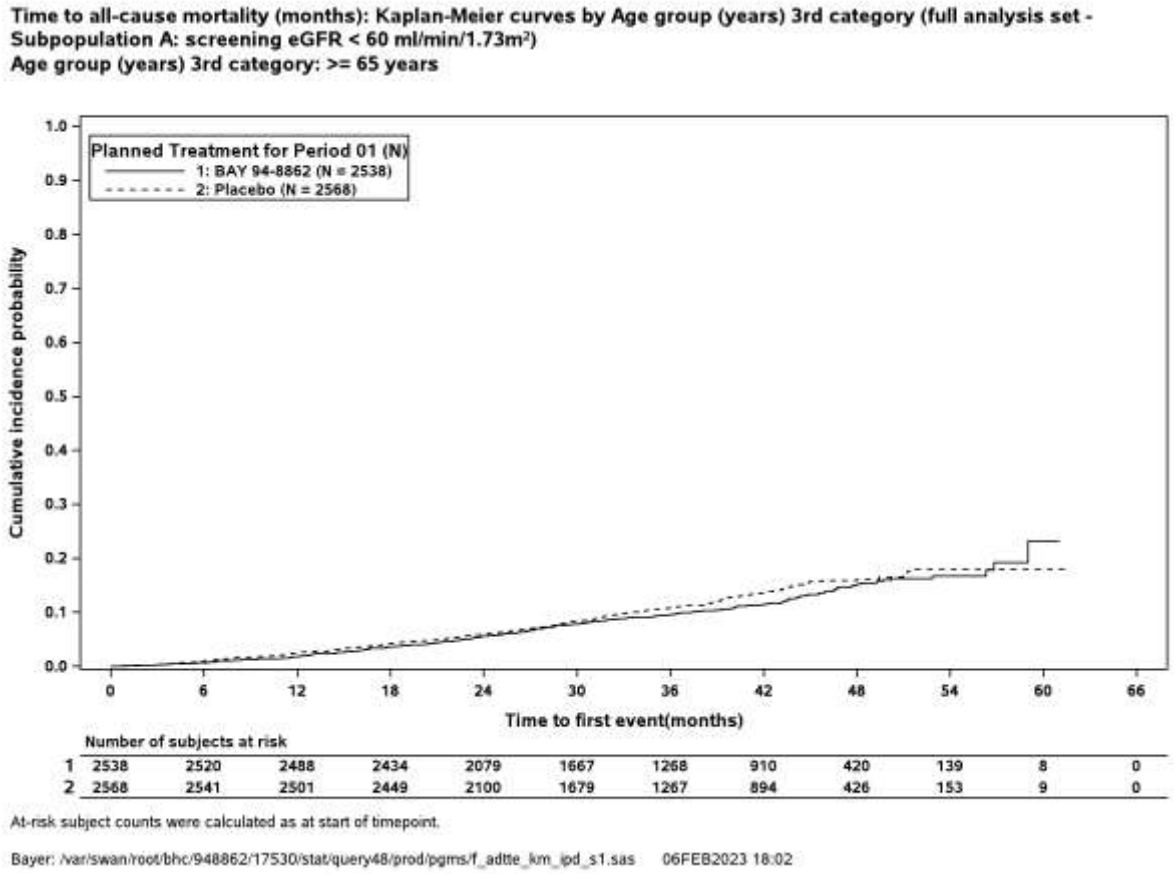


Figure 1.2.1 / 11: Time to onset of kidney failure, a sustained decrease of eGFR 40% or renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

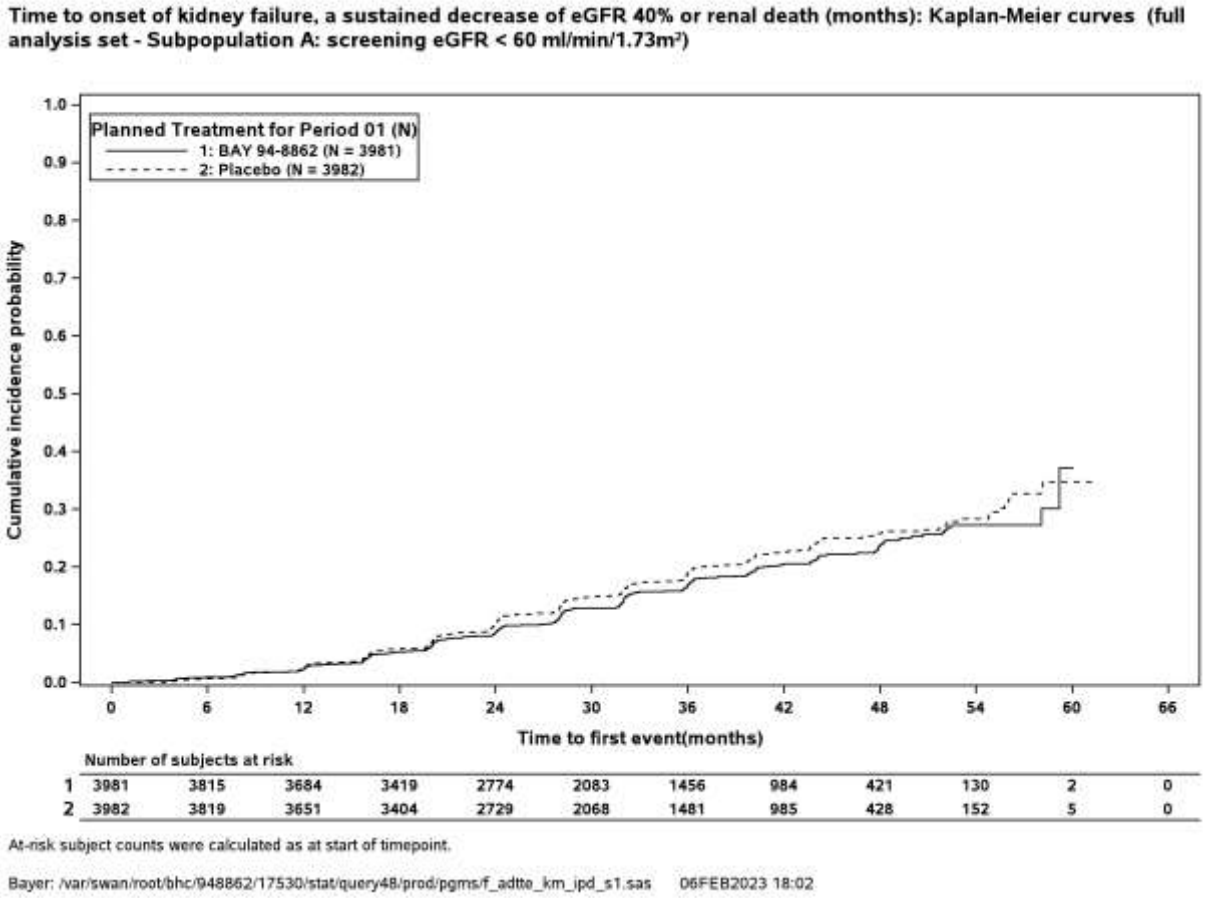


Figure 1.2.1 / 12: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

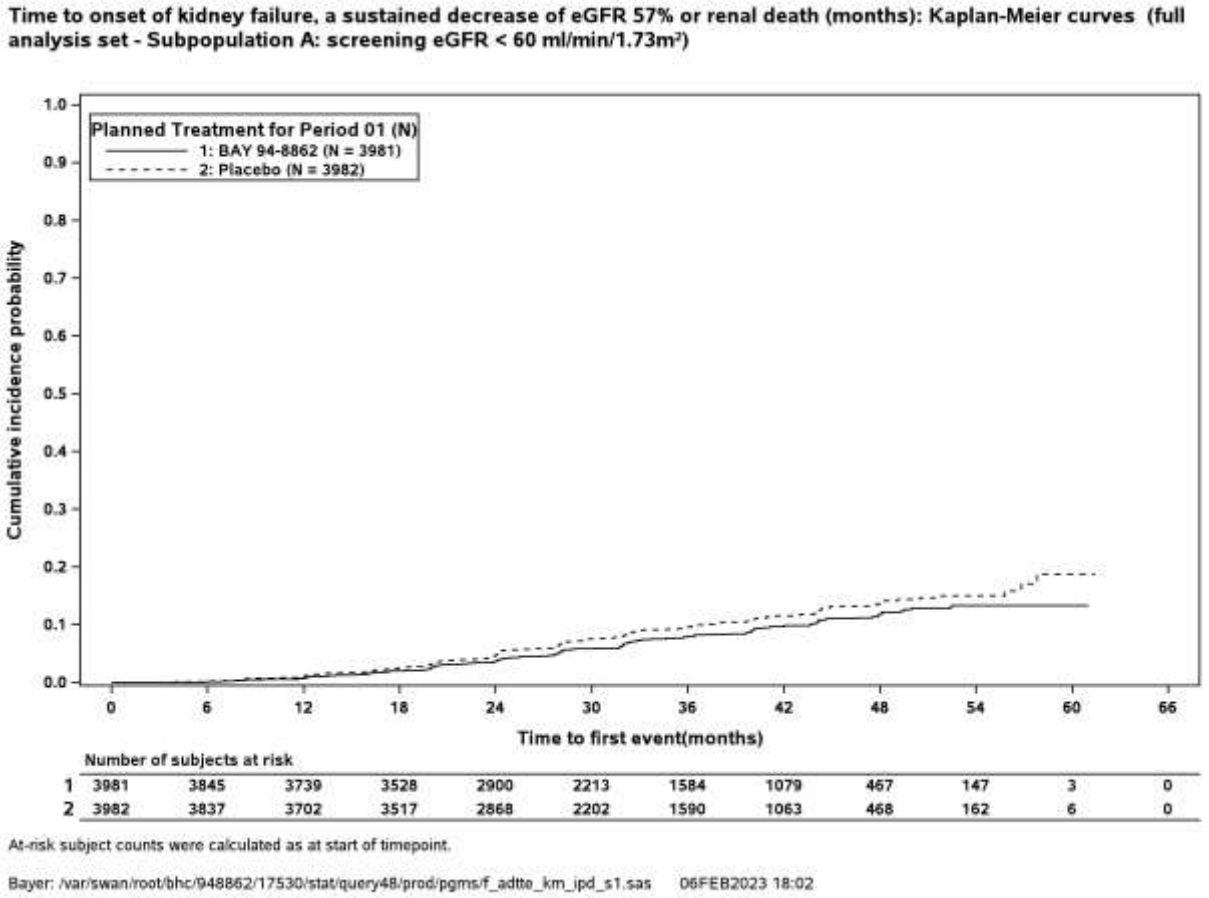


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

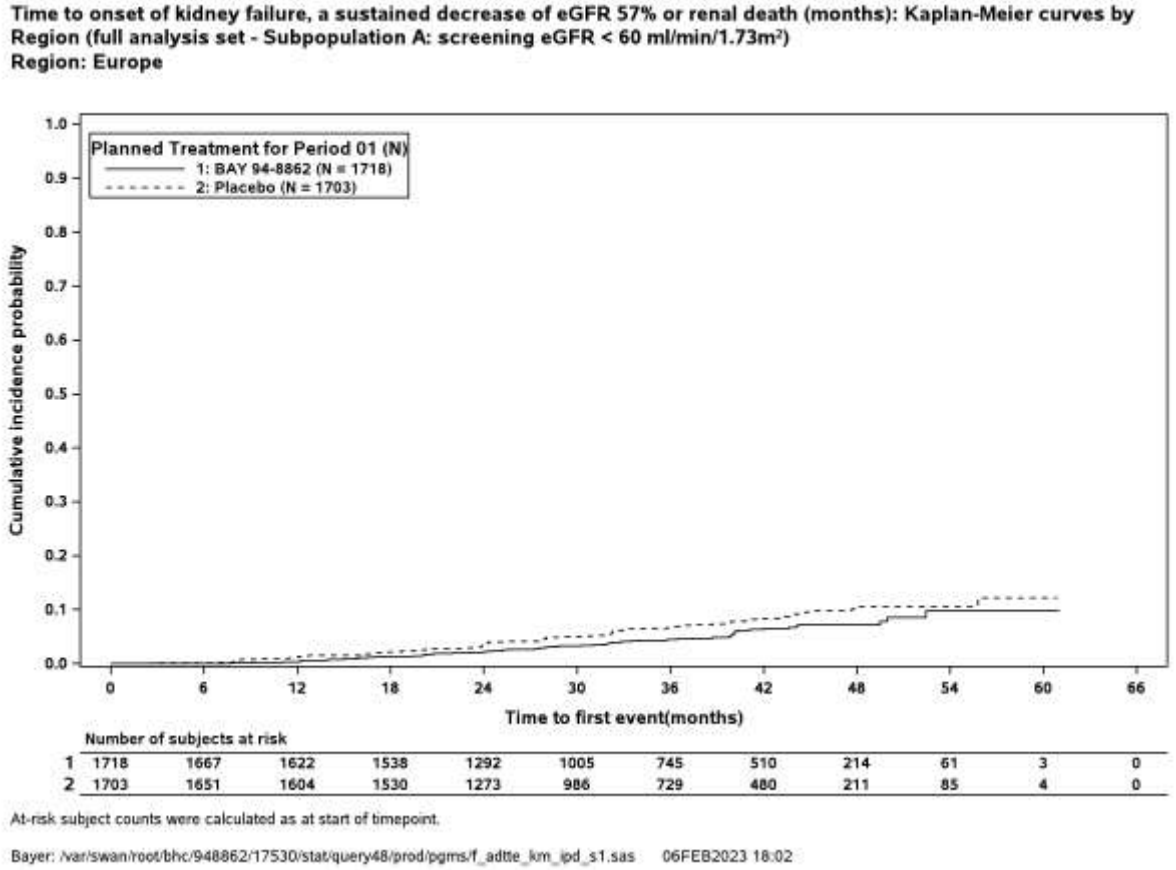


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

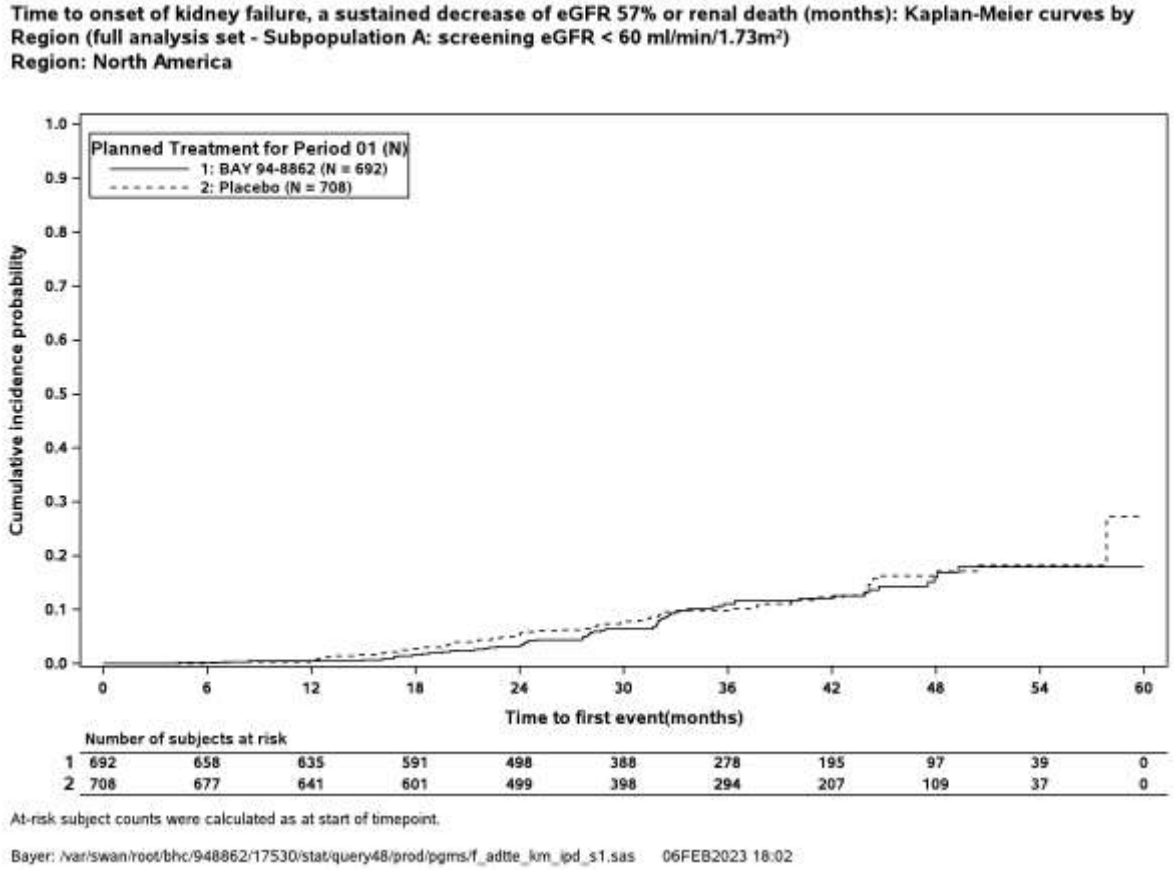


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

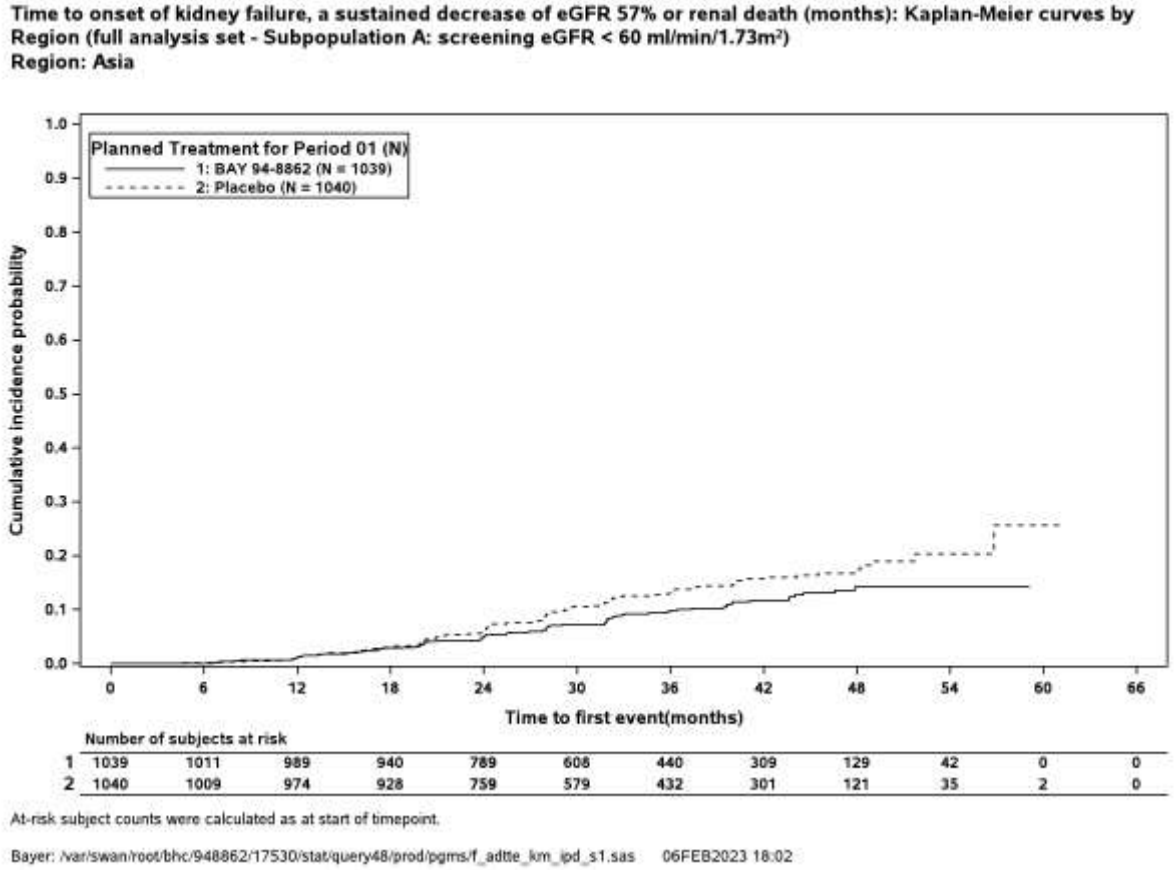


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

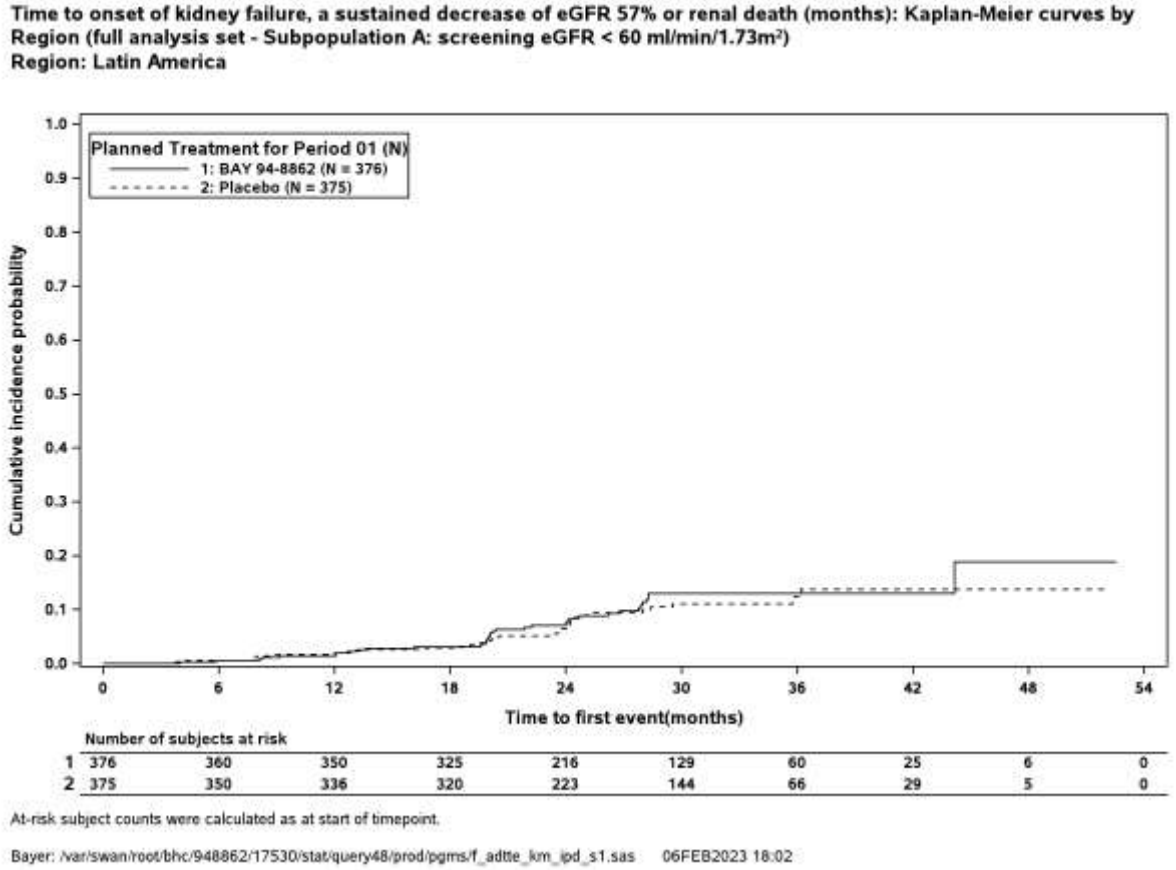


Figure 1.2.1 / 13: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

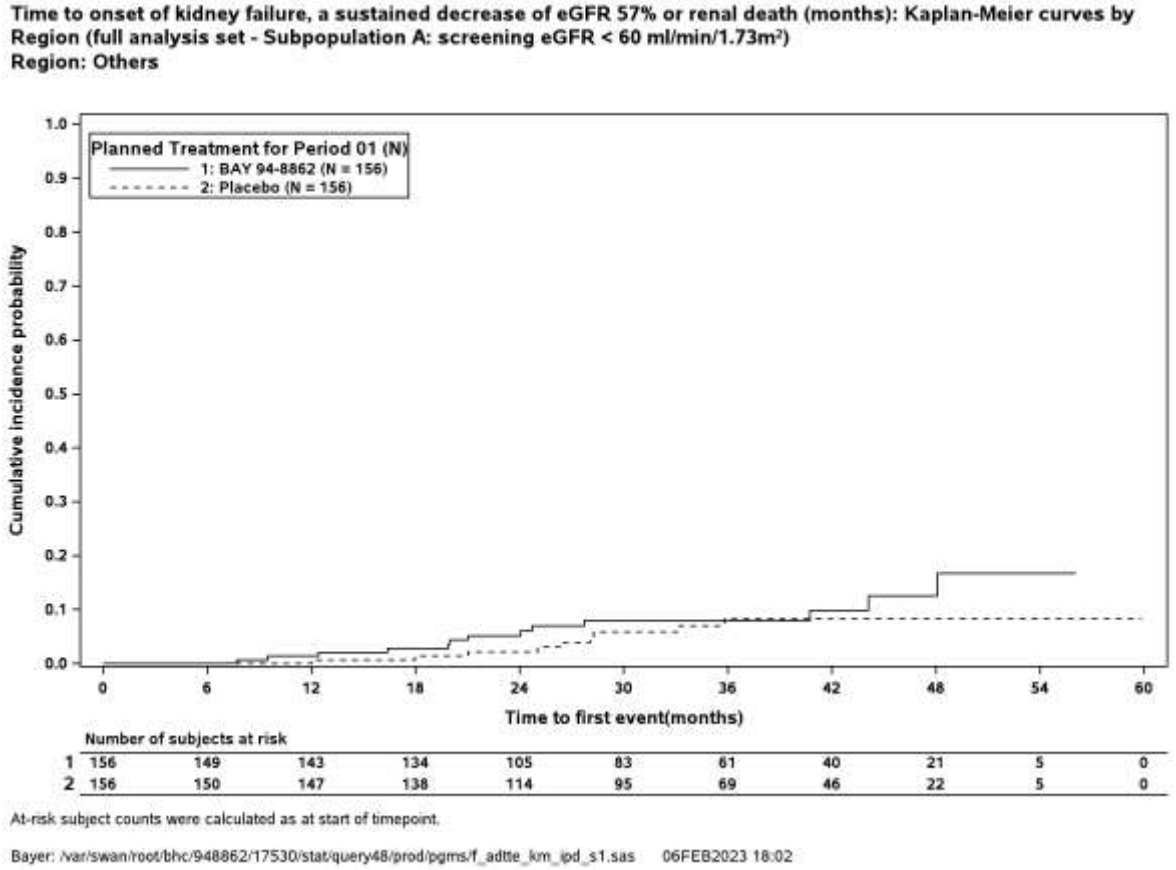


Figure 1.2.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

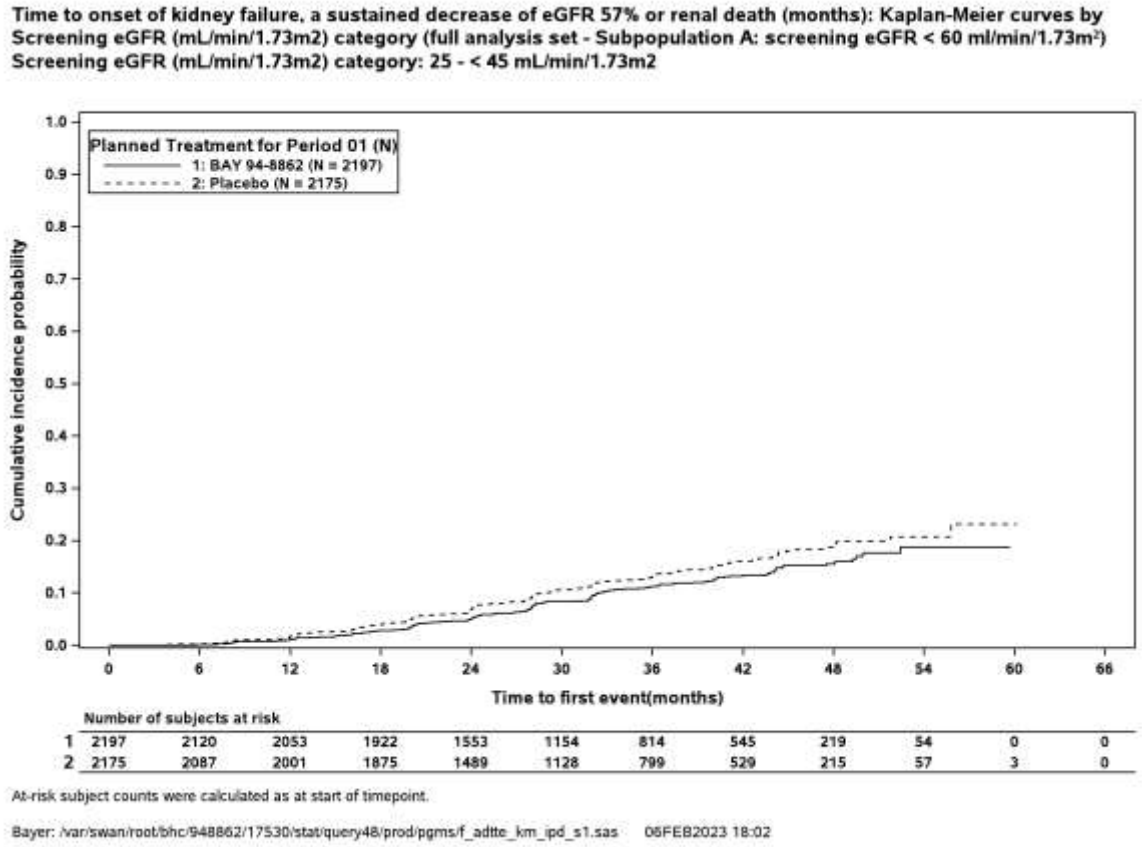


Figure 1.2.1 / 14: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

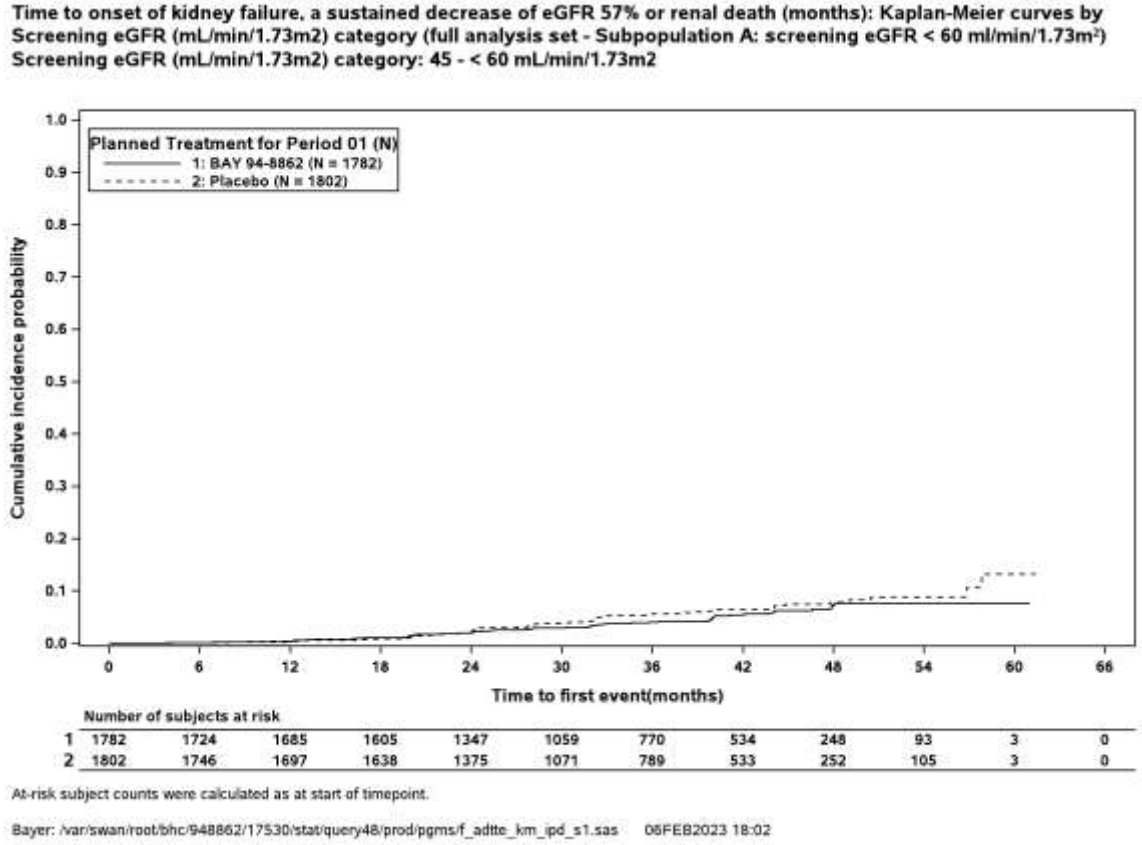


Figure 1.2.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

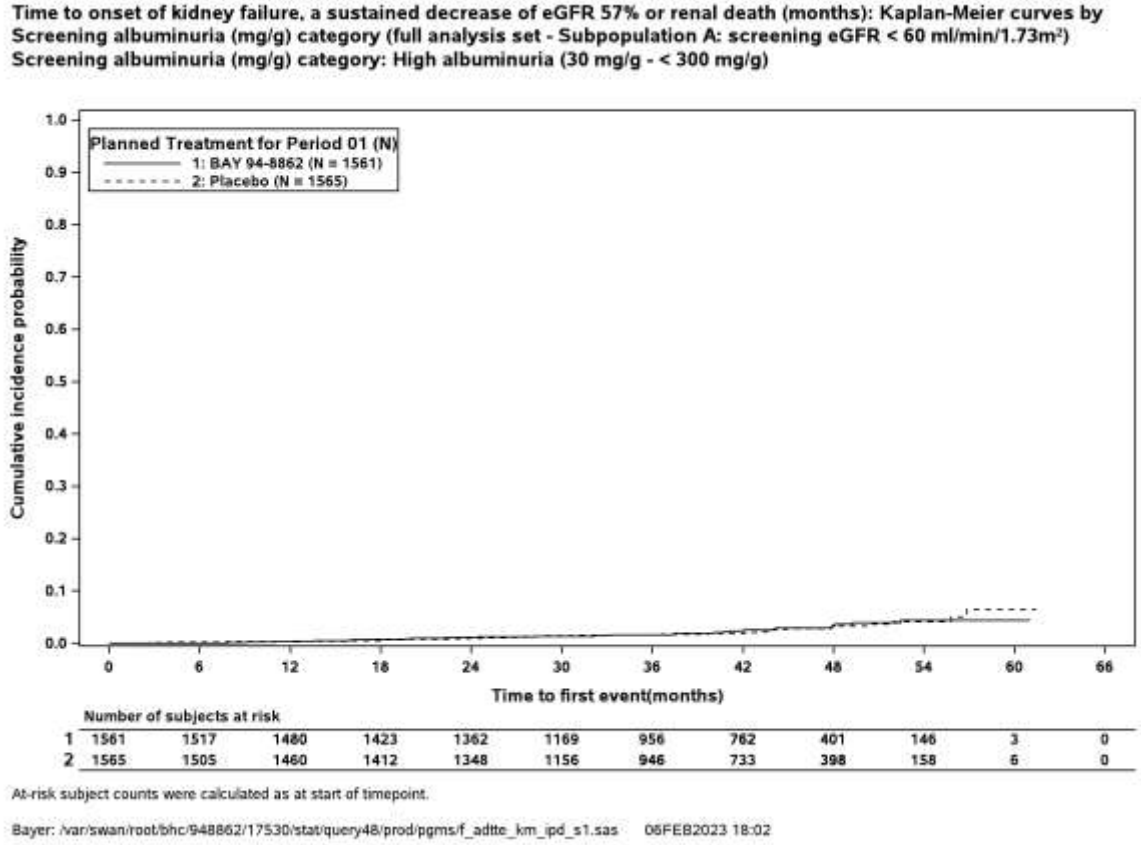
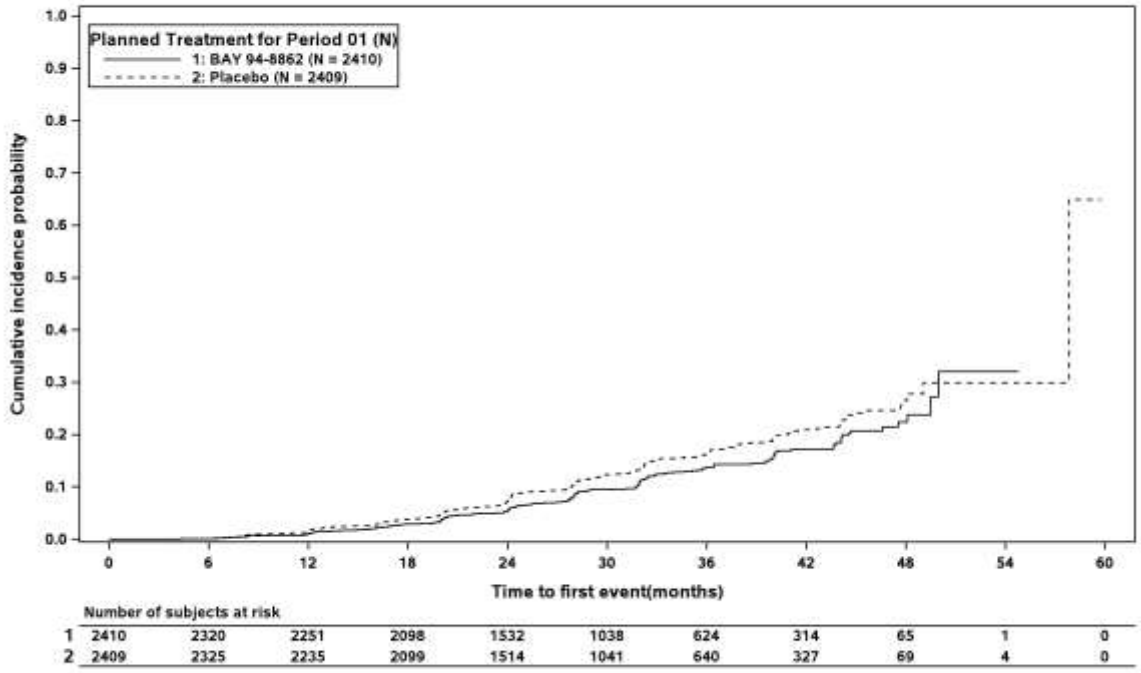


Figure 1.2.1 / 15: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	2410	2320	2251	2098	1532	1038	624	314	65	1	0
2	2409	2325	2235	2099	1514	1041	640	327	69	4	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

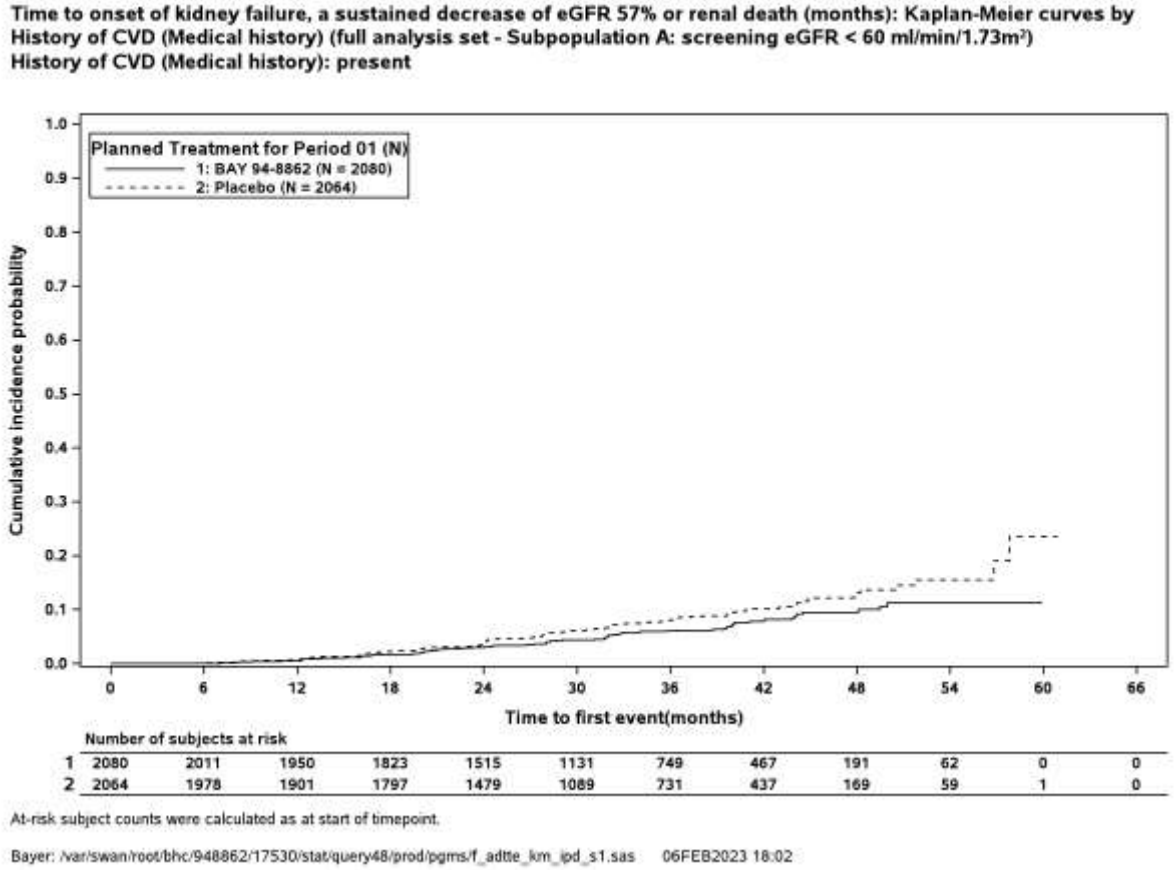


Figure 1.2.1 / 16: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

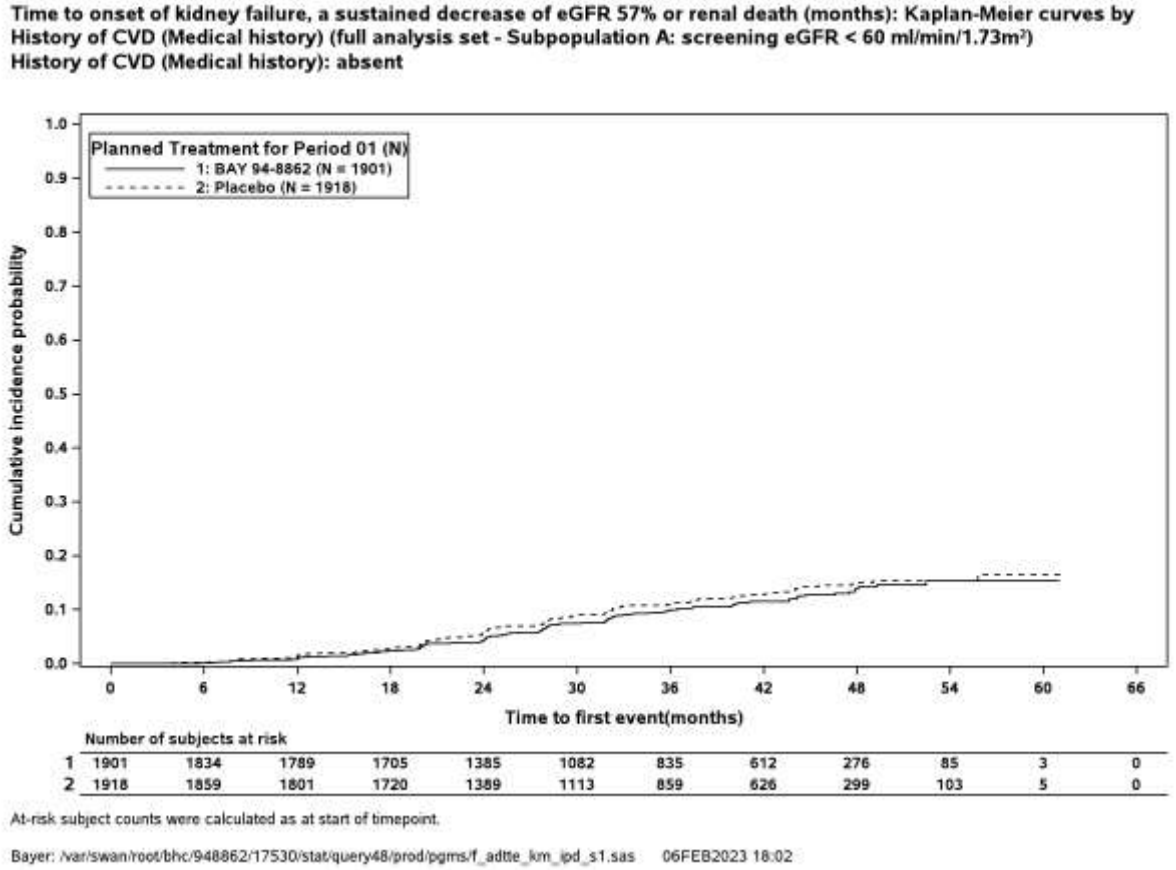


Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

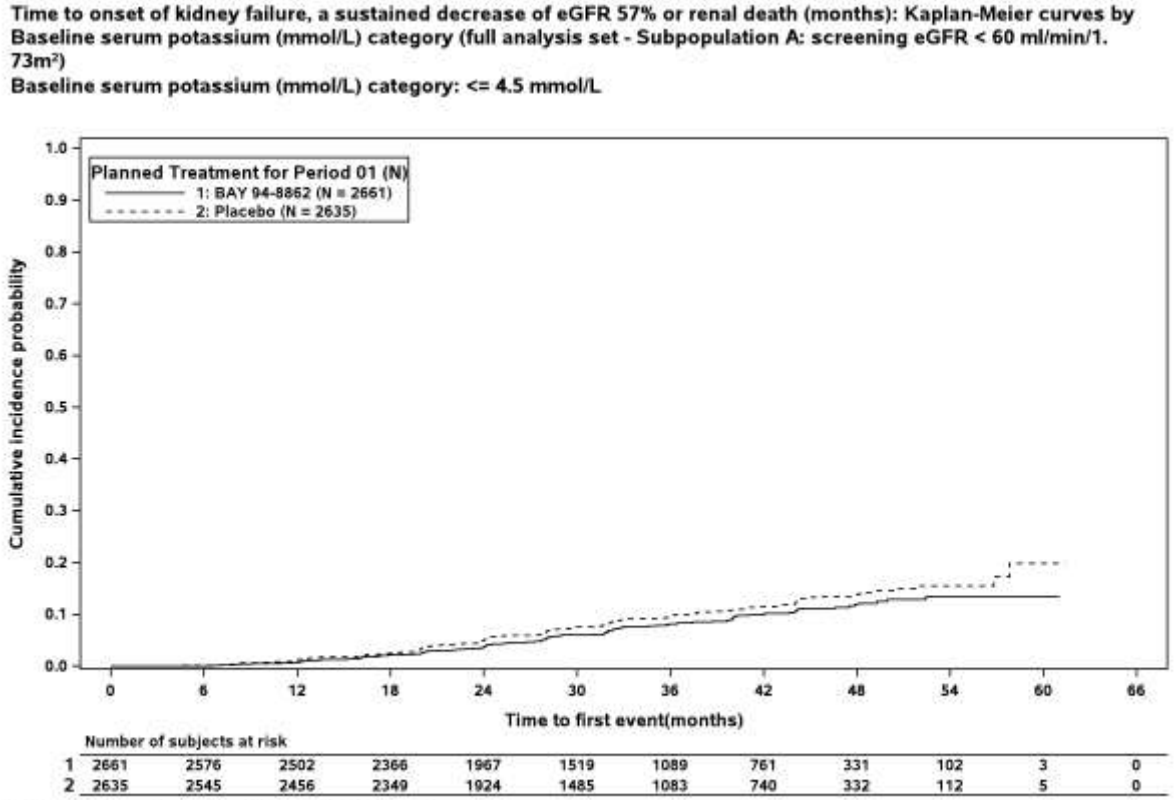


Figure 1.2.1 / 17: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

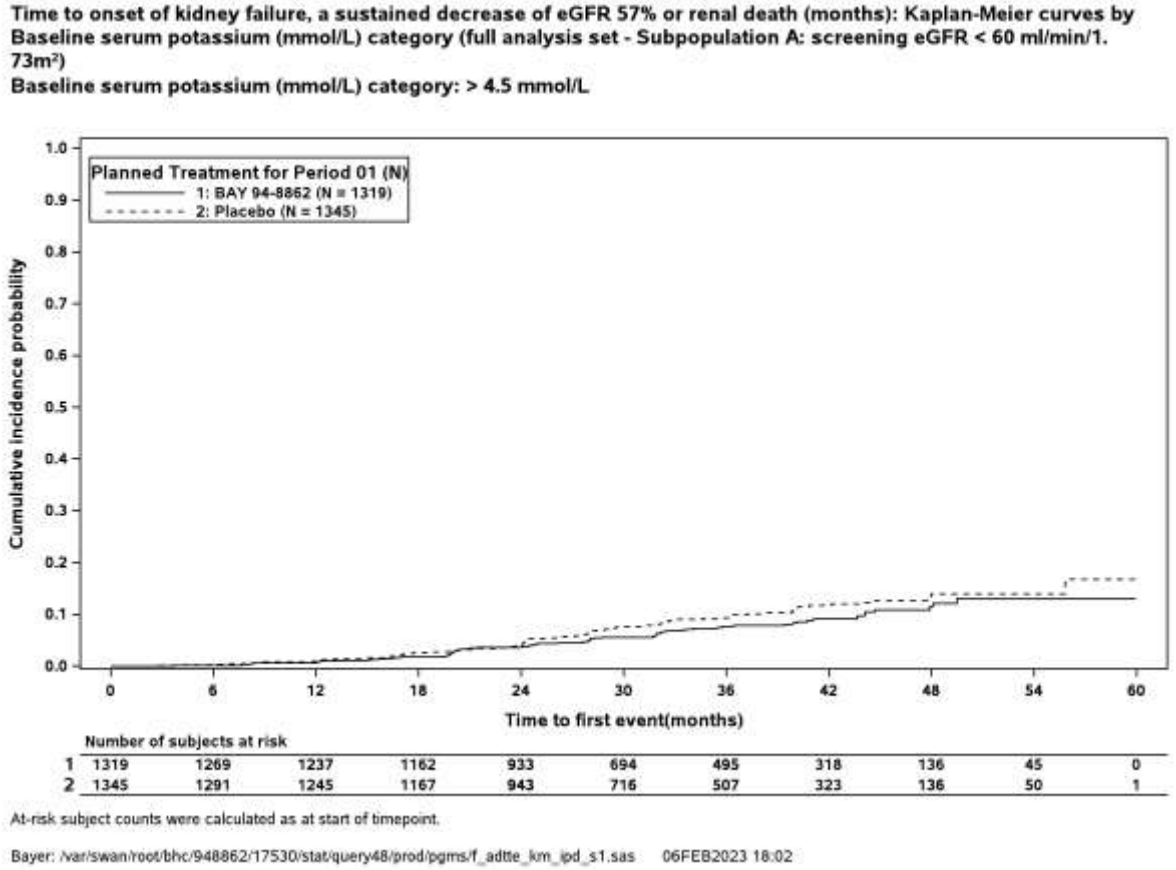


Figure 1.2.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

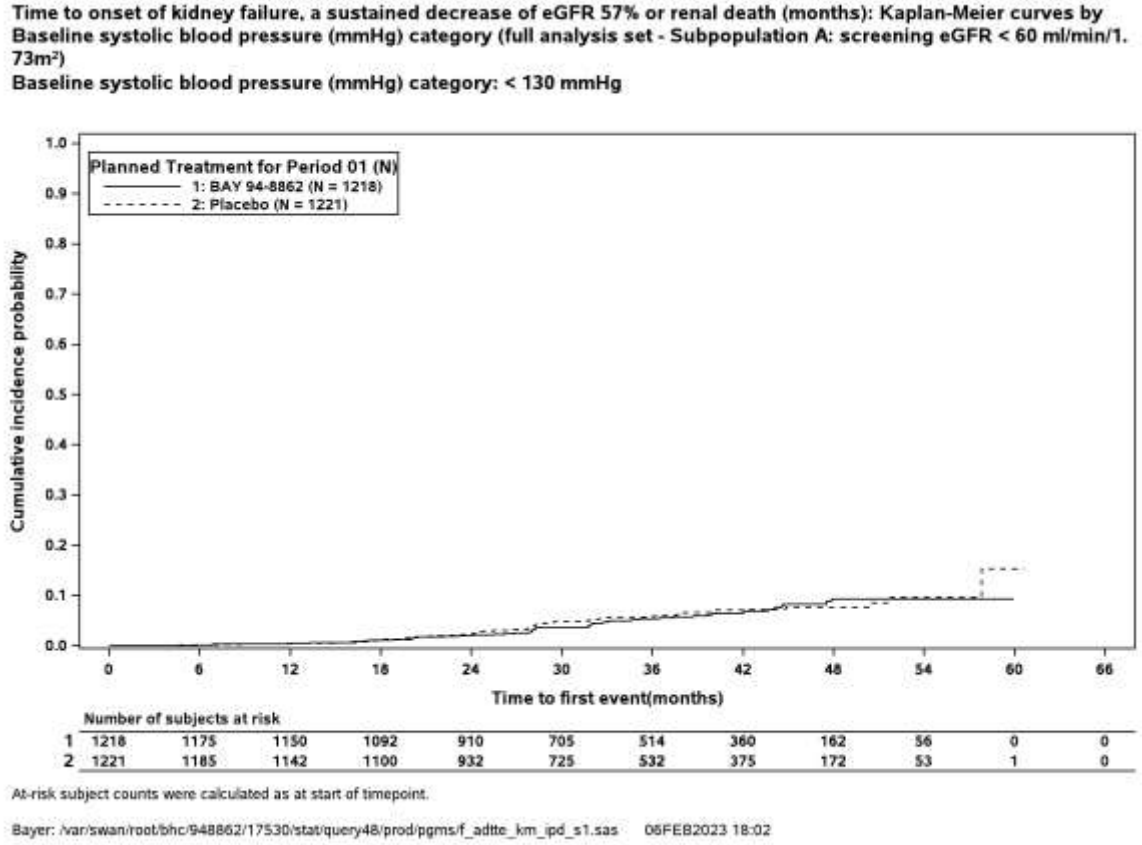


Figure 1.2.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

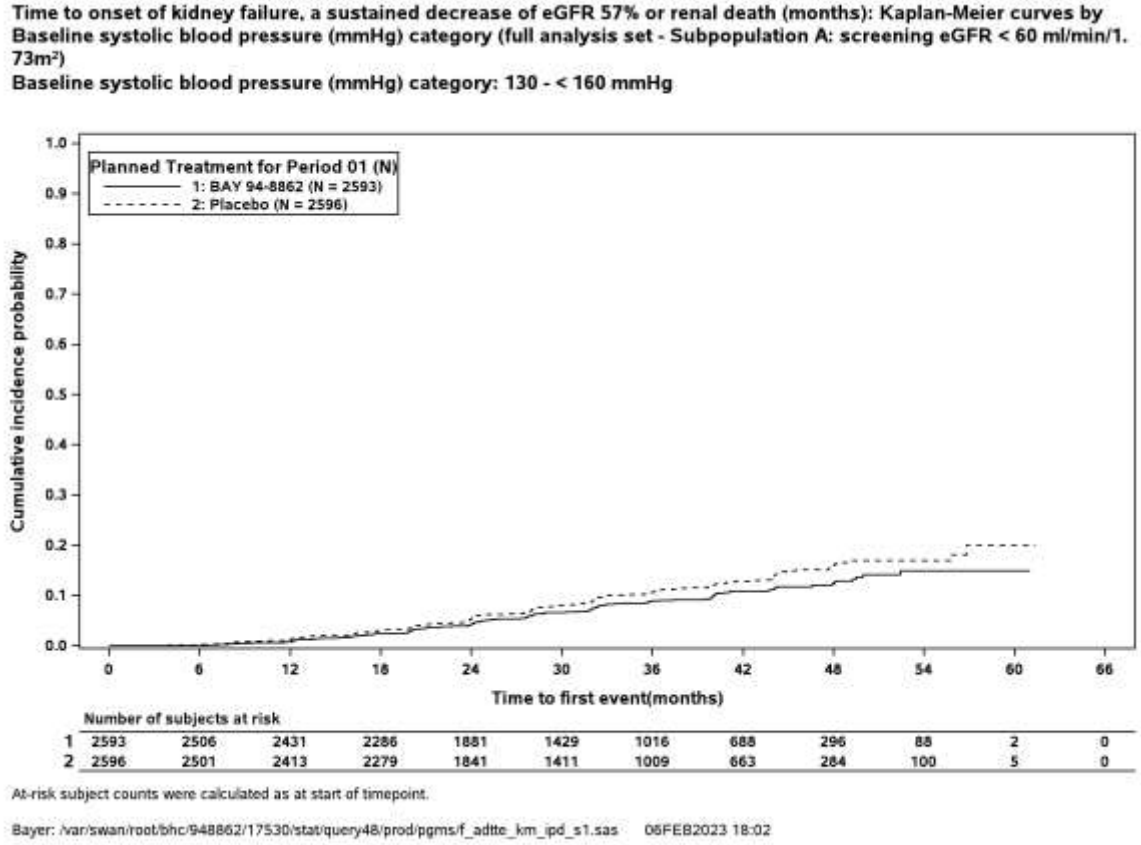


Figure 1.2.1 / 18: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

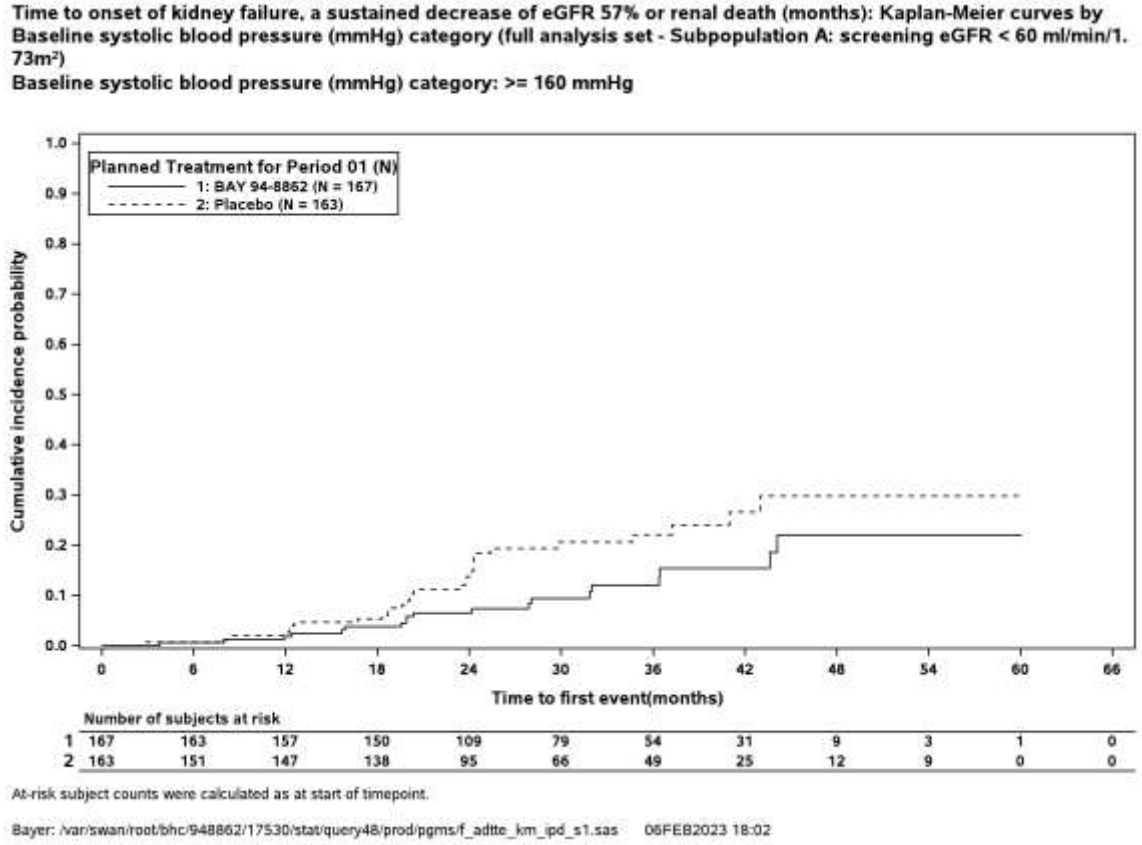


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

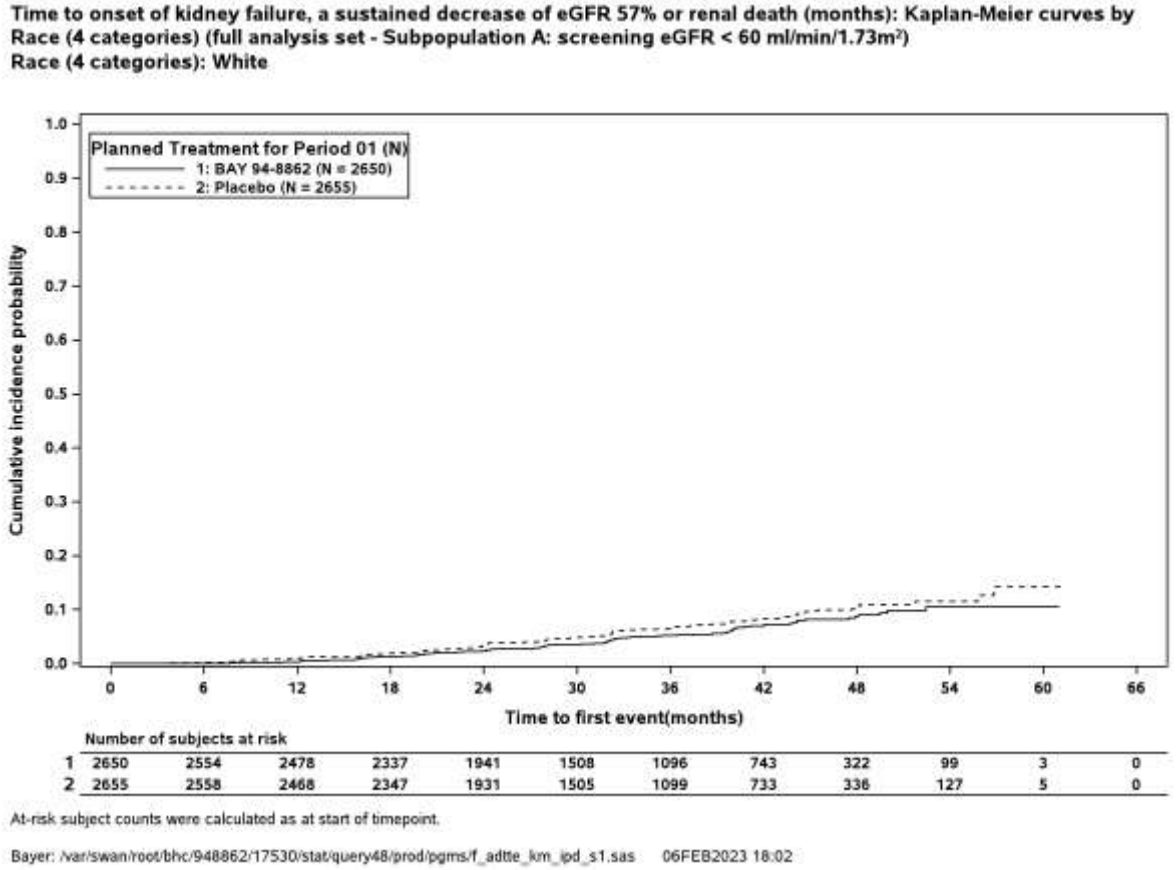


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

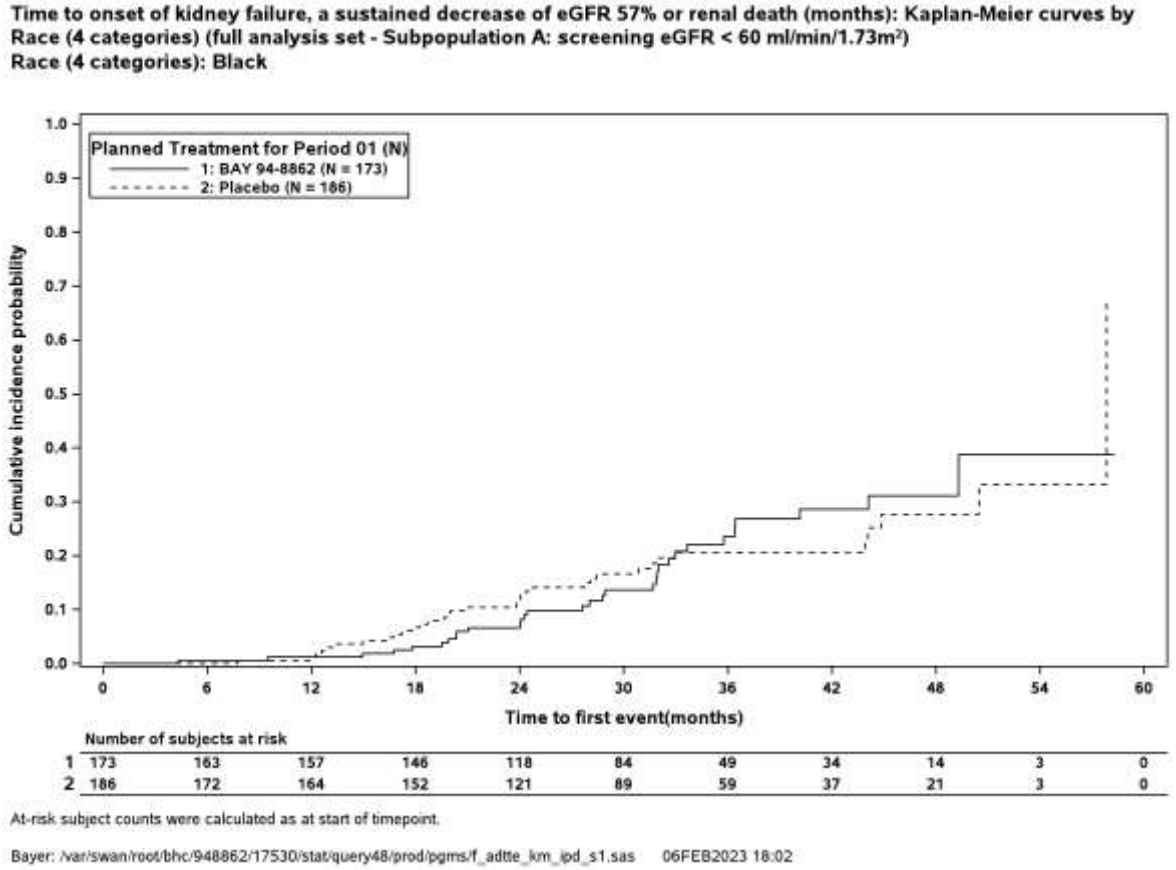


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

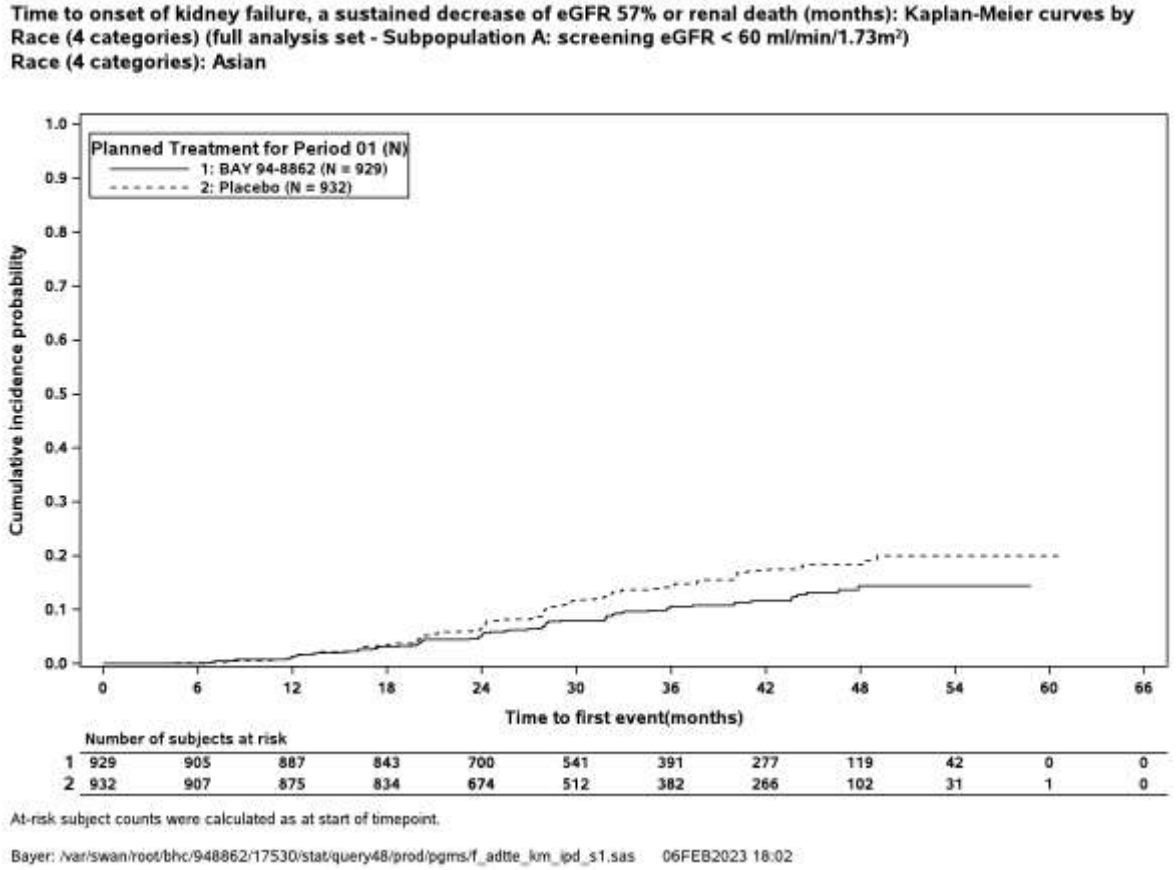


Figure 1.2.1 / 19: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

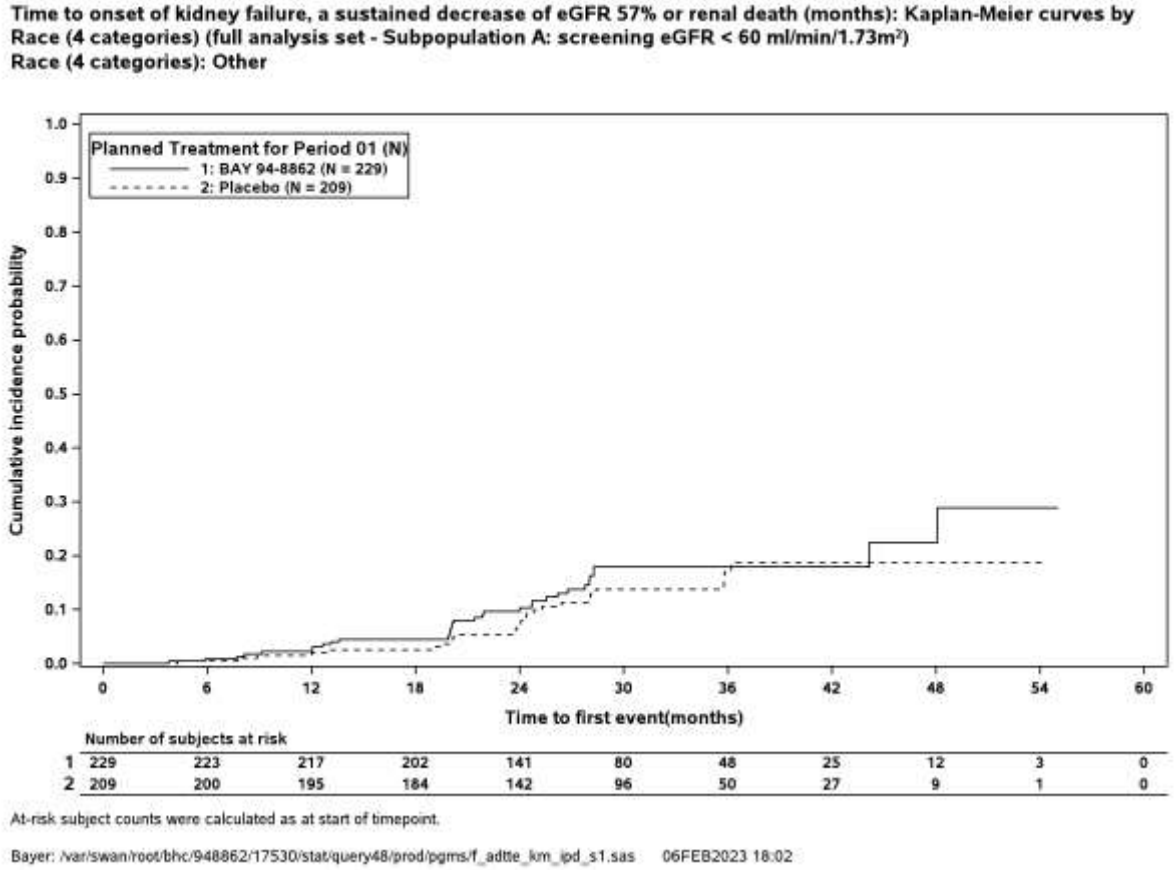


Figure 1.2.1 / 20: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

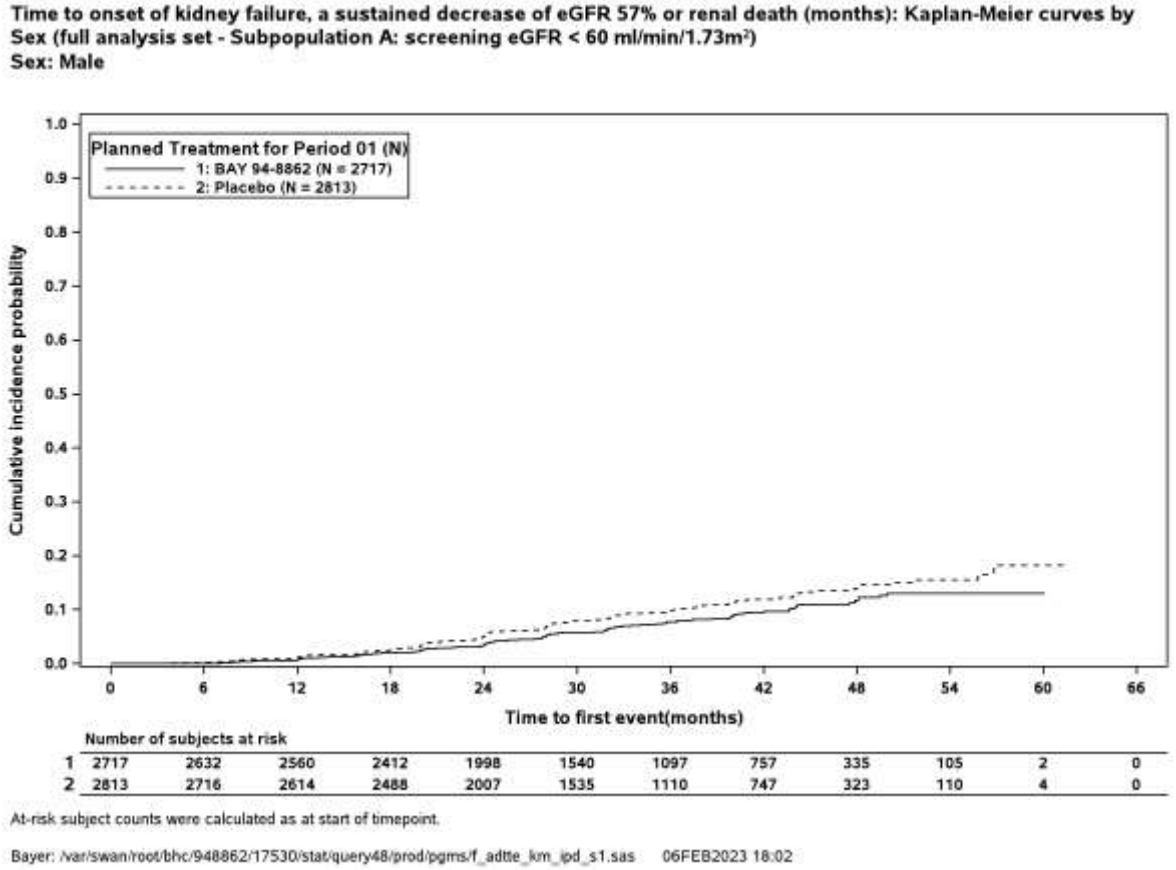


Figure 1.2.1 / 20: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

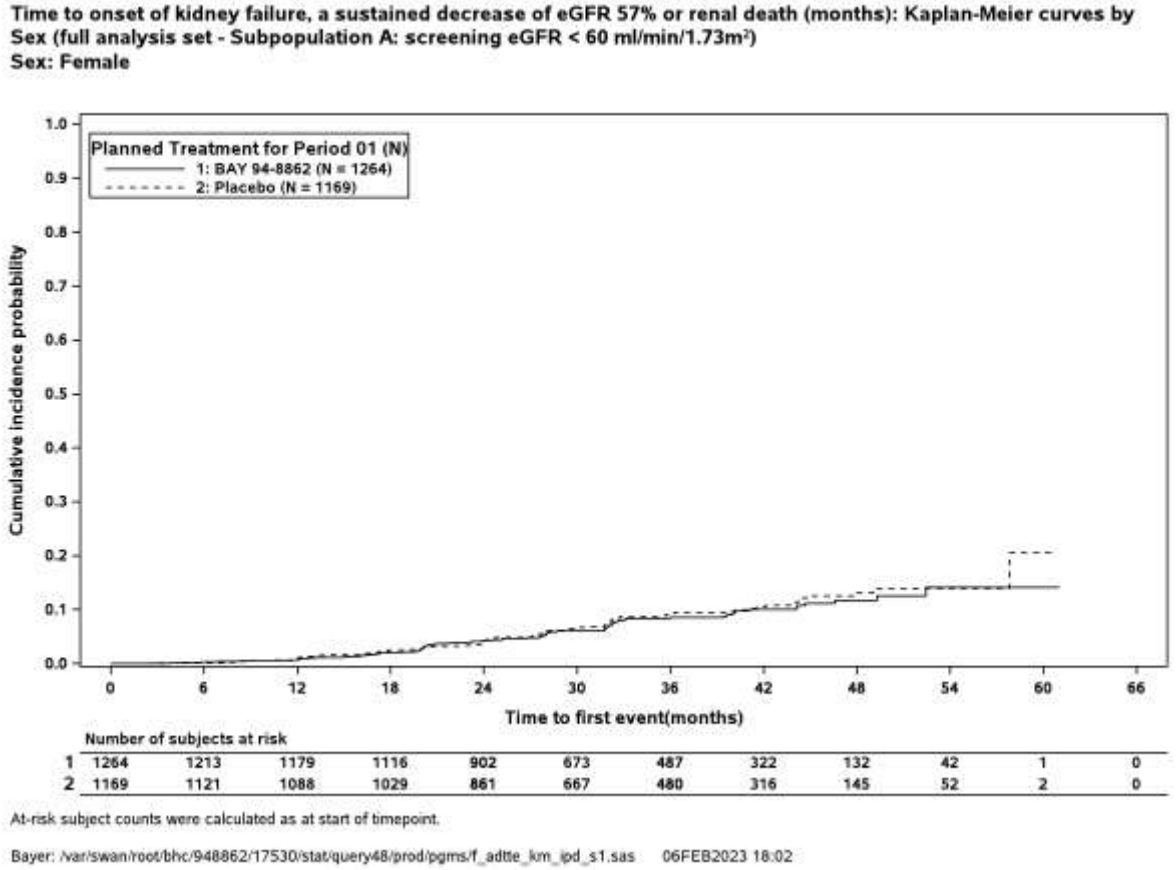


Figure 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

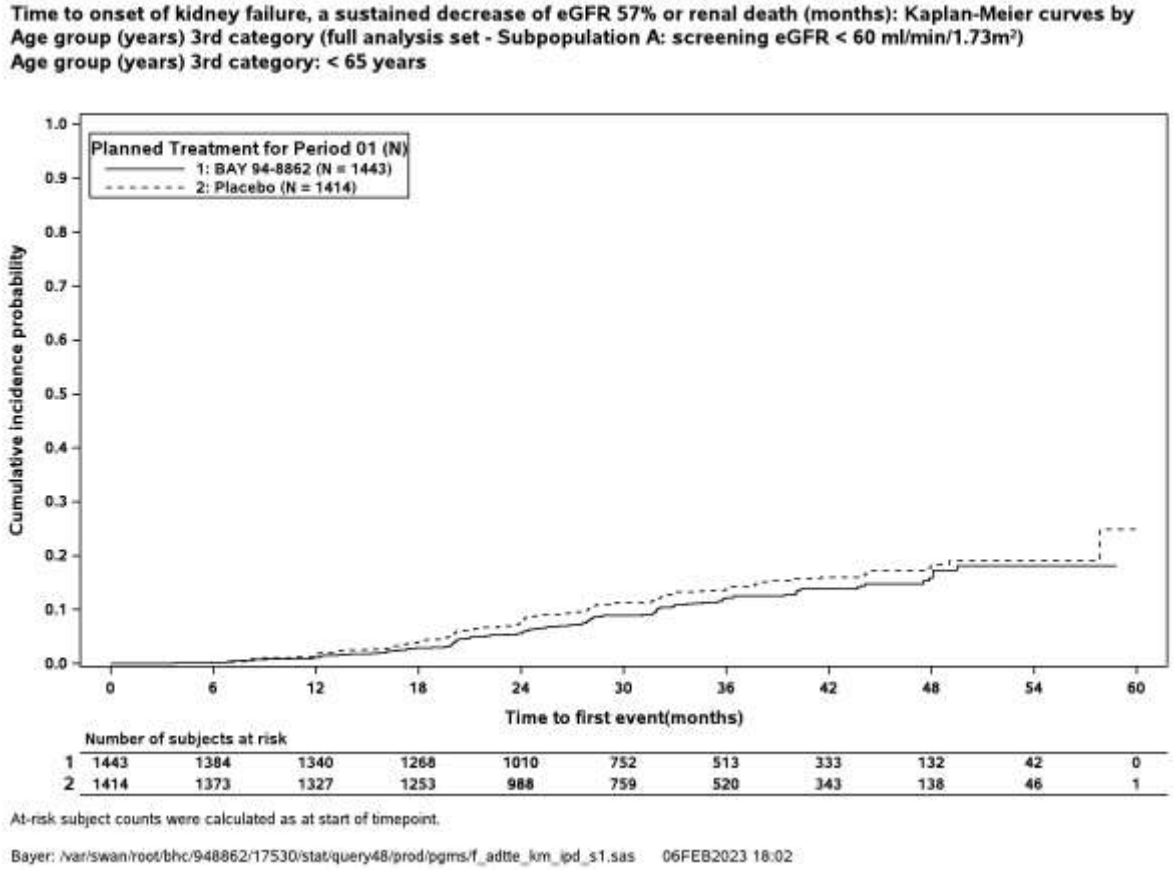


Figure 1.2.1 / 21: Time to onset of kidney failure, a sustained decrease of eGFR 57% or renal death (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

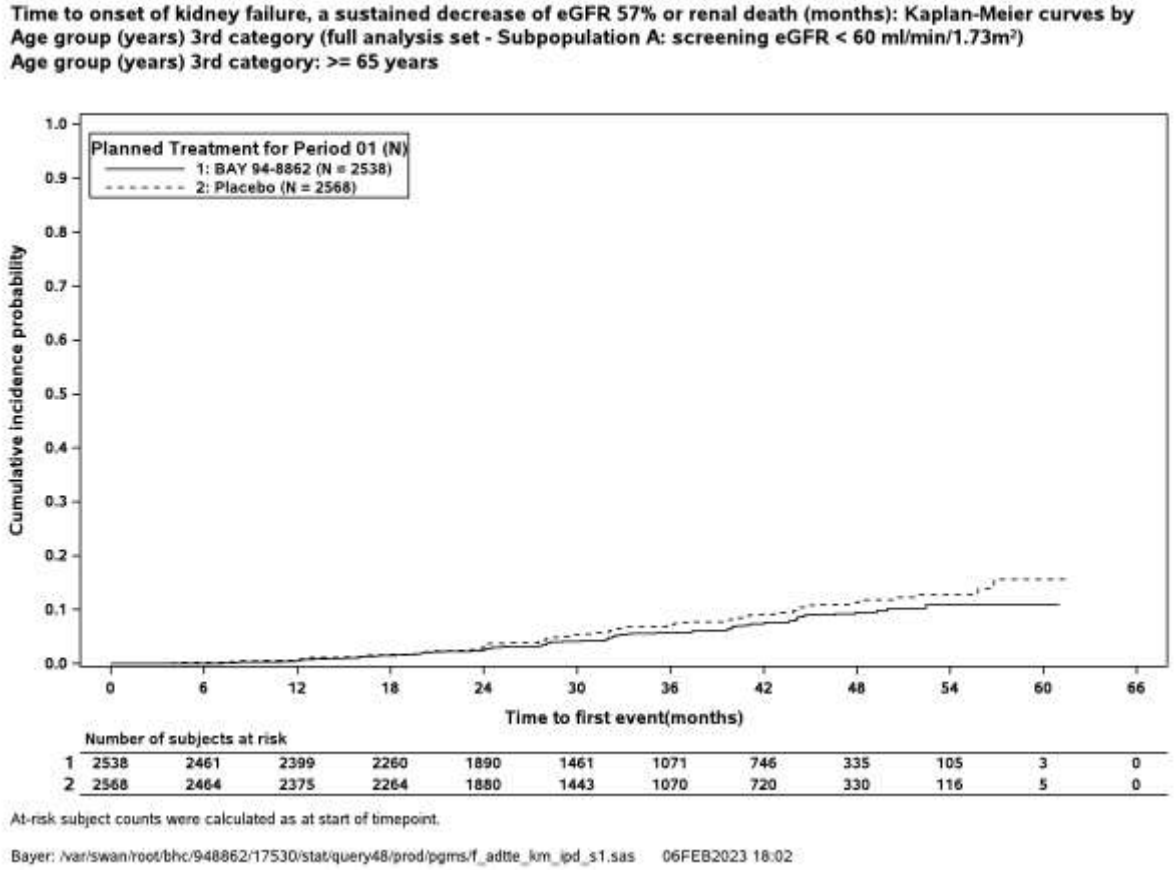


Figure 1.2.1 / 22: Time to onset of kidney failure (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

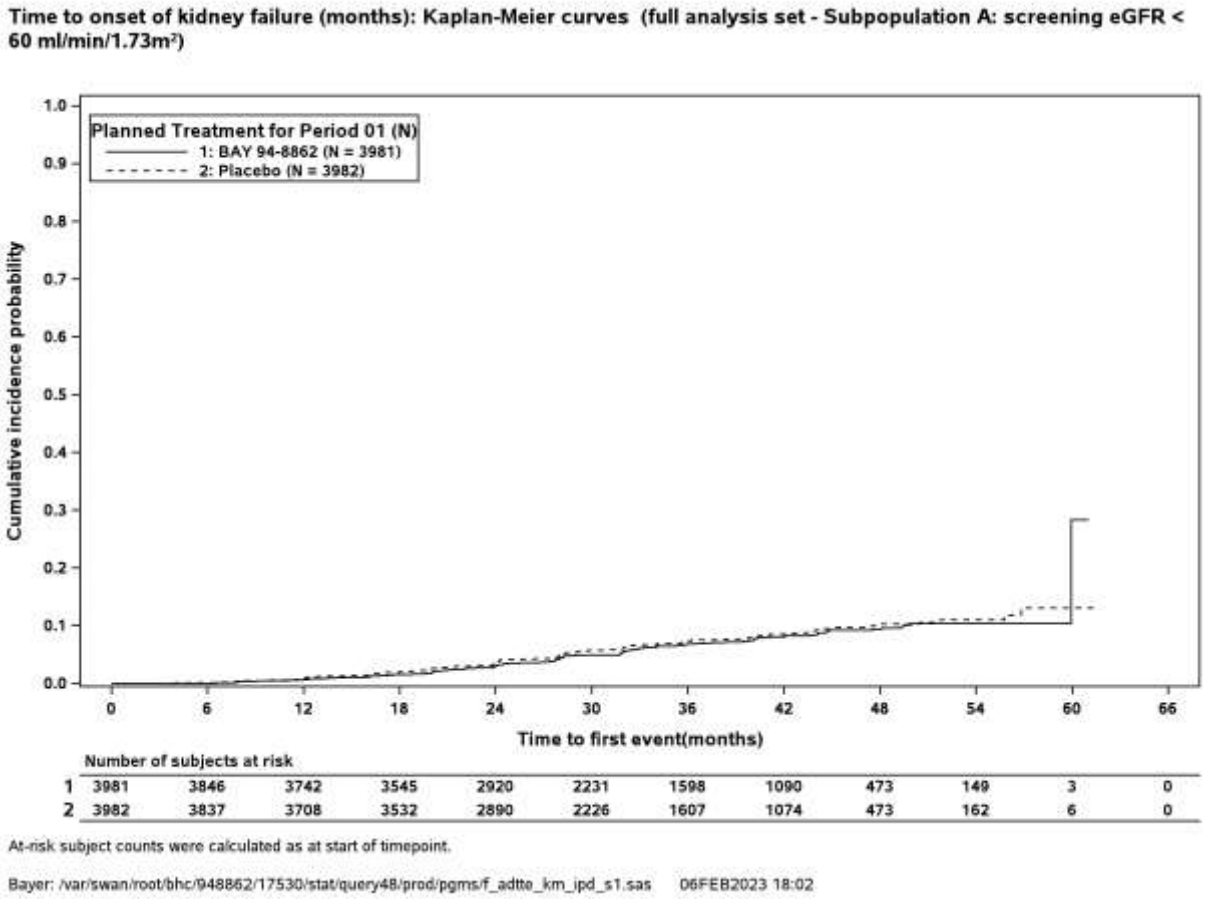


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

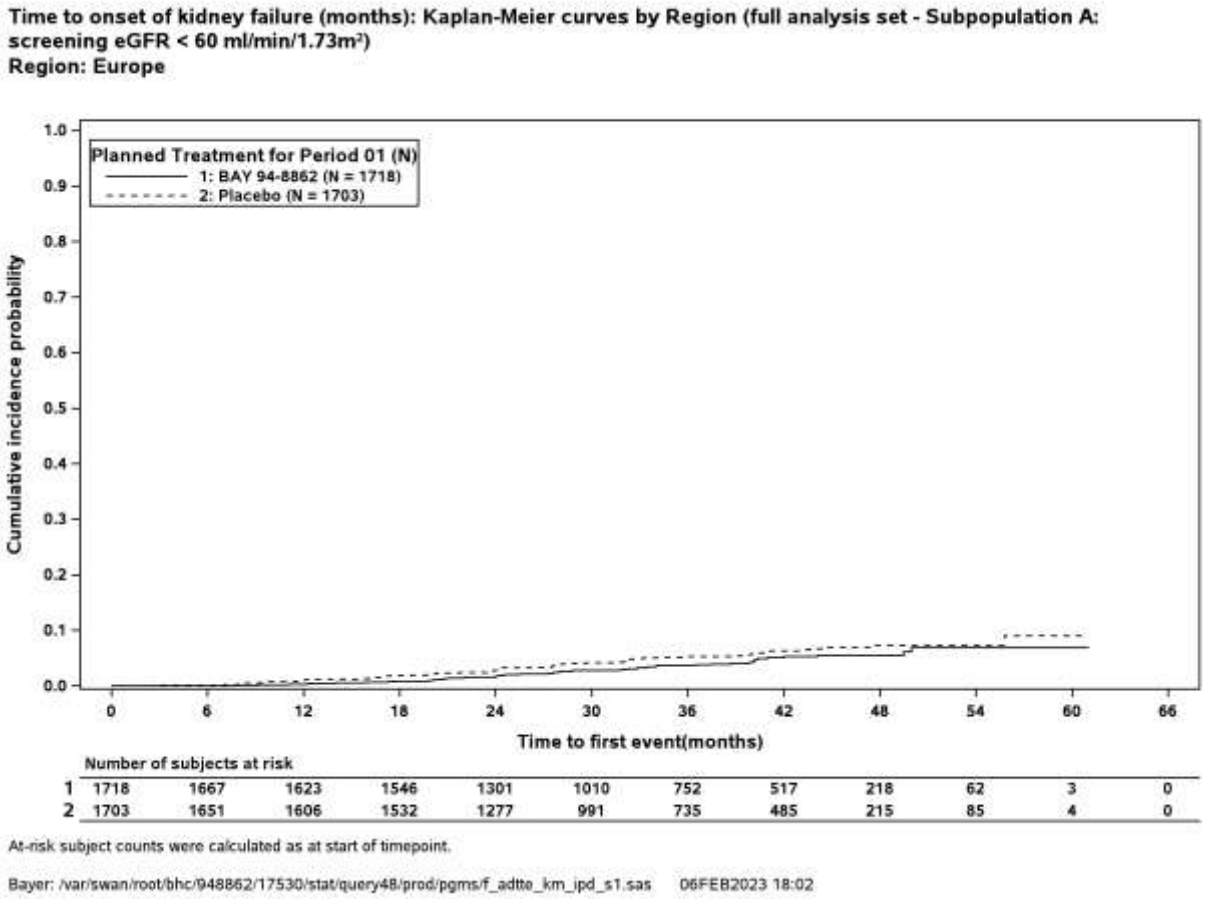


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

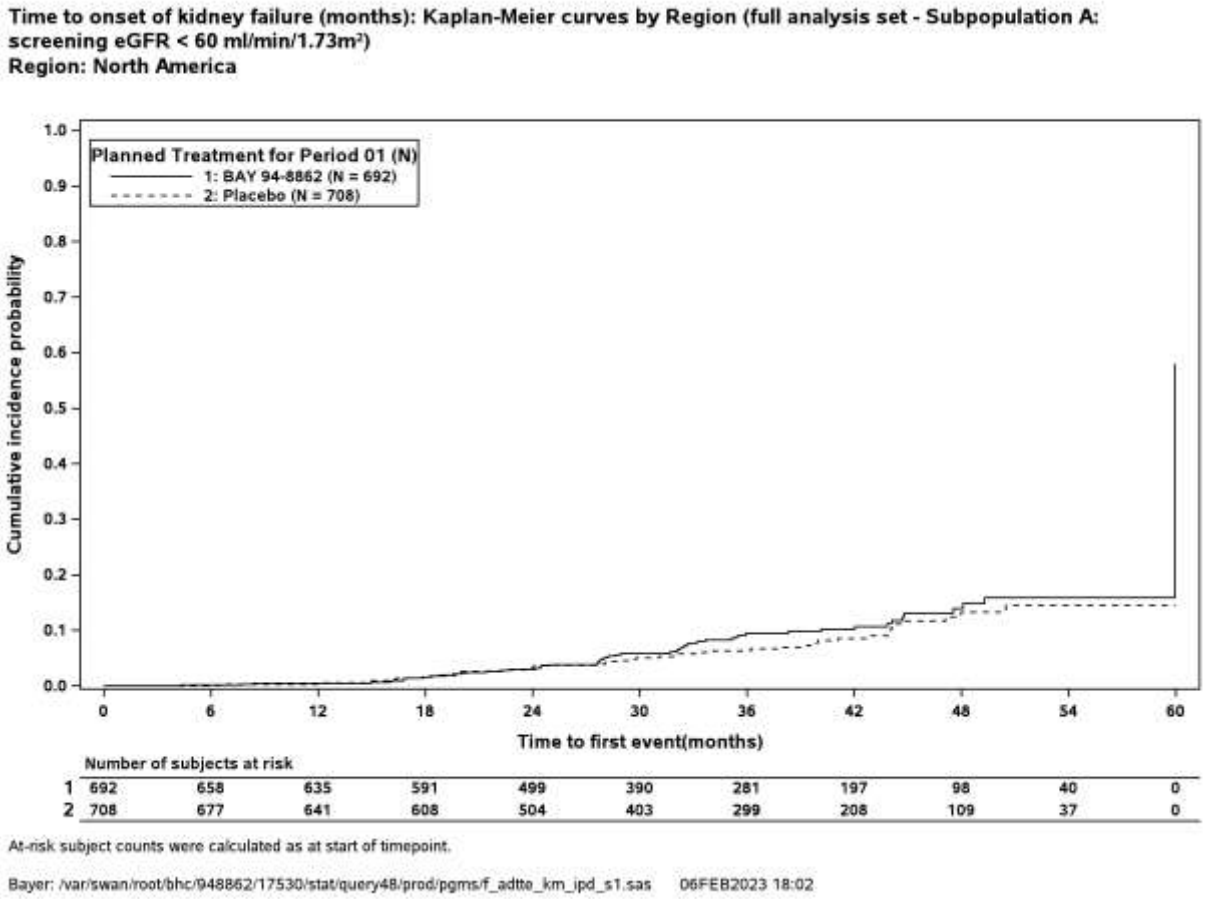


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

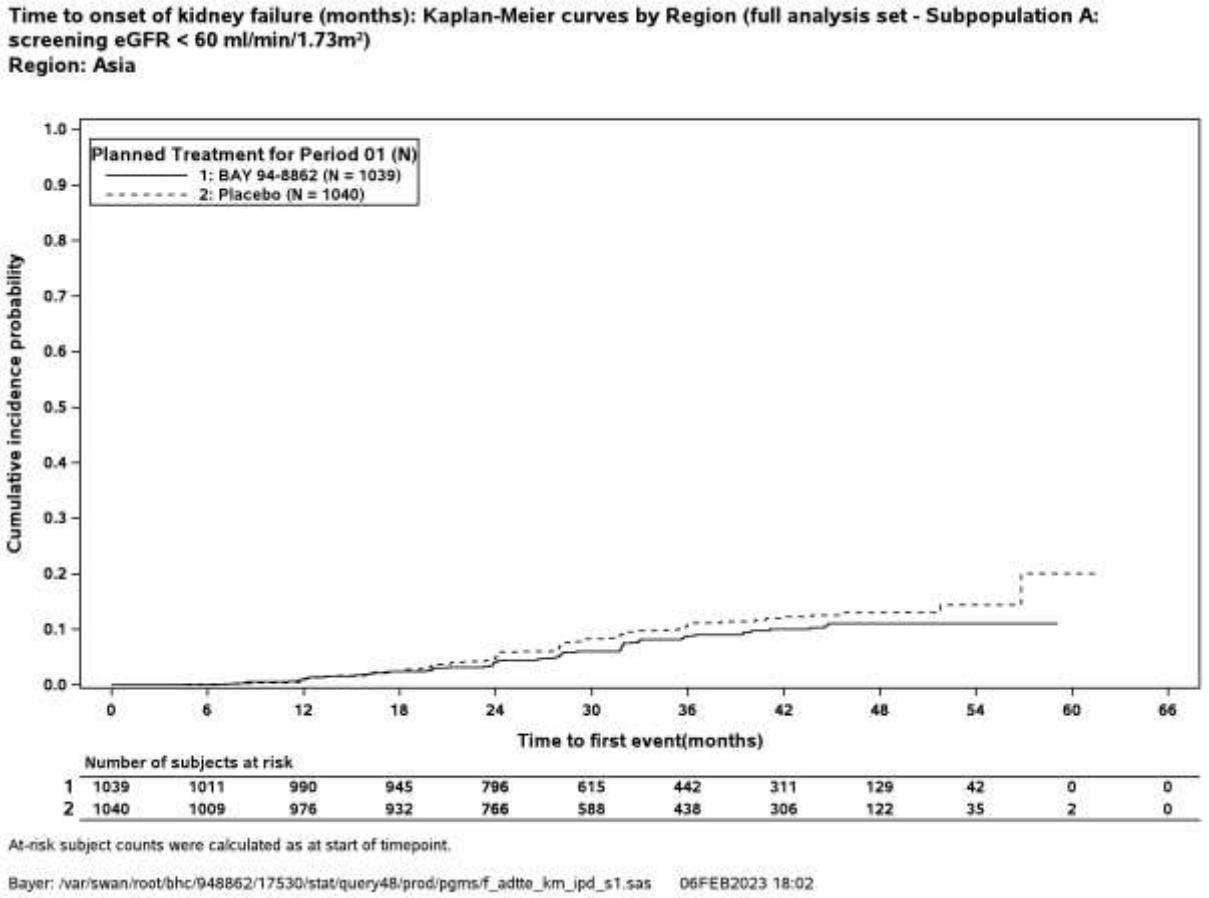


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

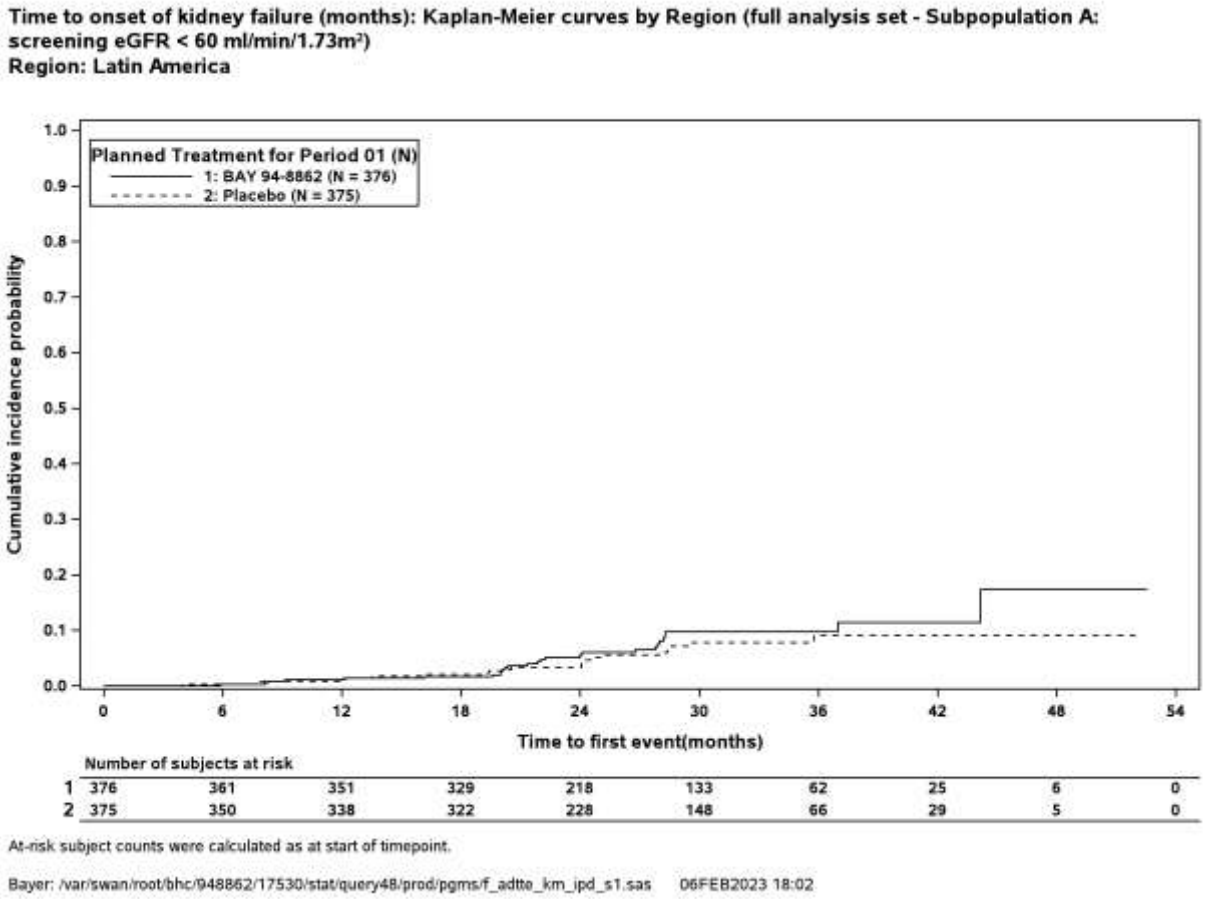


Figure 1.2.1 / 23: Time to onset of kidney failure (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

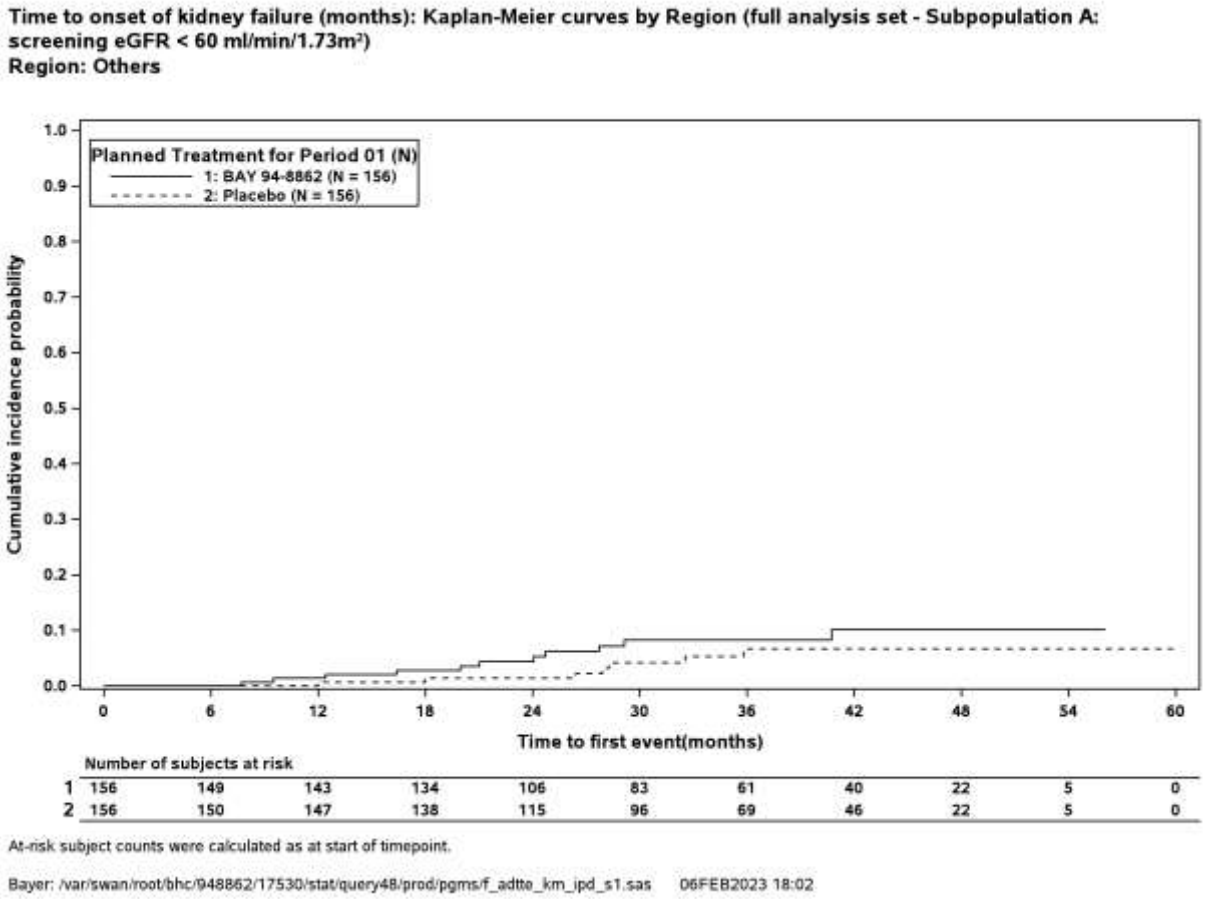


Figure 1.2.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

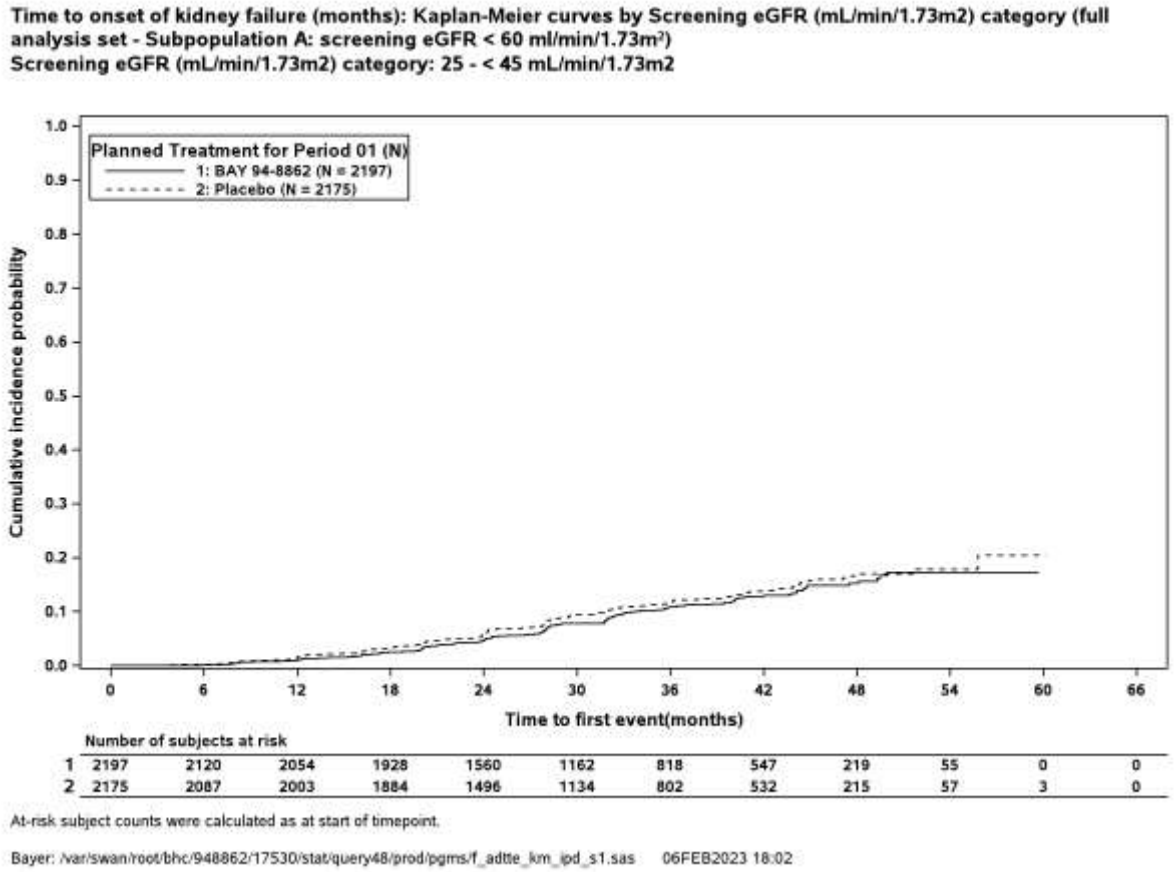


Figure 1.2.1 / 24: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

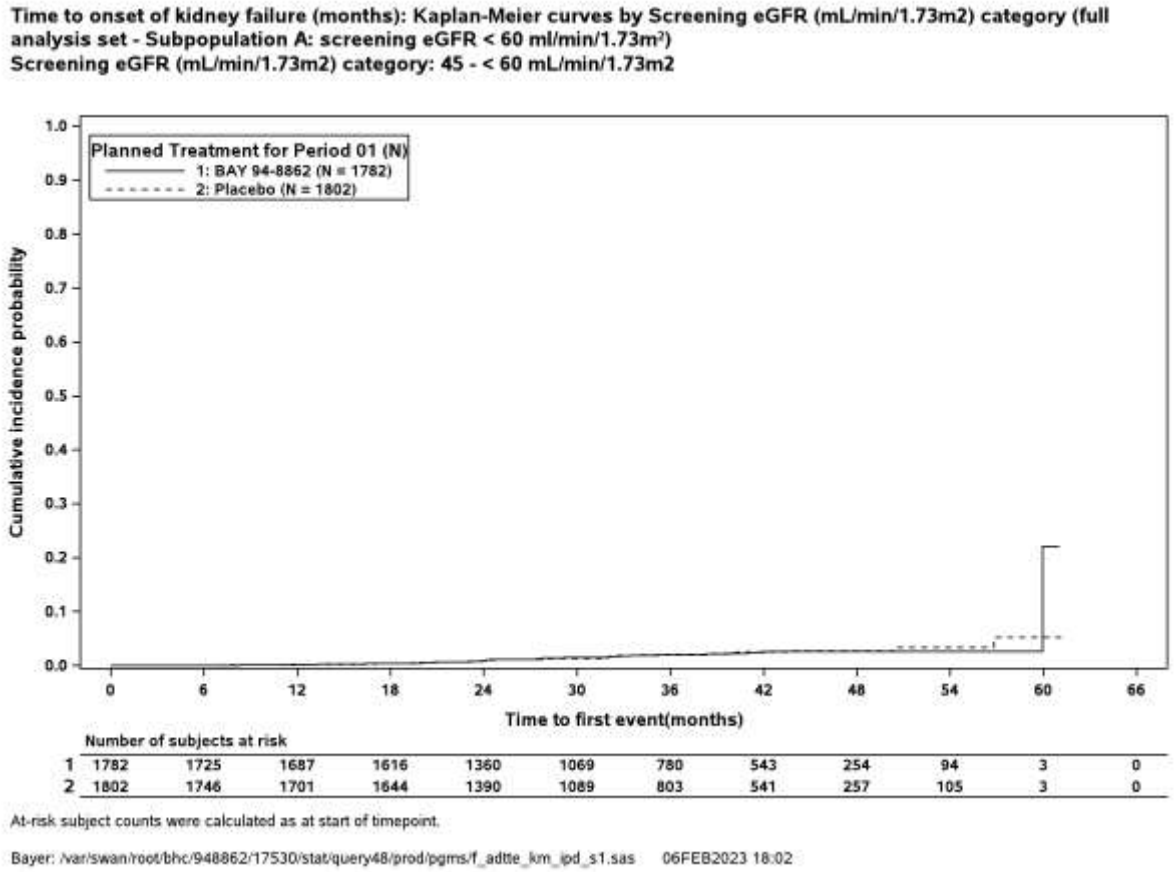


Figure 1.2.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

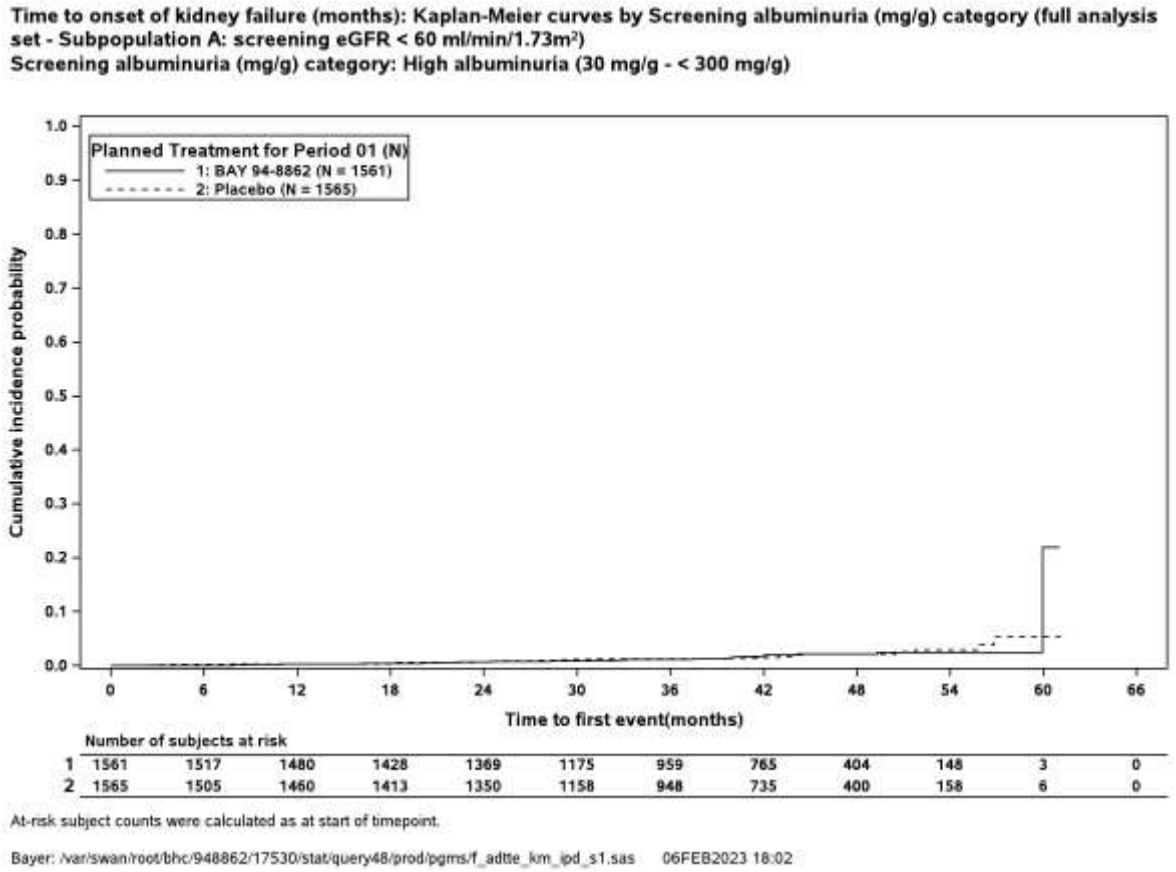


Figure 1.2.1 / 25: Time to onset of kidney failure (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

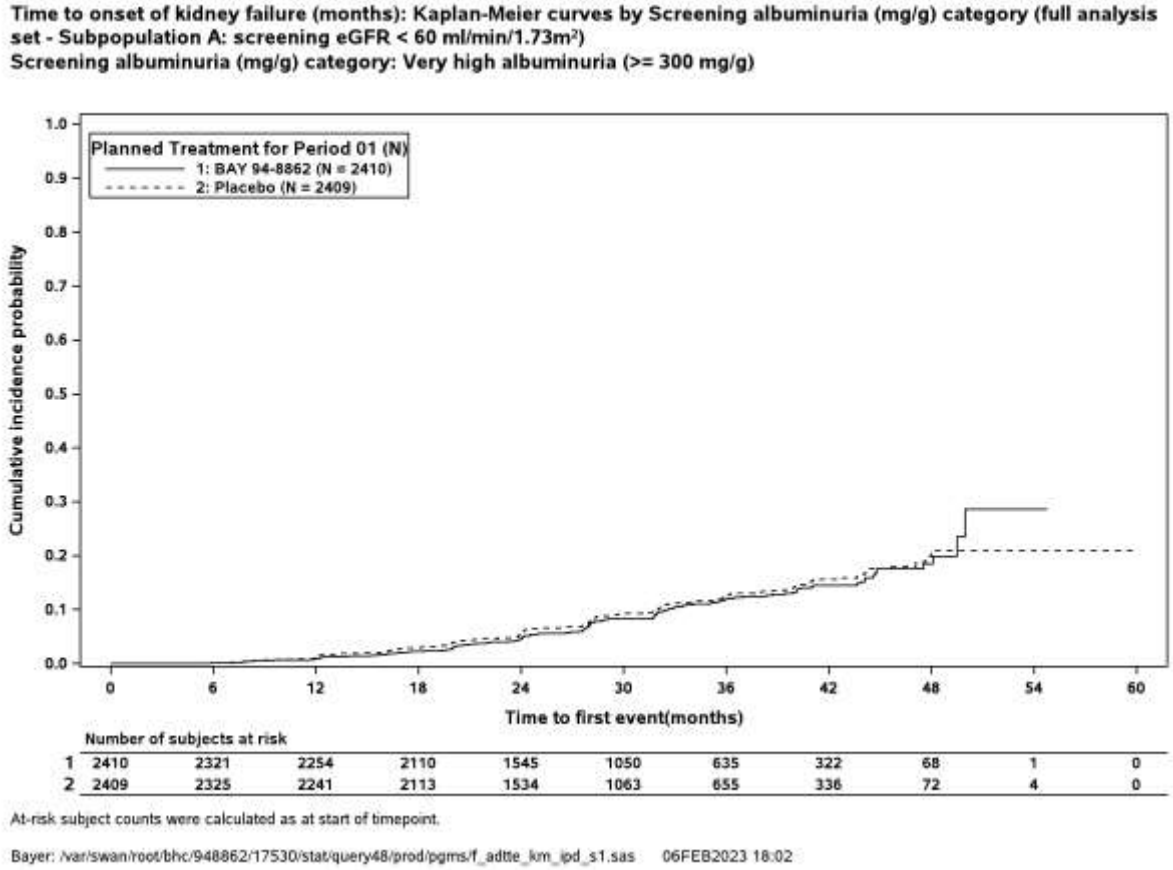


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

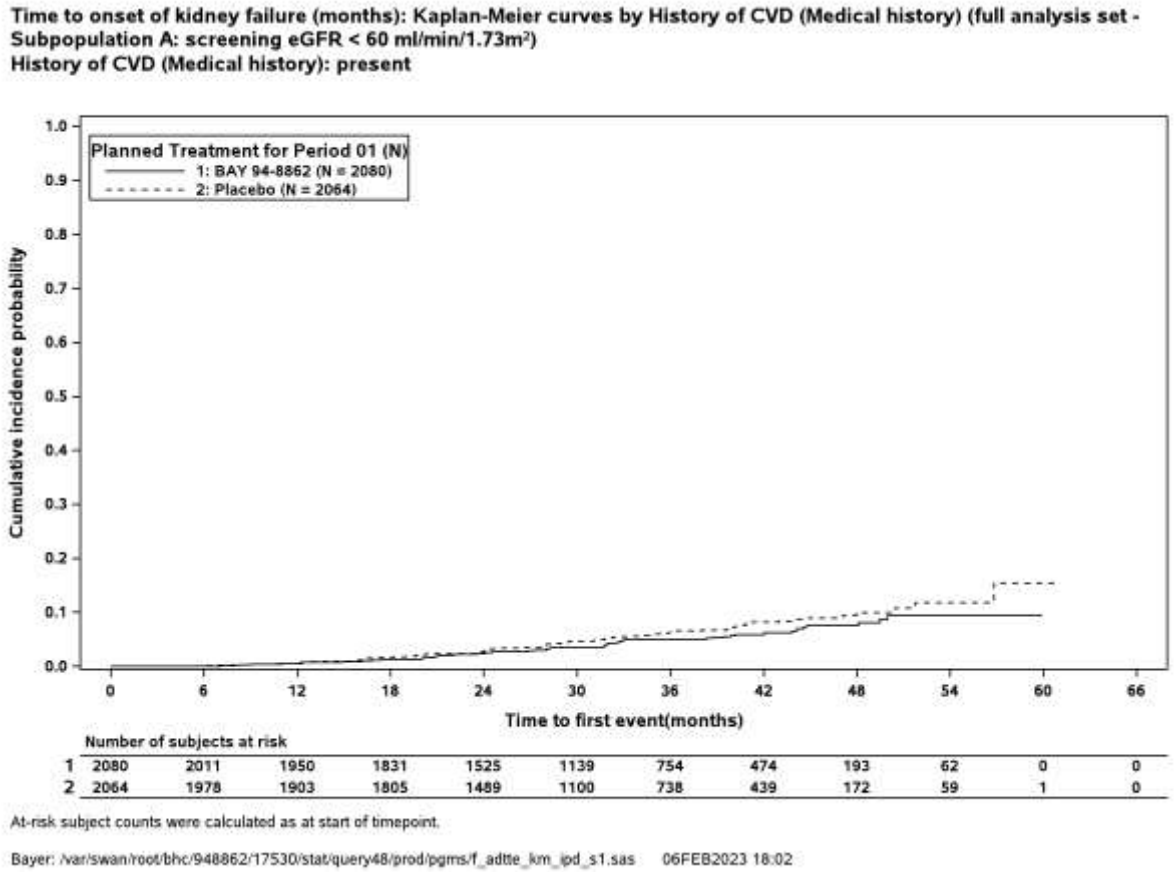


Figure 1.2.1 / 26: Time to onset of kidney failure (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

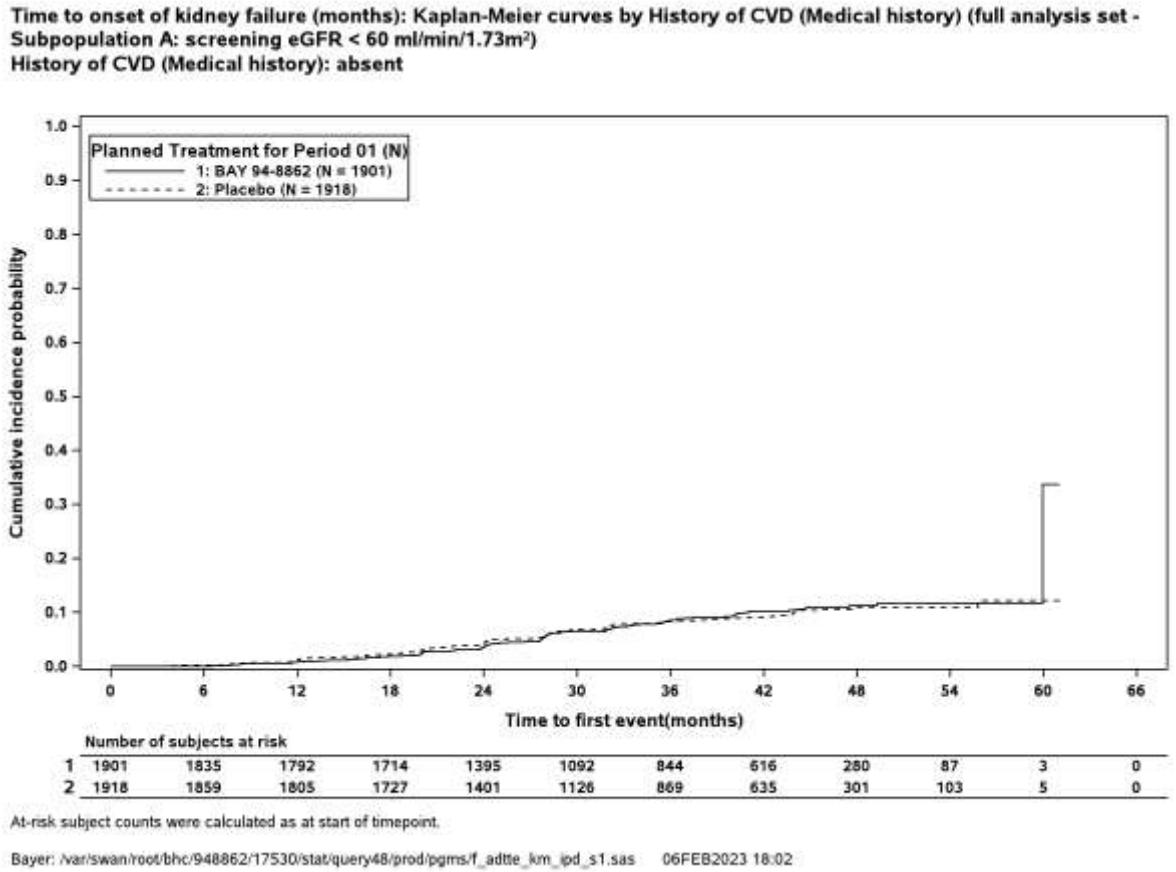


Figure 1.2.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

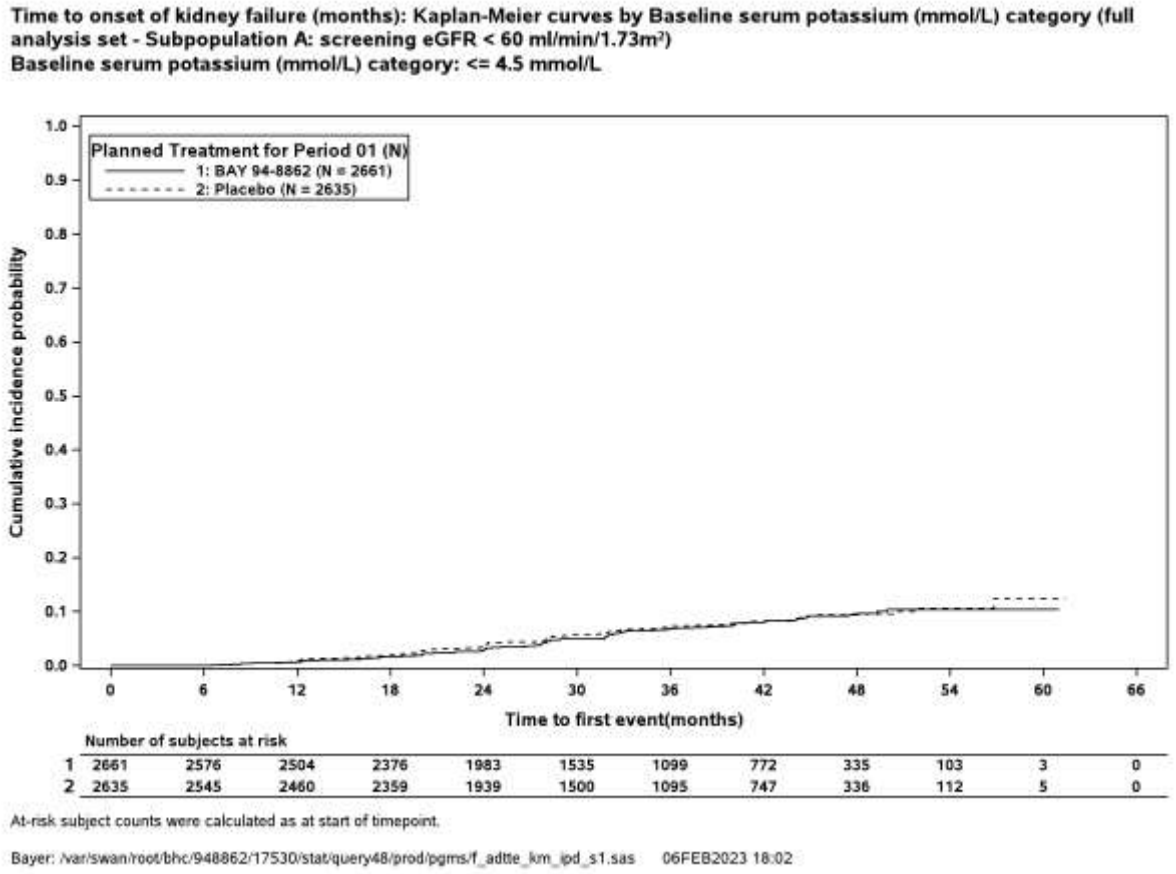


Figure 1.2.1 / 27: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

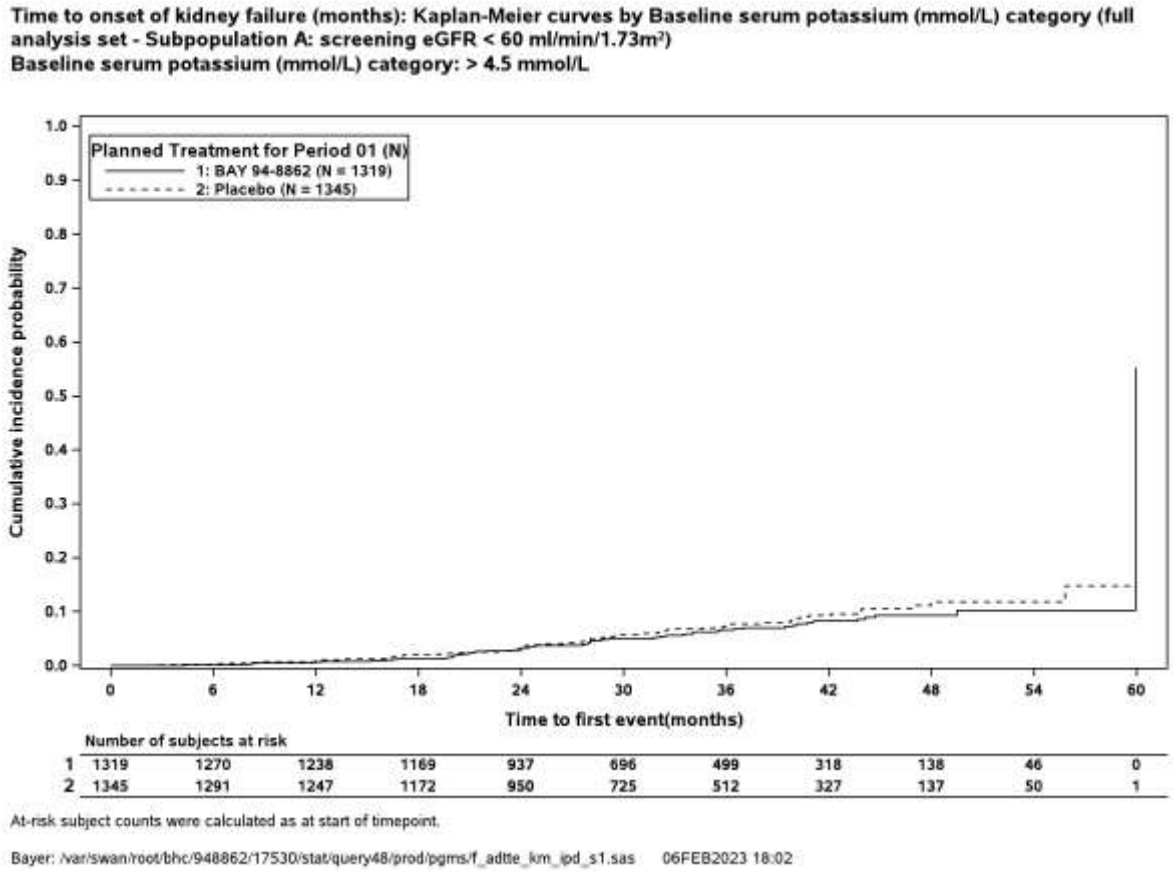


Figure 1.2.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

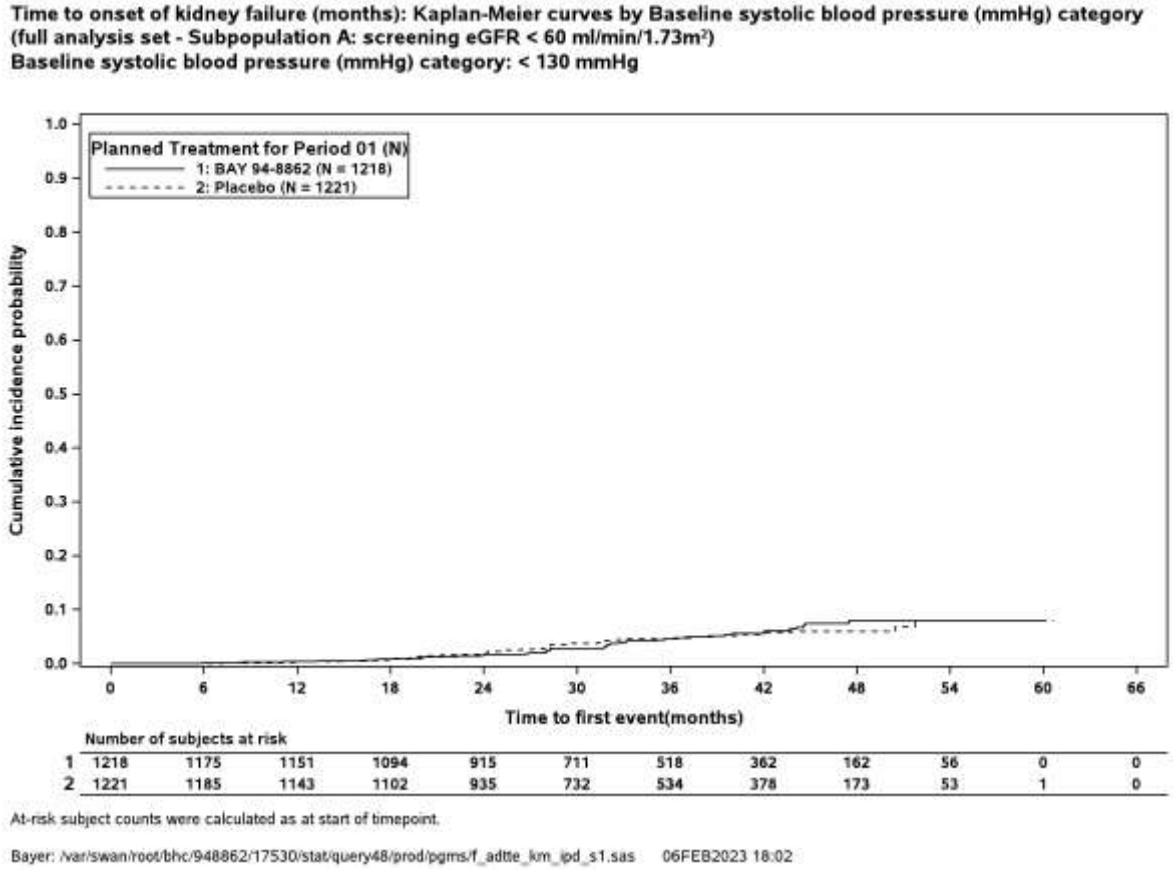


Figure 1.2.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

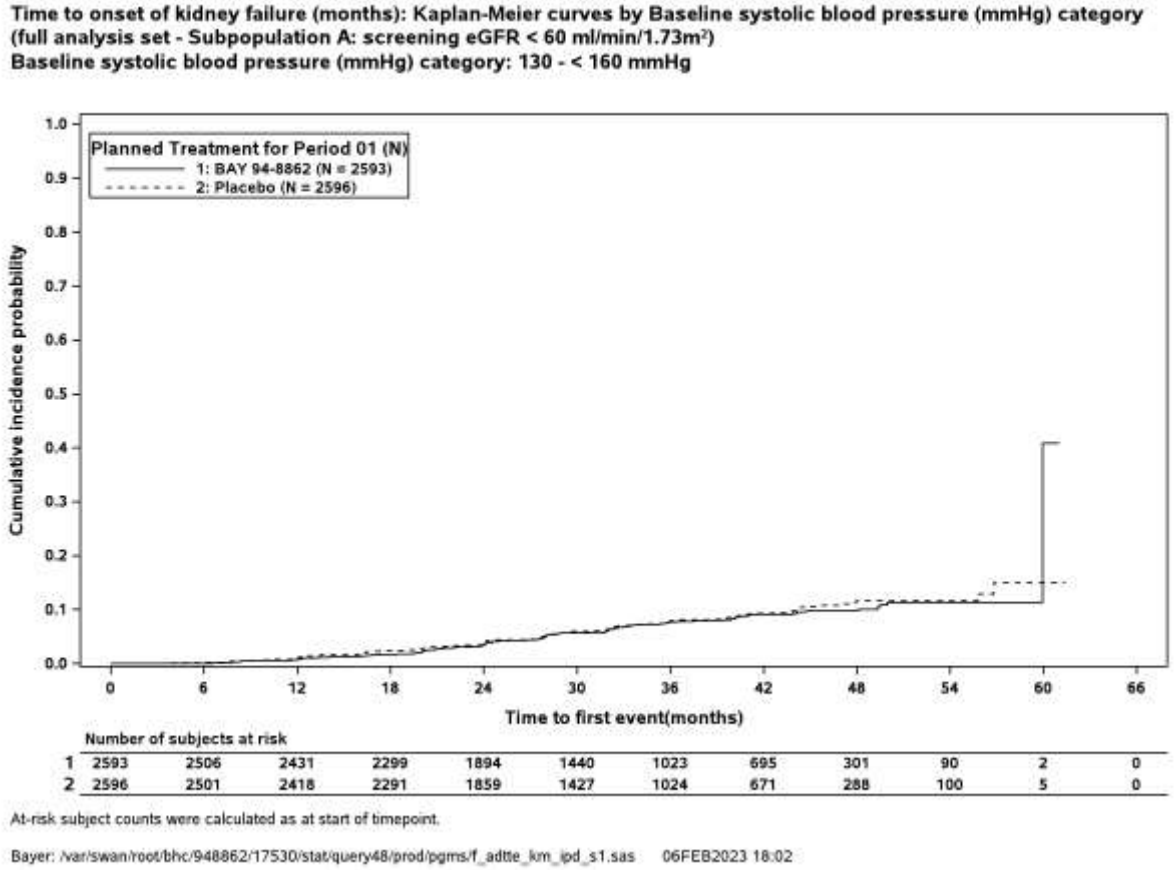


Figure 1.2.1 / 28: Time to onset of kidney failure (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

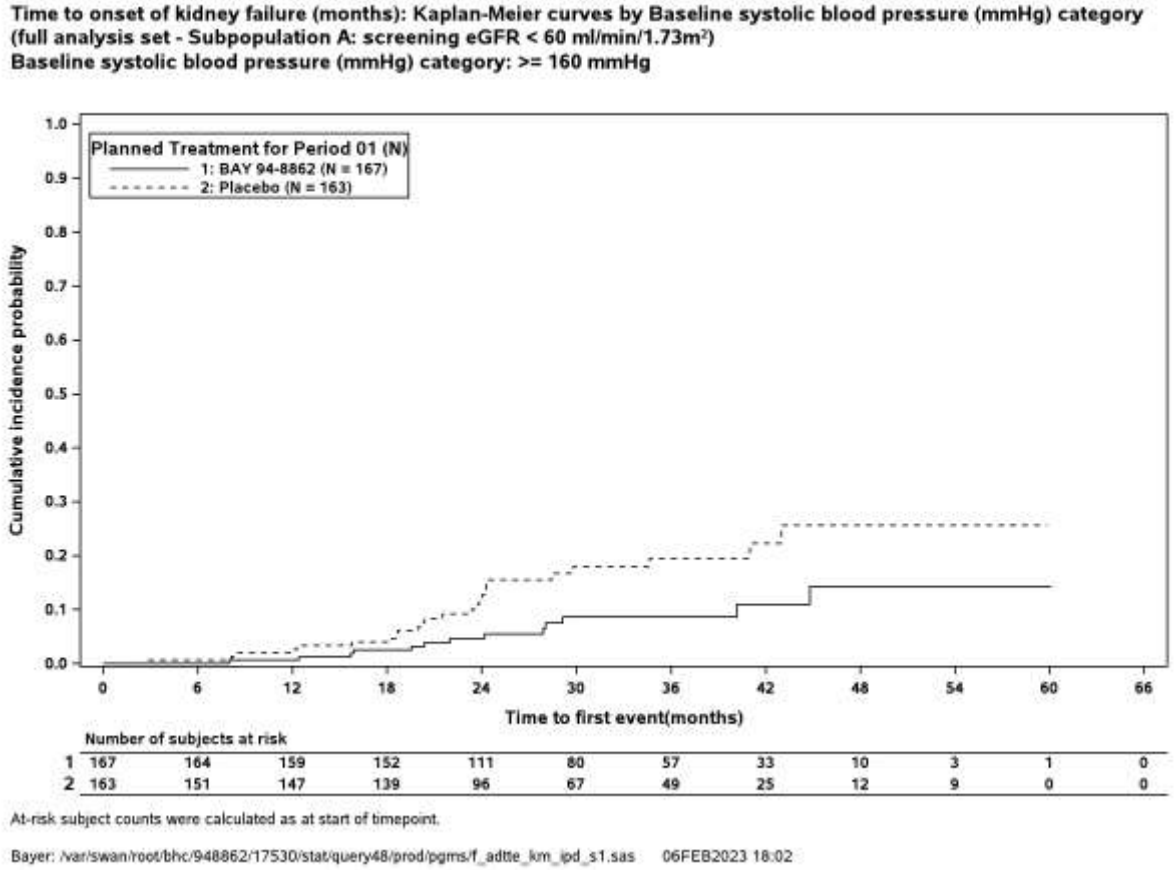


Figure 1.2.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

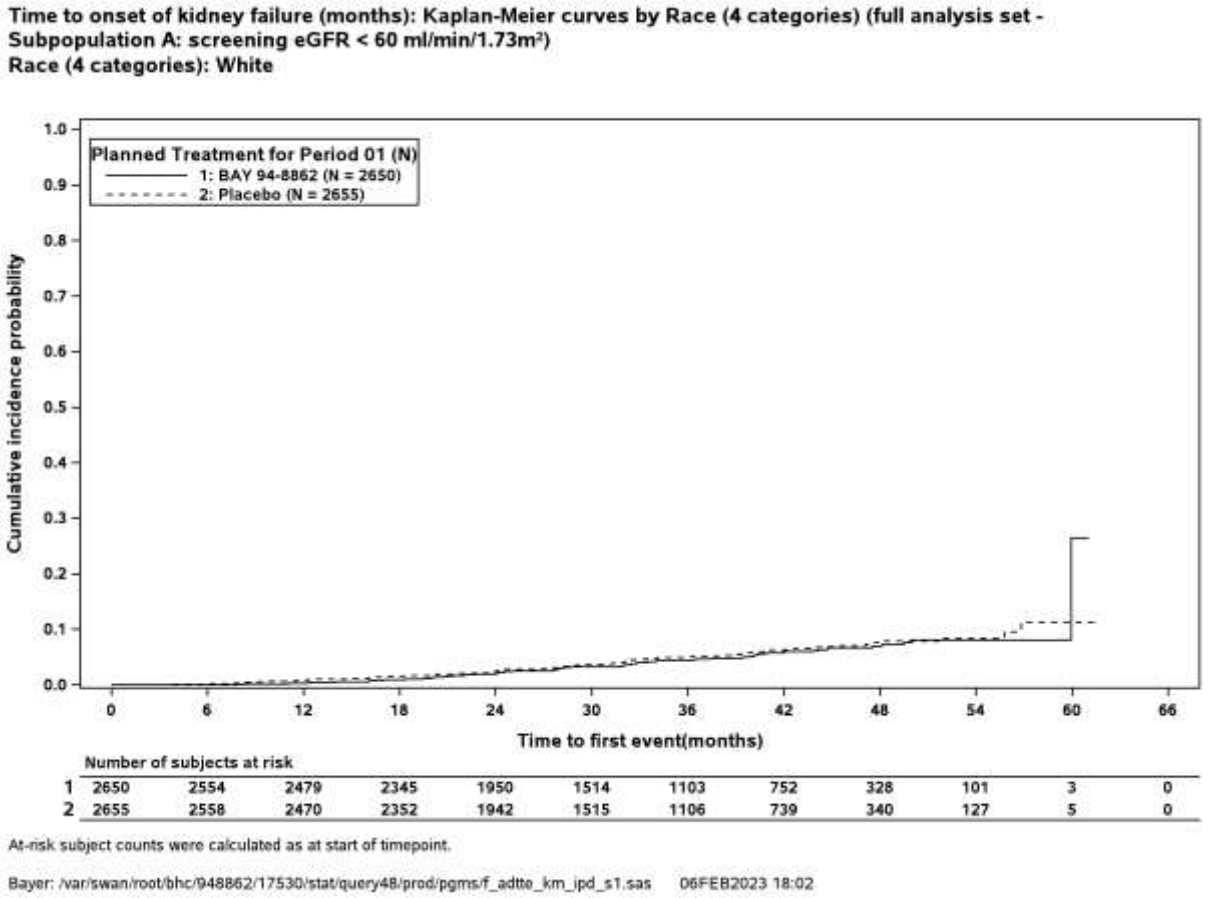


Figure 1.2.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

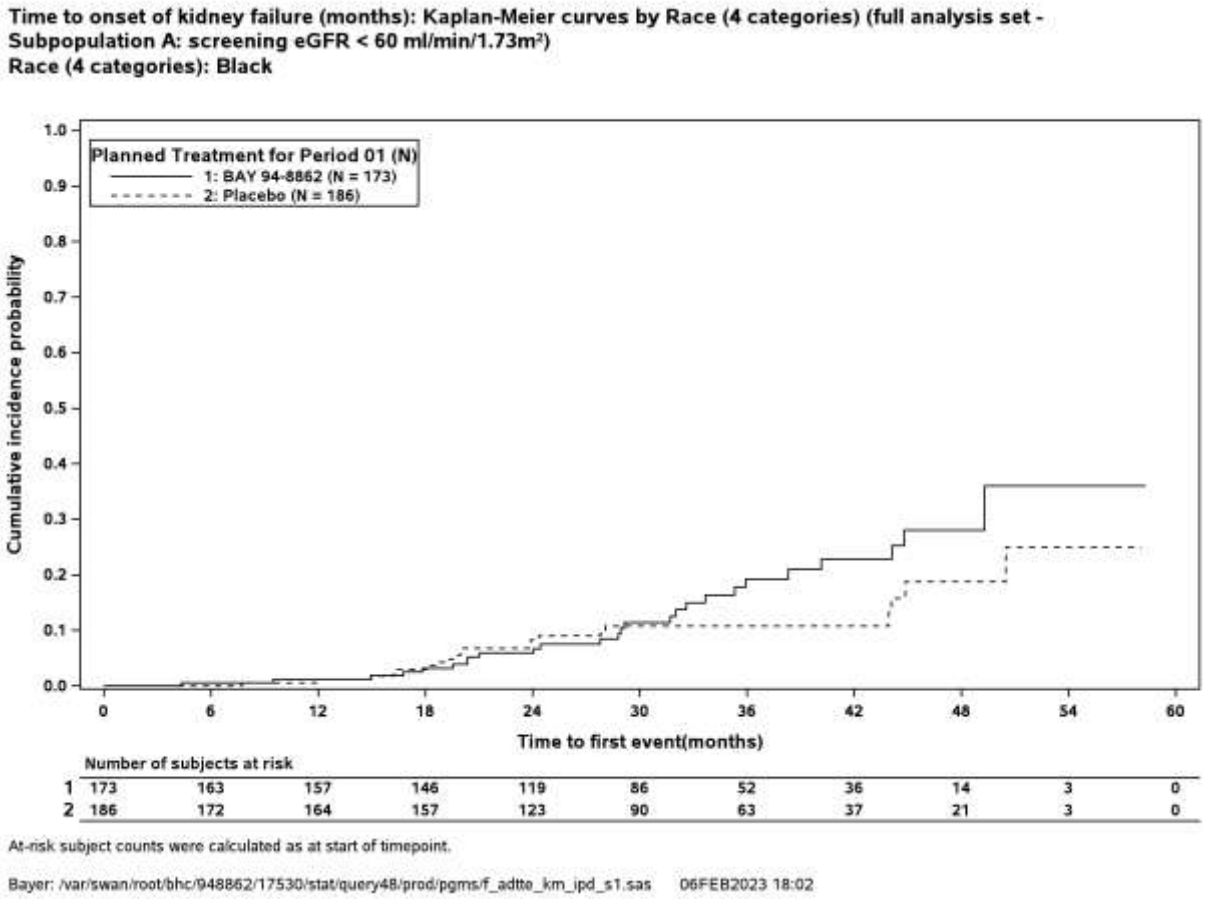


Figure 1.2.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

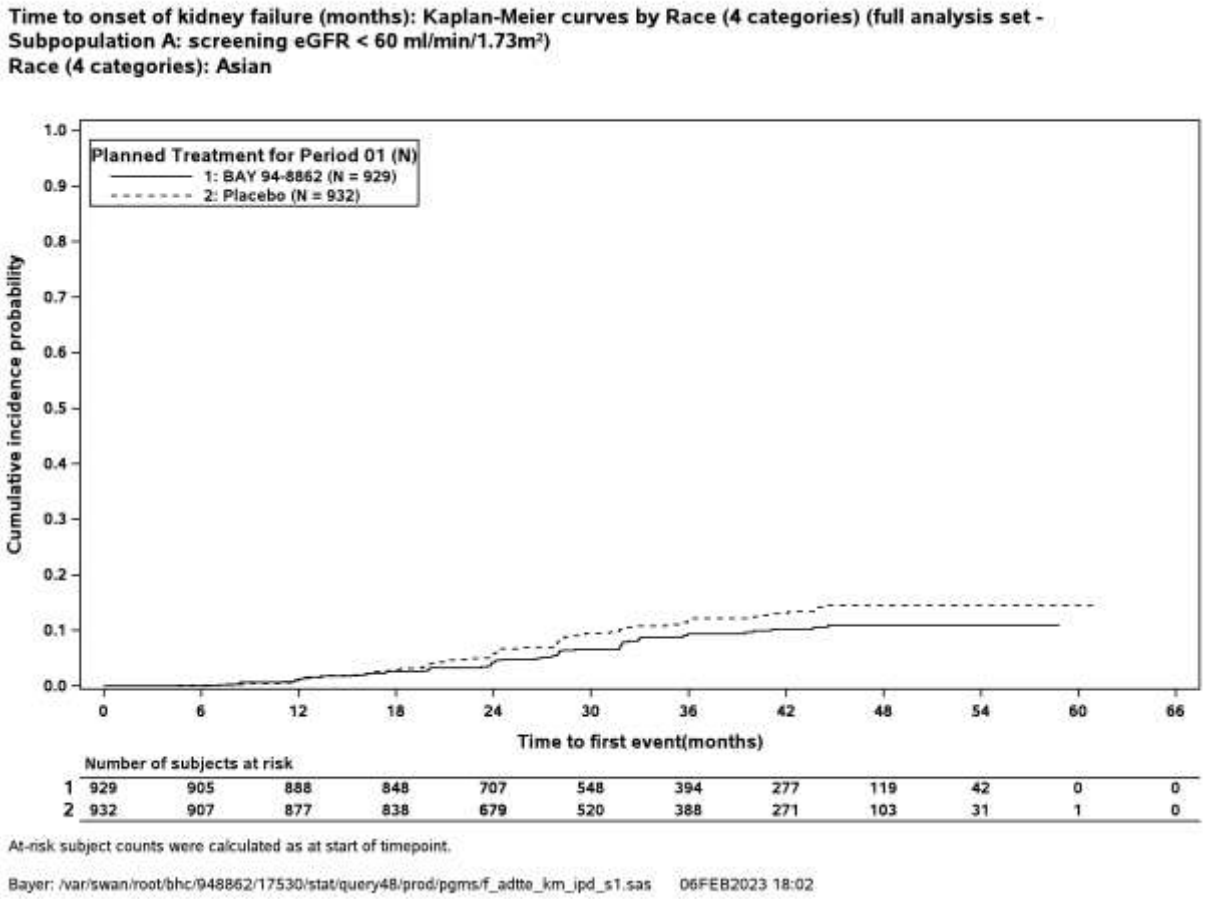


Figure 1.2.1 / 29: Time to onset of kidney failure (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

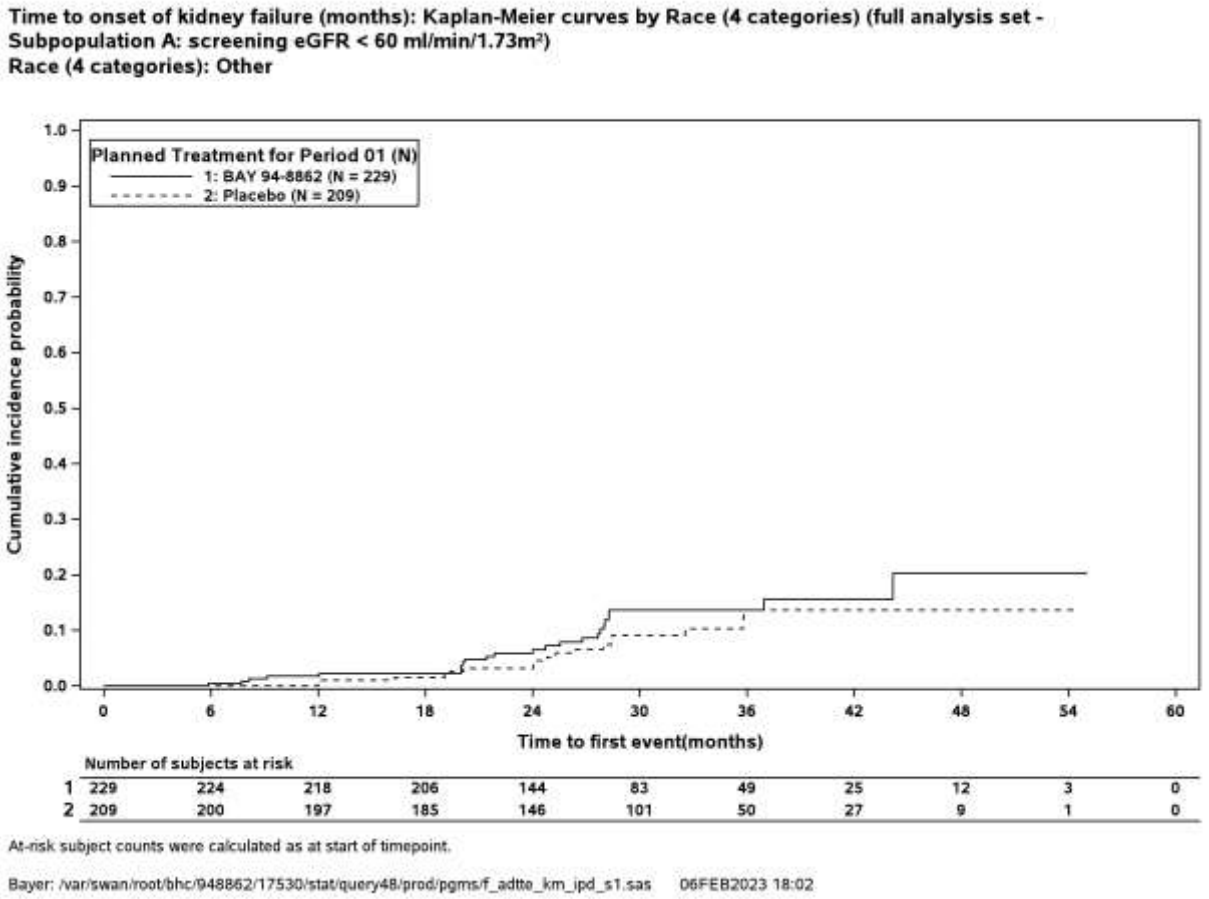


Figure 1.2.1 / 30: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

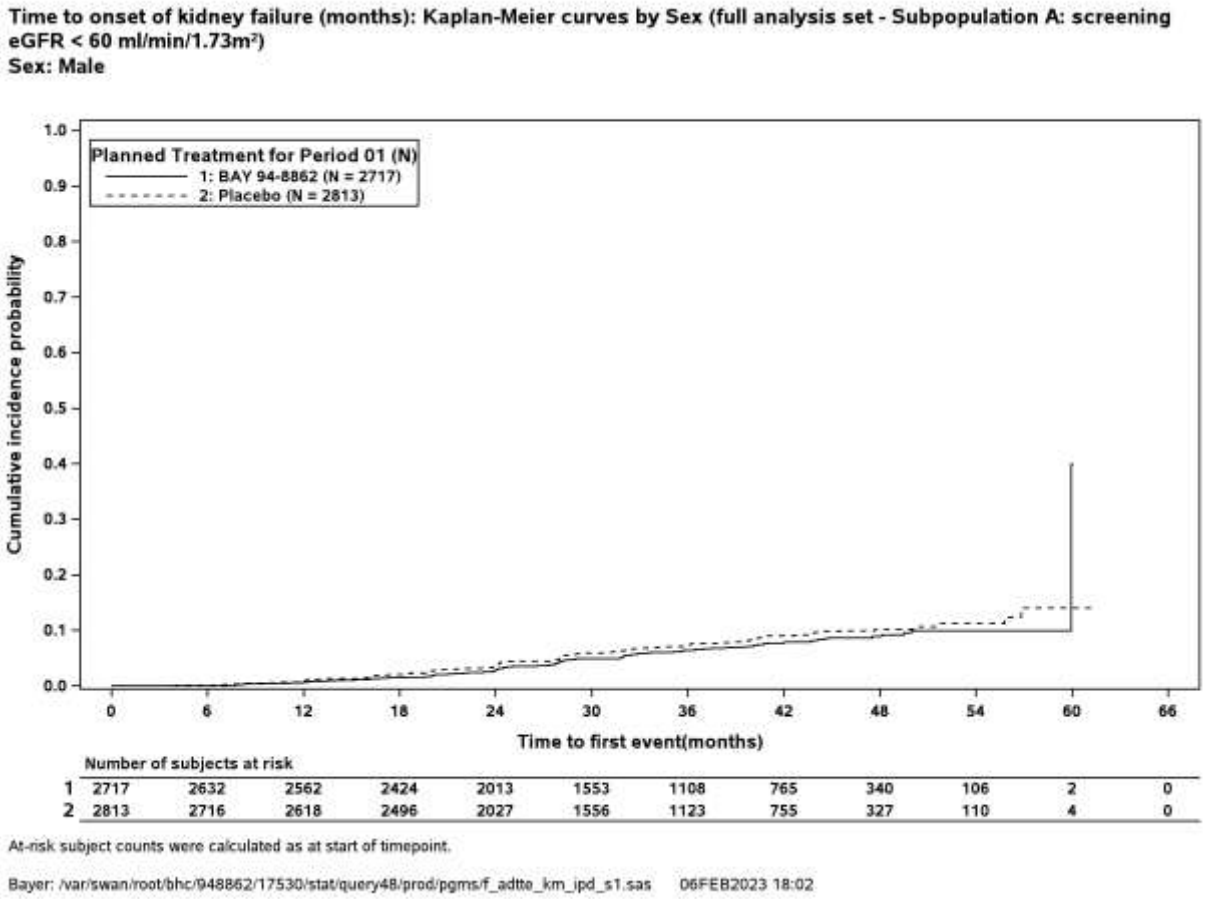


Figure 1.2.1 / 30: Time to onset of kidney failure (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

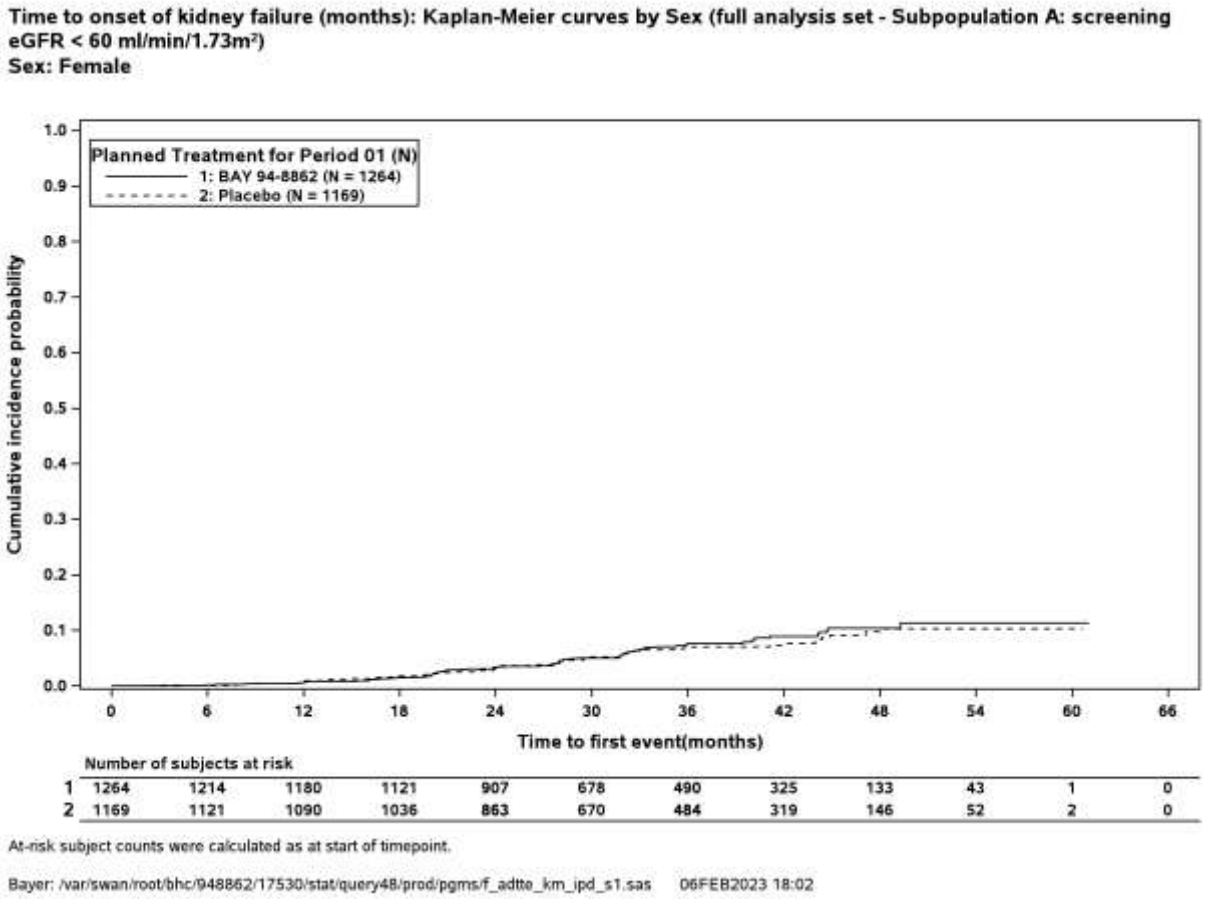


Figure 1.2.1 / 31: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

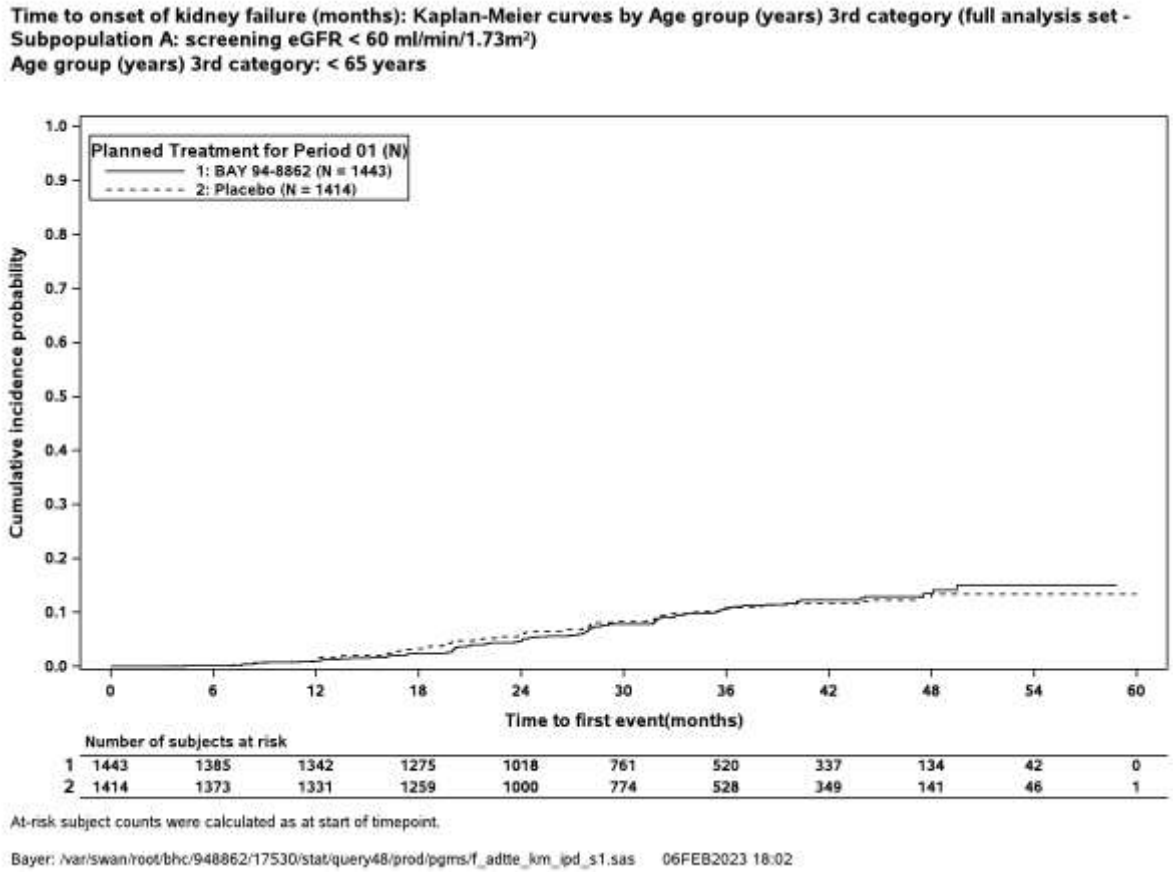


Figure 1.2.1 / 31: Time to onset of kidney failure (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

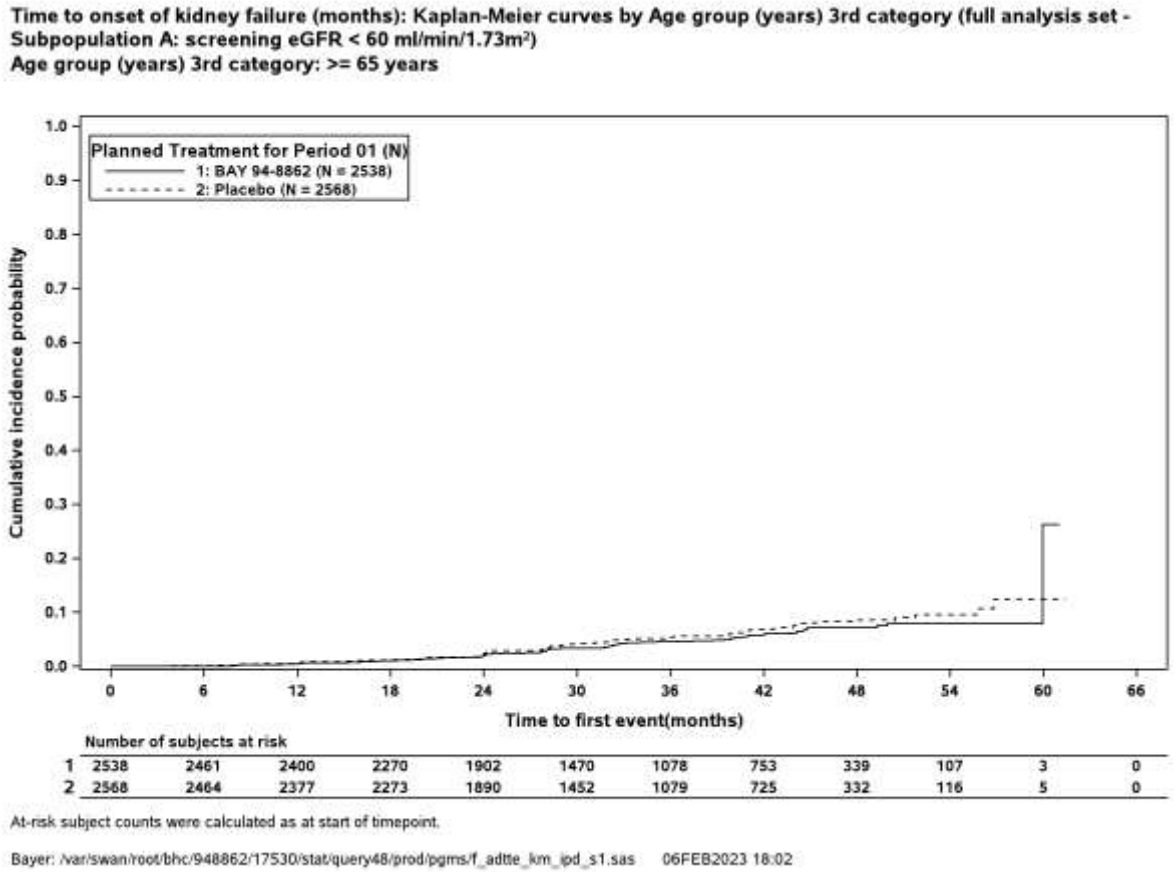


Figure 1.2.1 / 32: Time to onset of ESRD (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

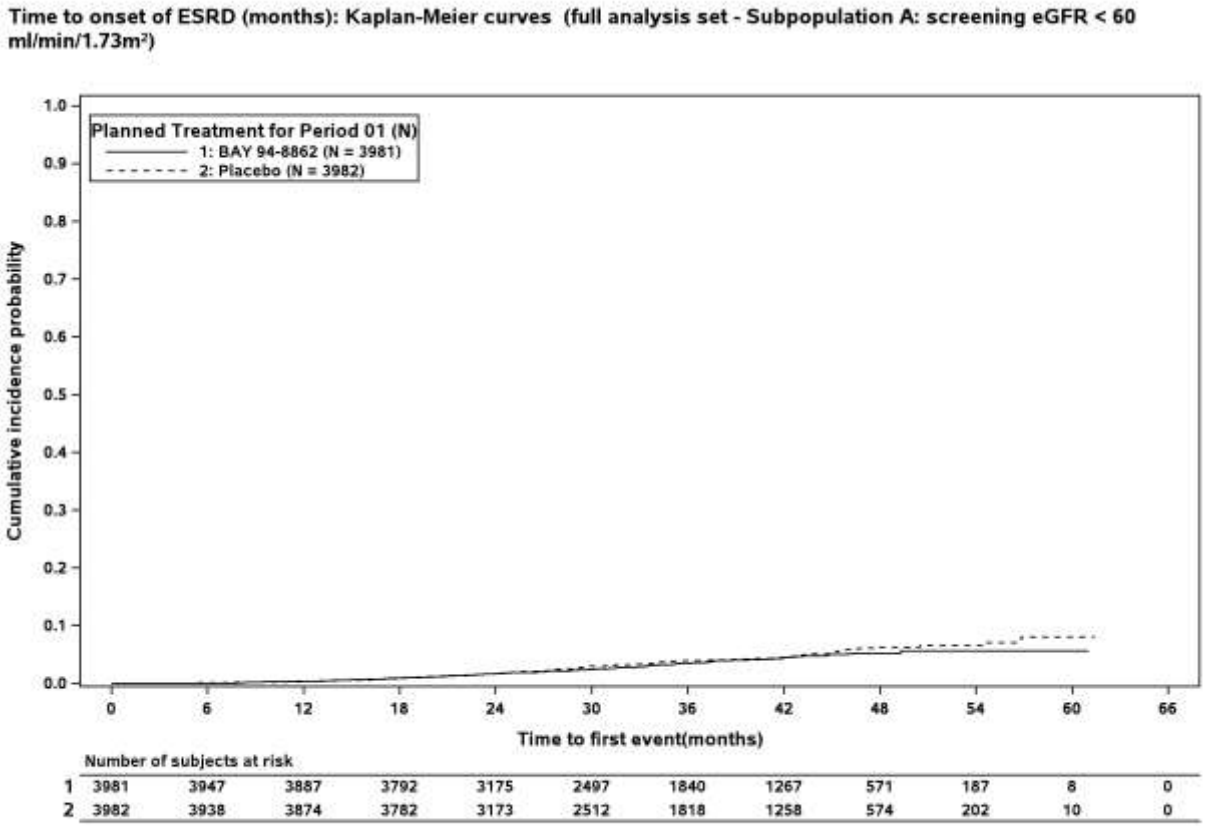


Figure 1.2.1 / 33: Time to onset of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

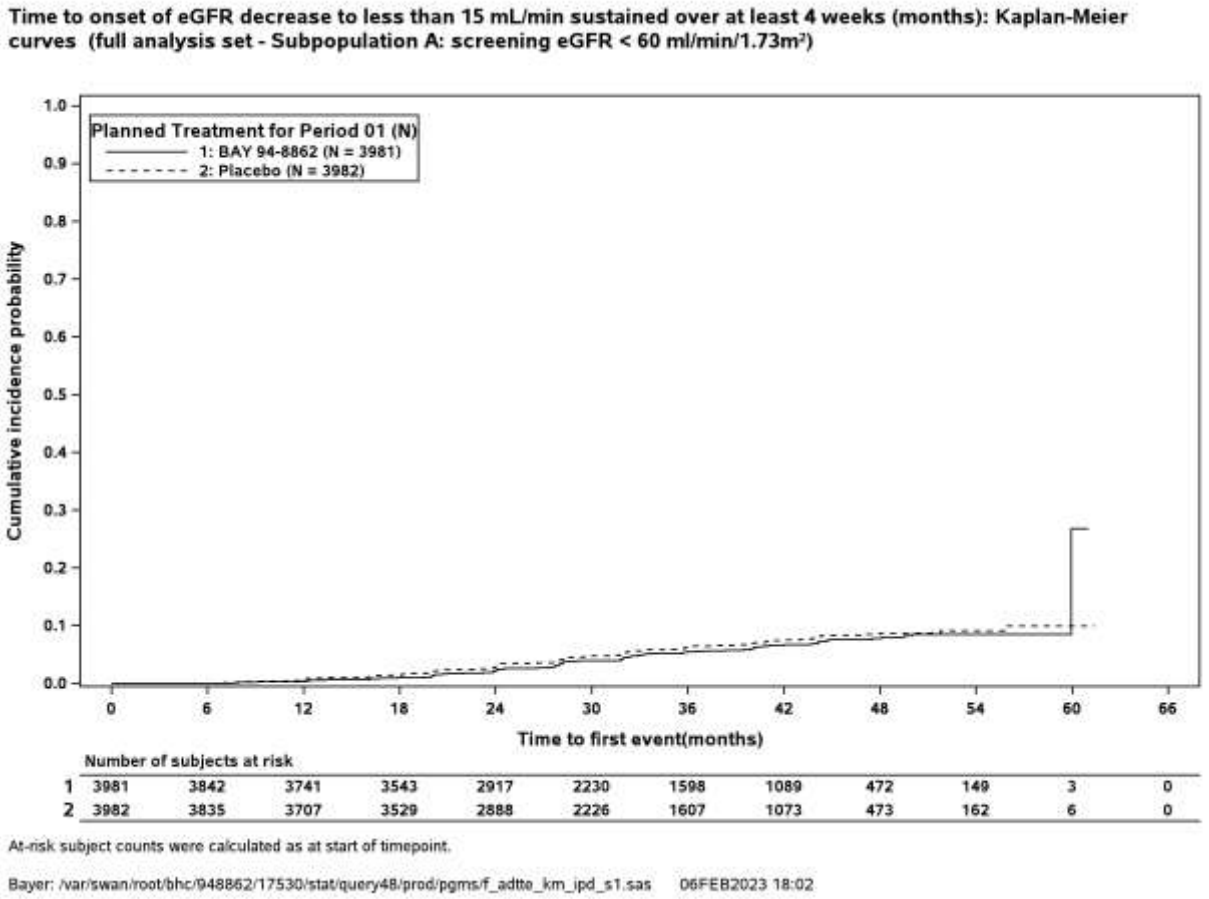


Figure 1.2.1 / 34: Time to onset of eGFR decrease of >=57% sustained over at least 4 weeks (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

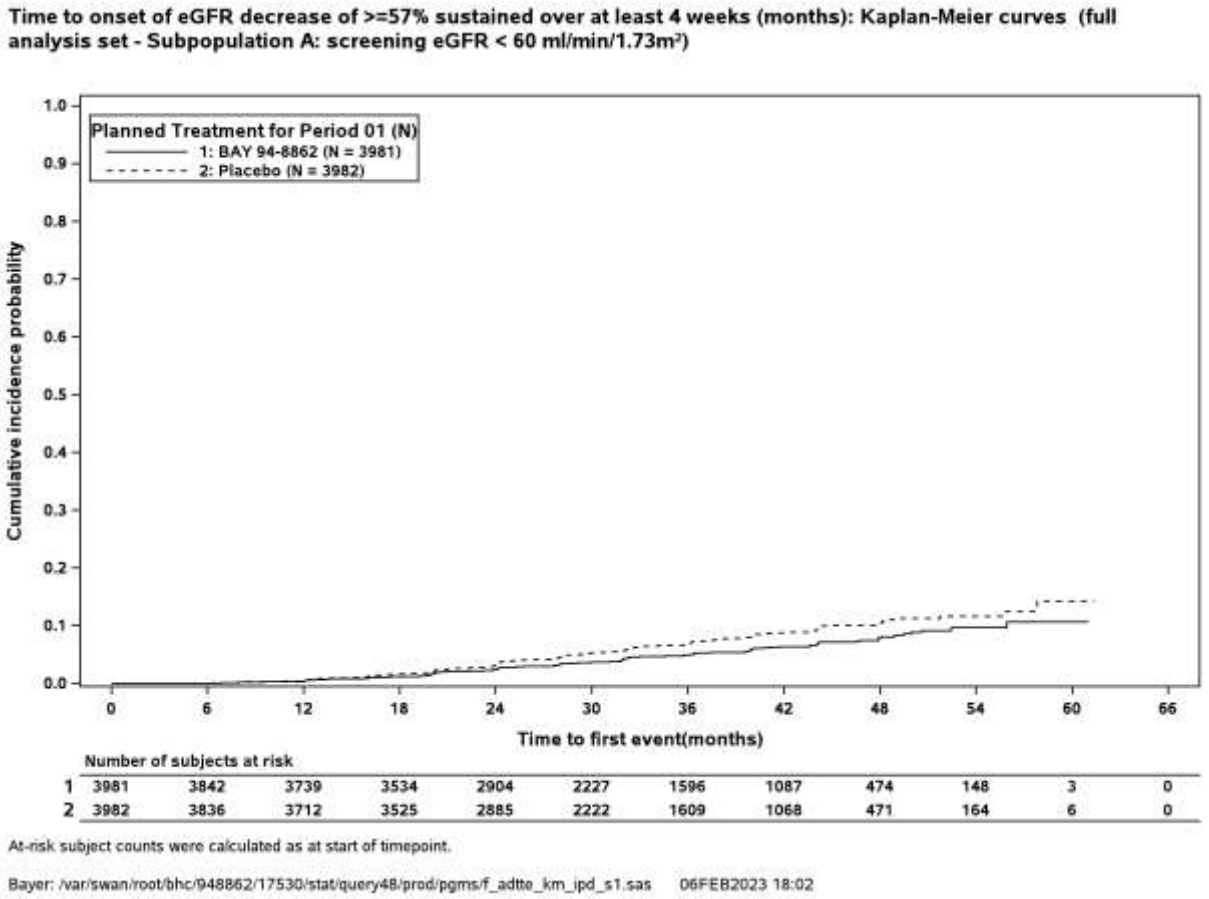


Figure 1.2.1 / 35: Time to renal death (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

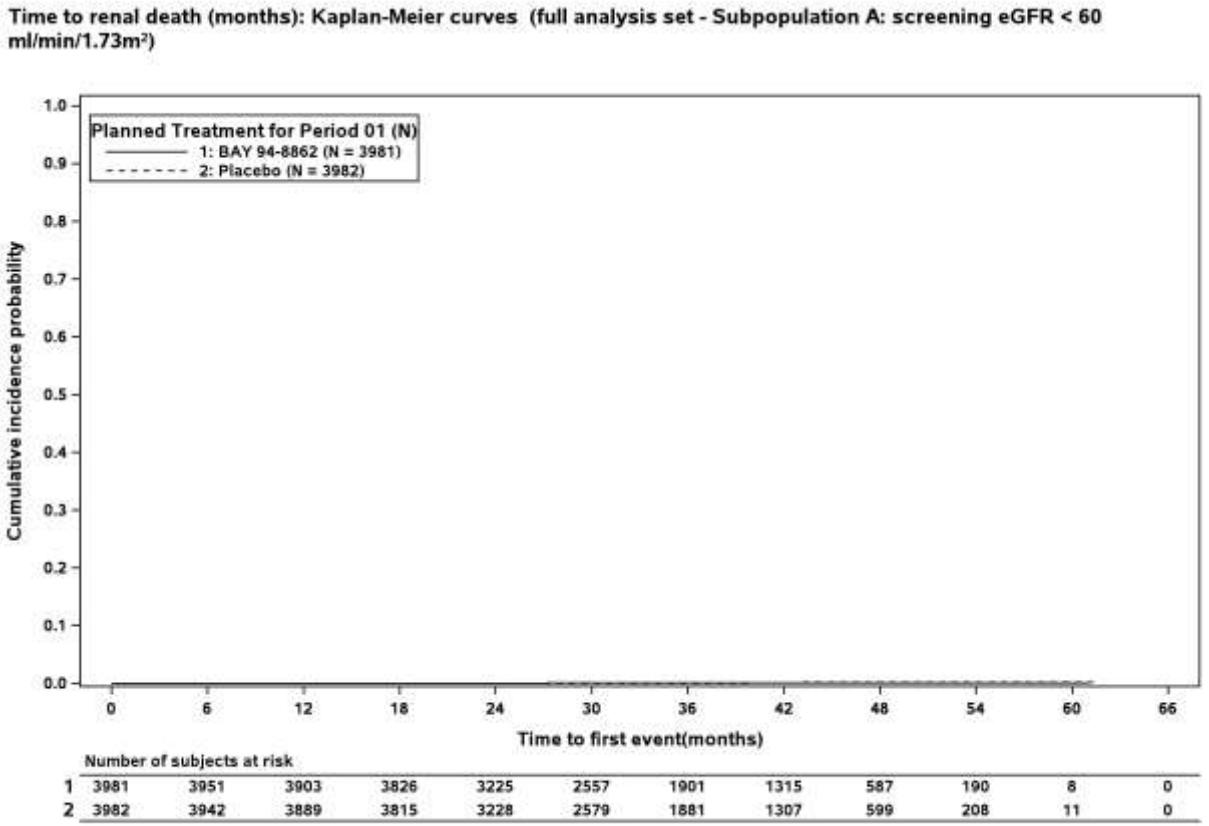


Figure 1.2.1 / 36: Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

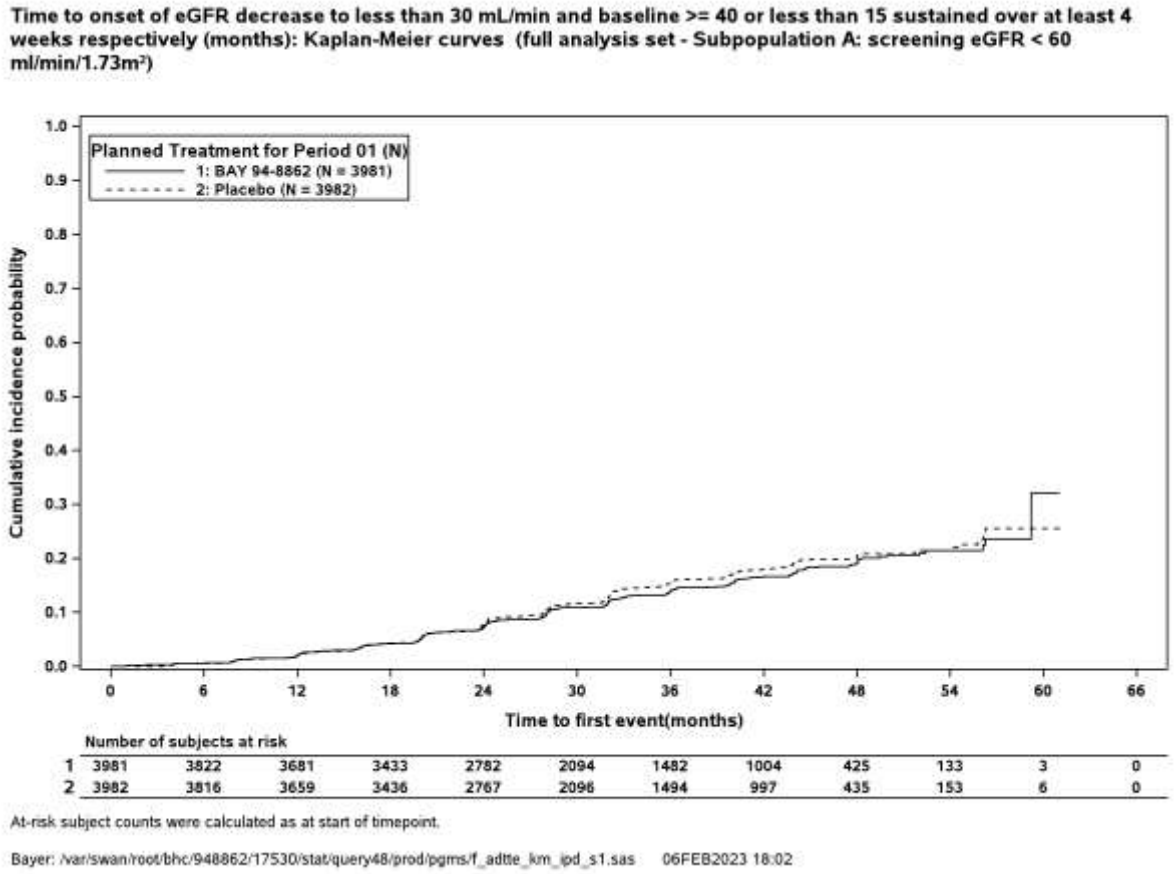


Figure 1.2.1 / 37: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

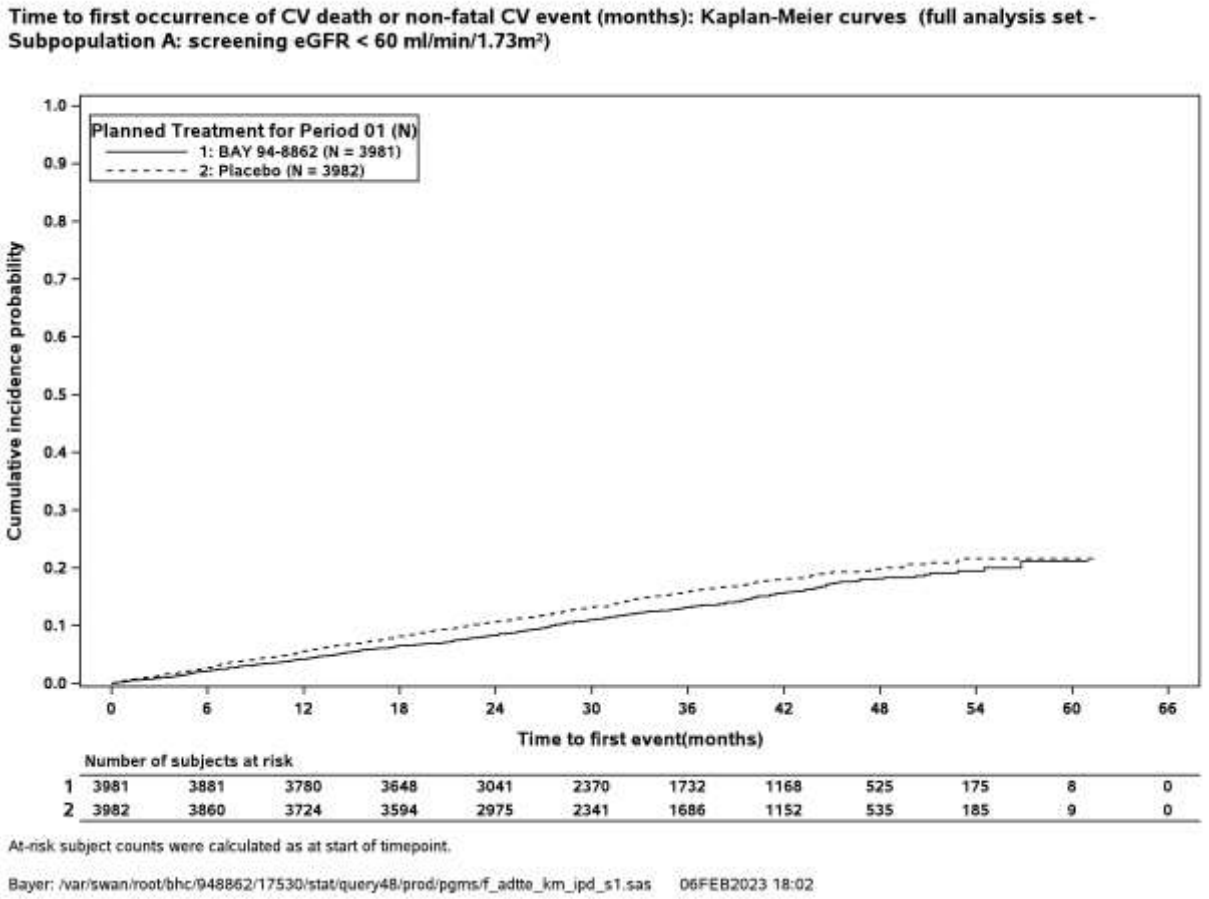


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

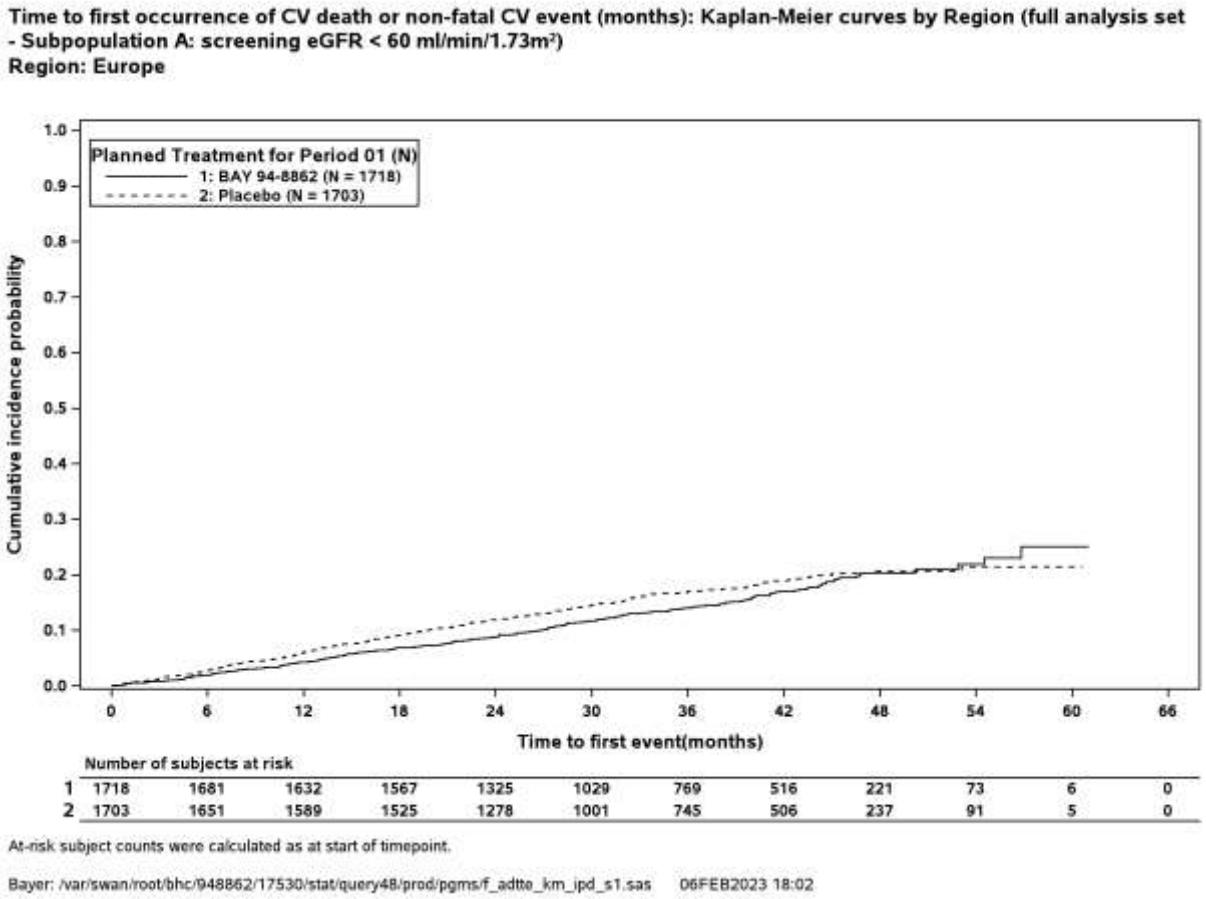


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

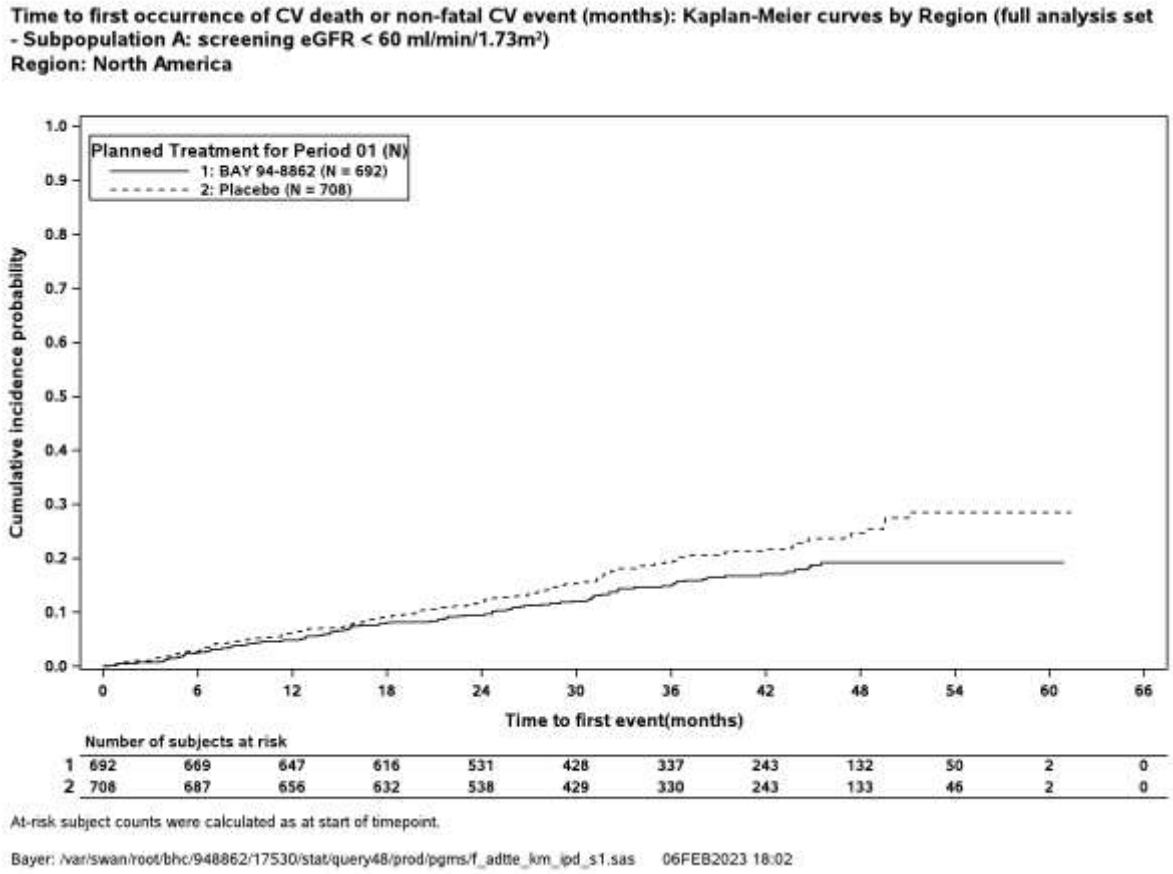


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

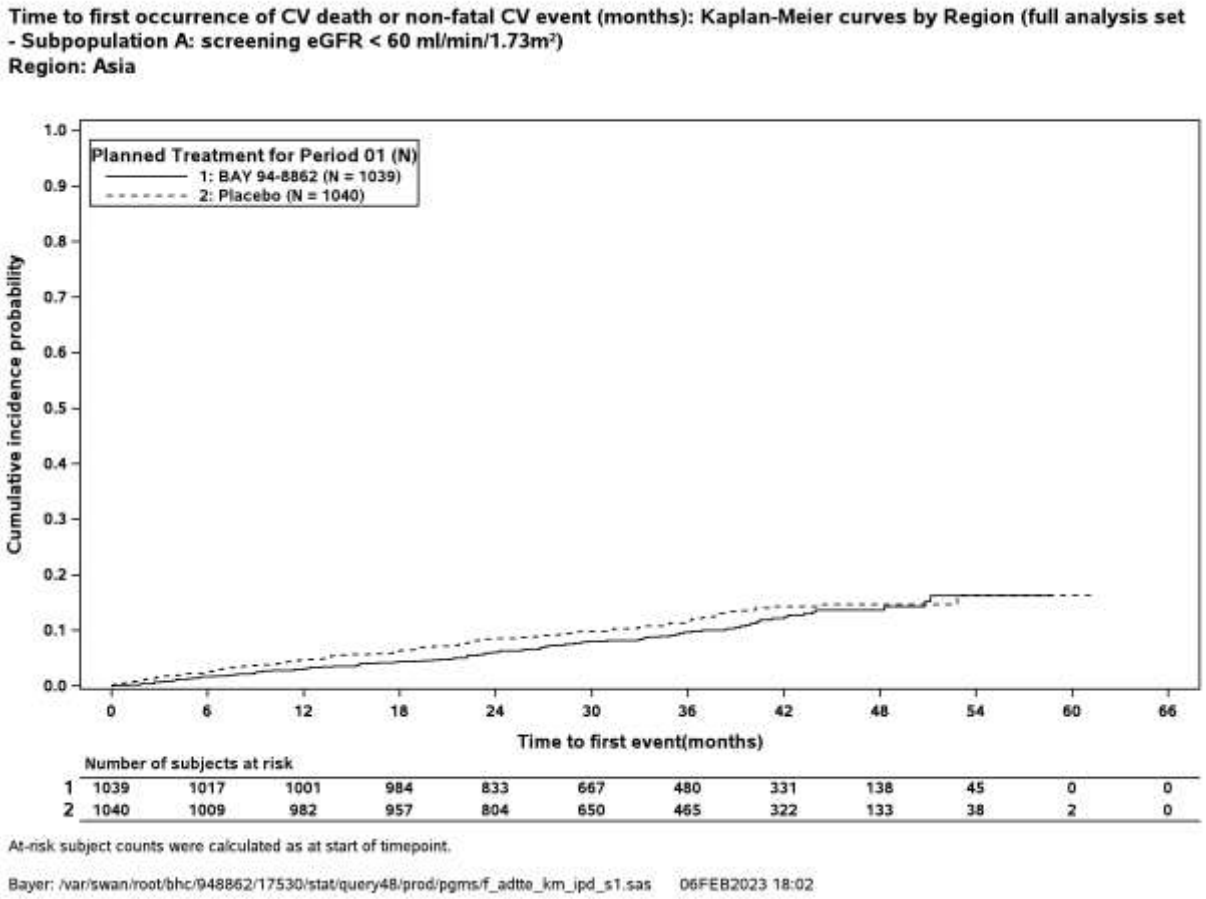


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

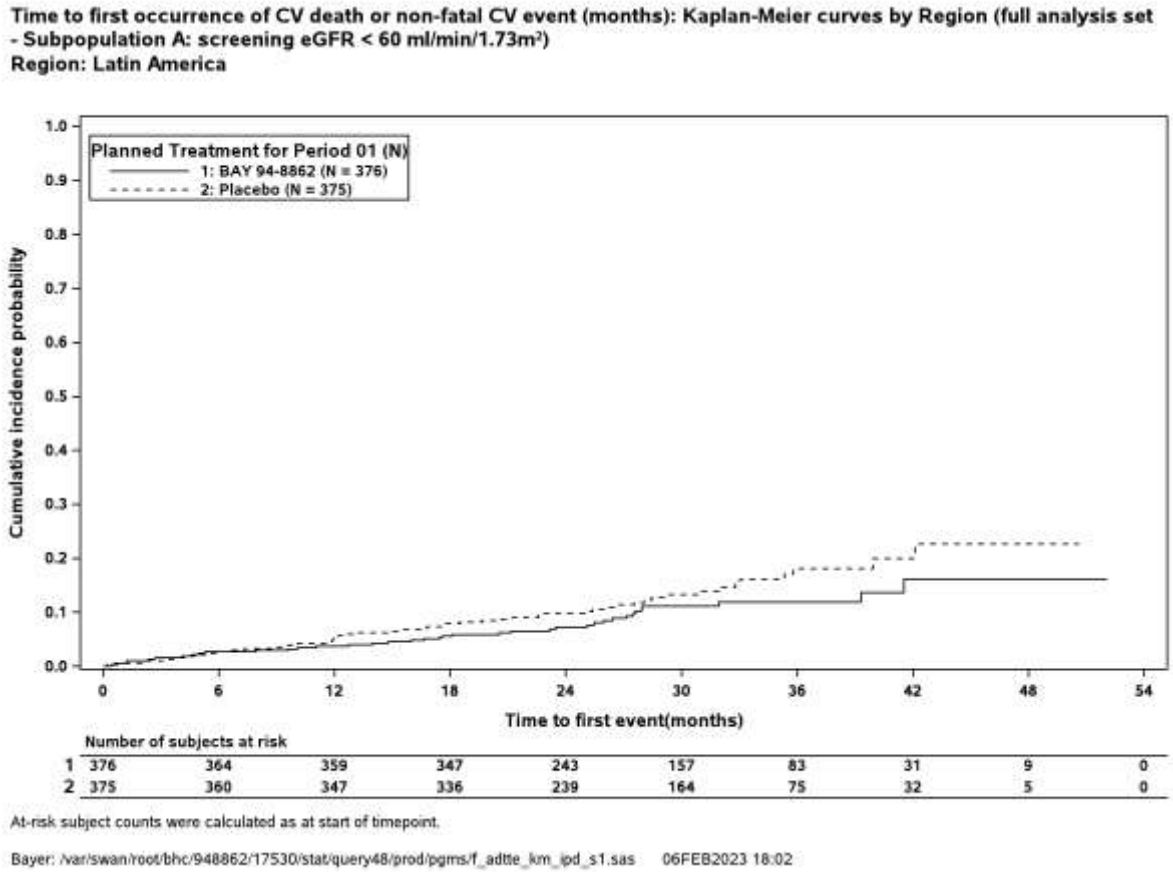


Figure 1.2.1 / 38: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

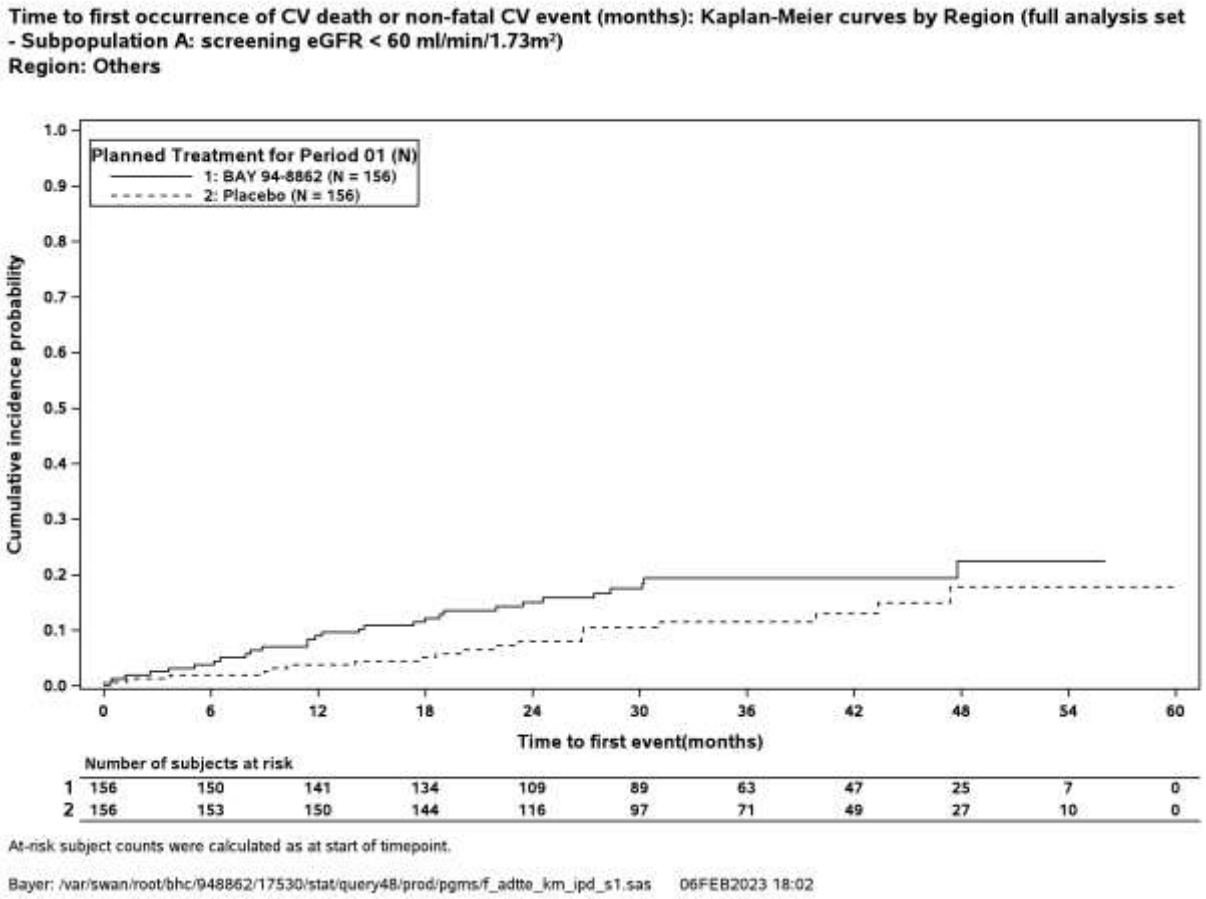


Figure 1.2.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

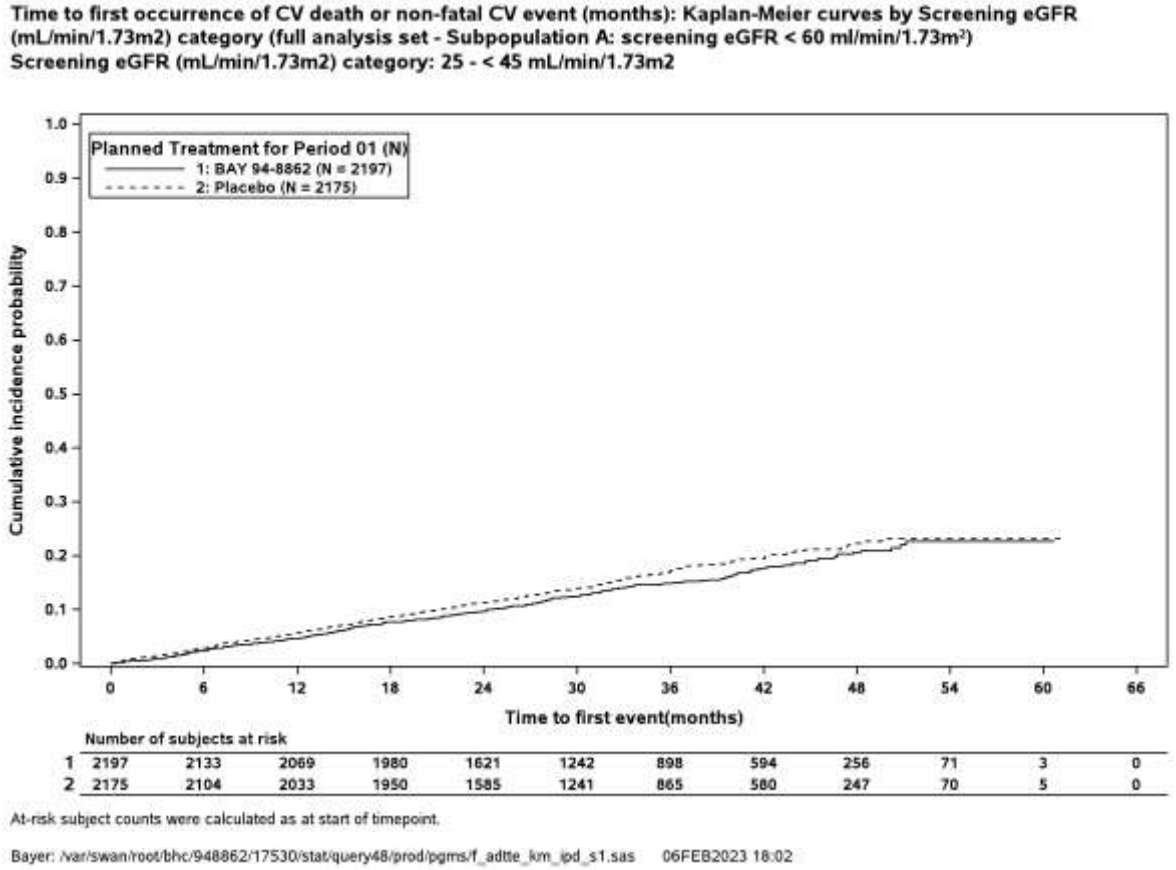


Figure 1.2.1 / 39: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

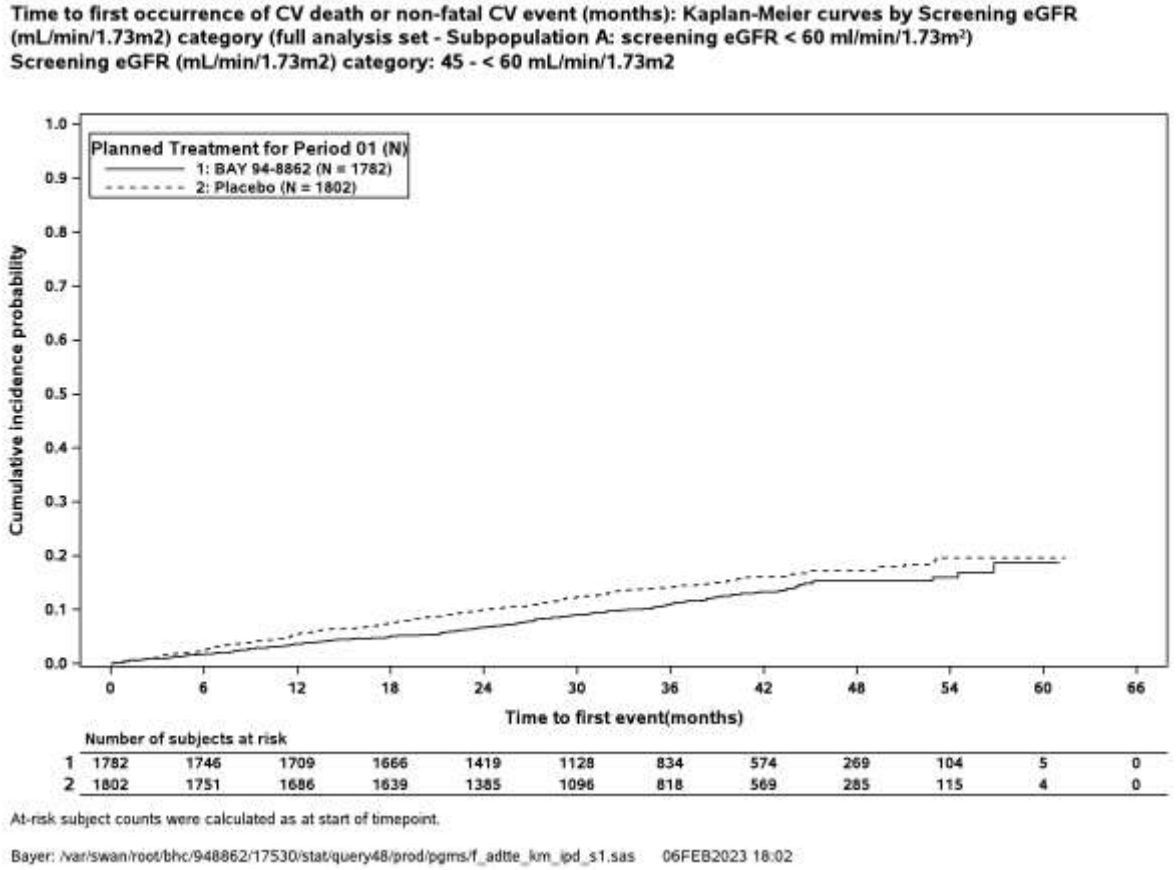


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

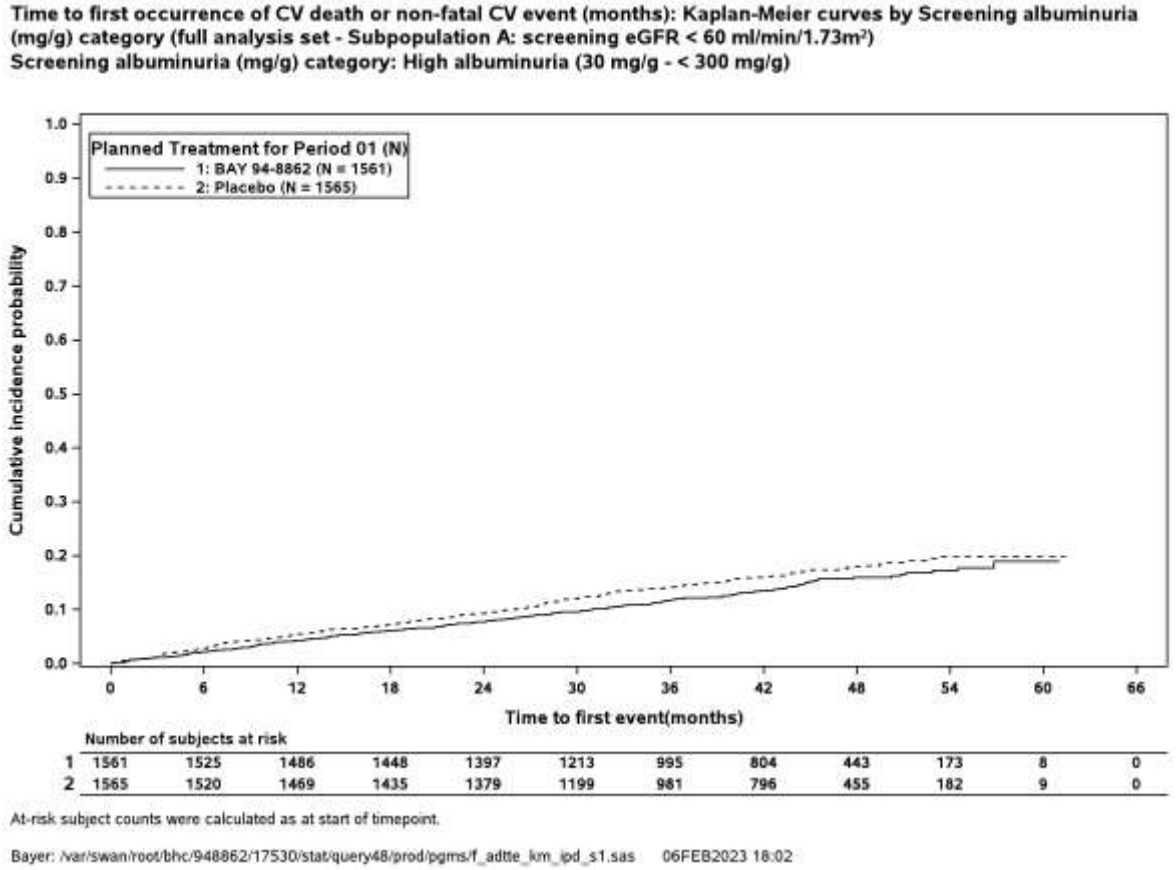


Figure 1.2.1 / 40: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

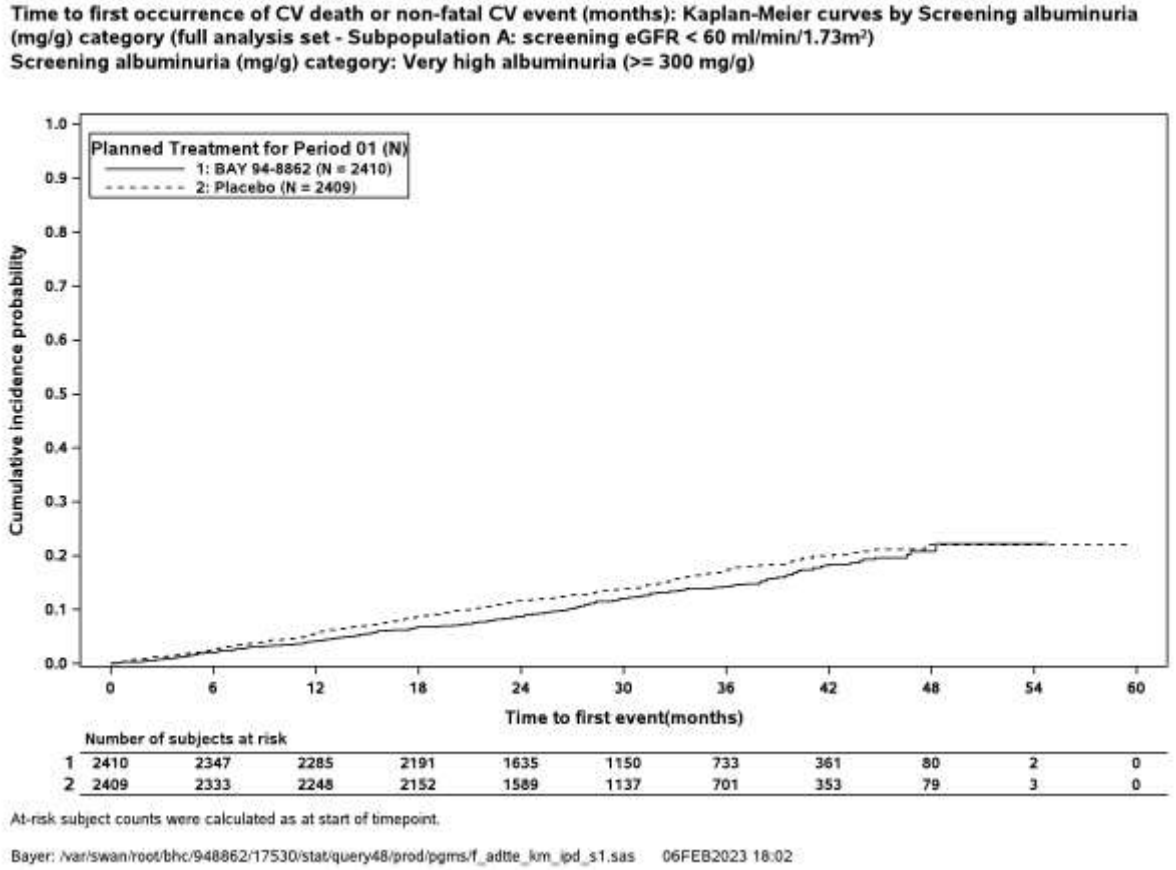


Figure 1.2.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

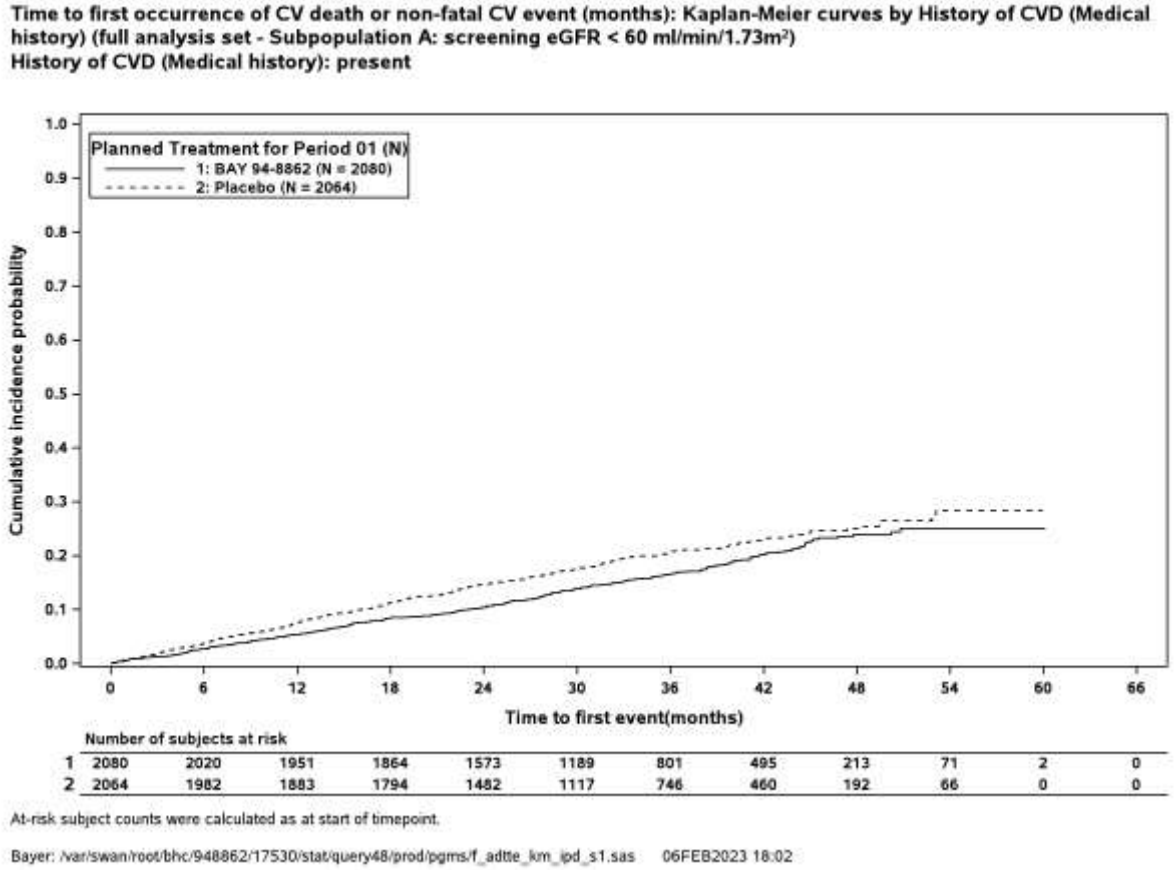


Figure 1.2.1 / 41: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

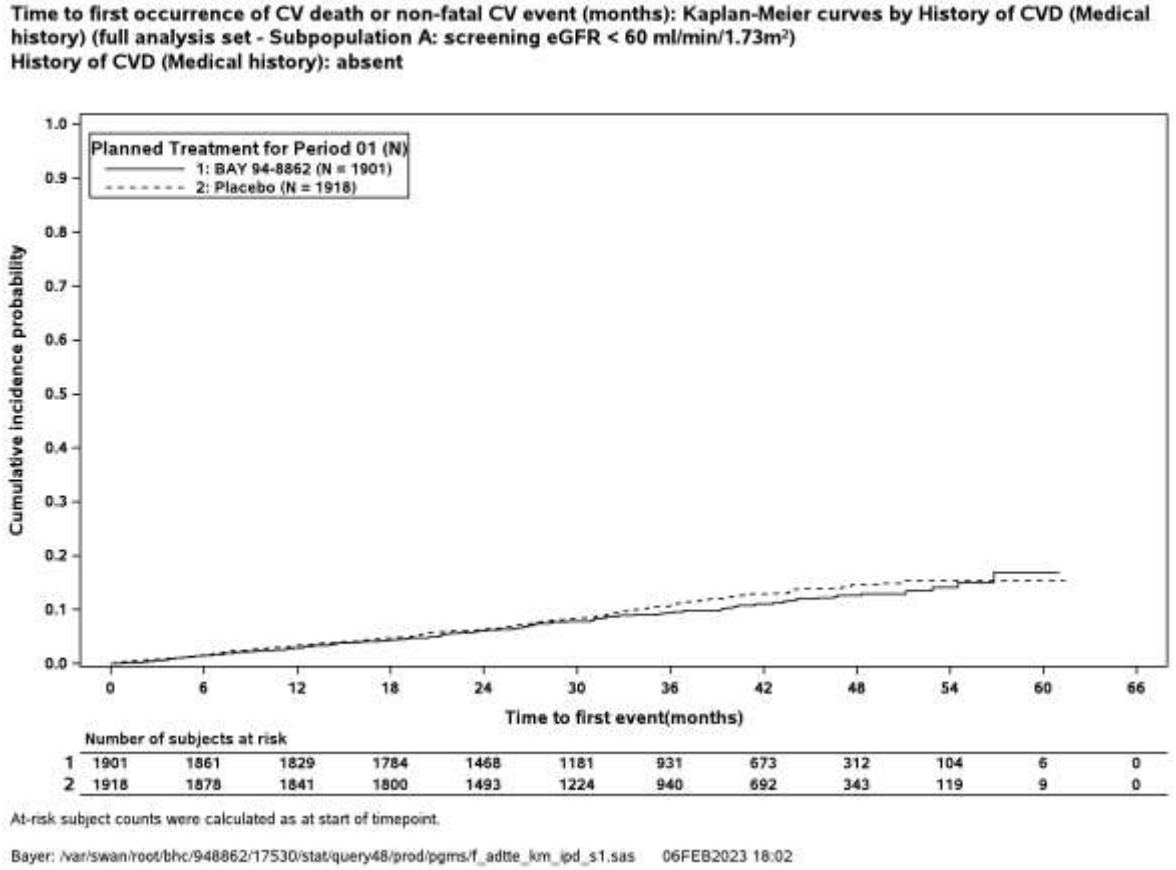


Figure 1.2.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

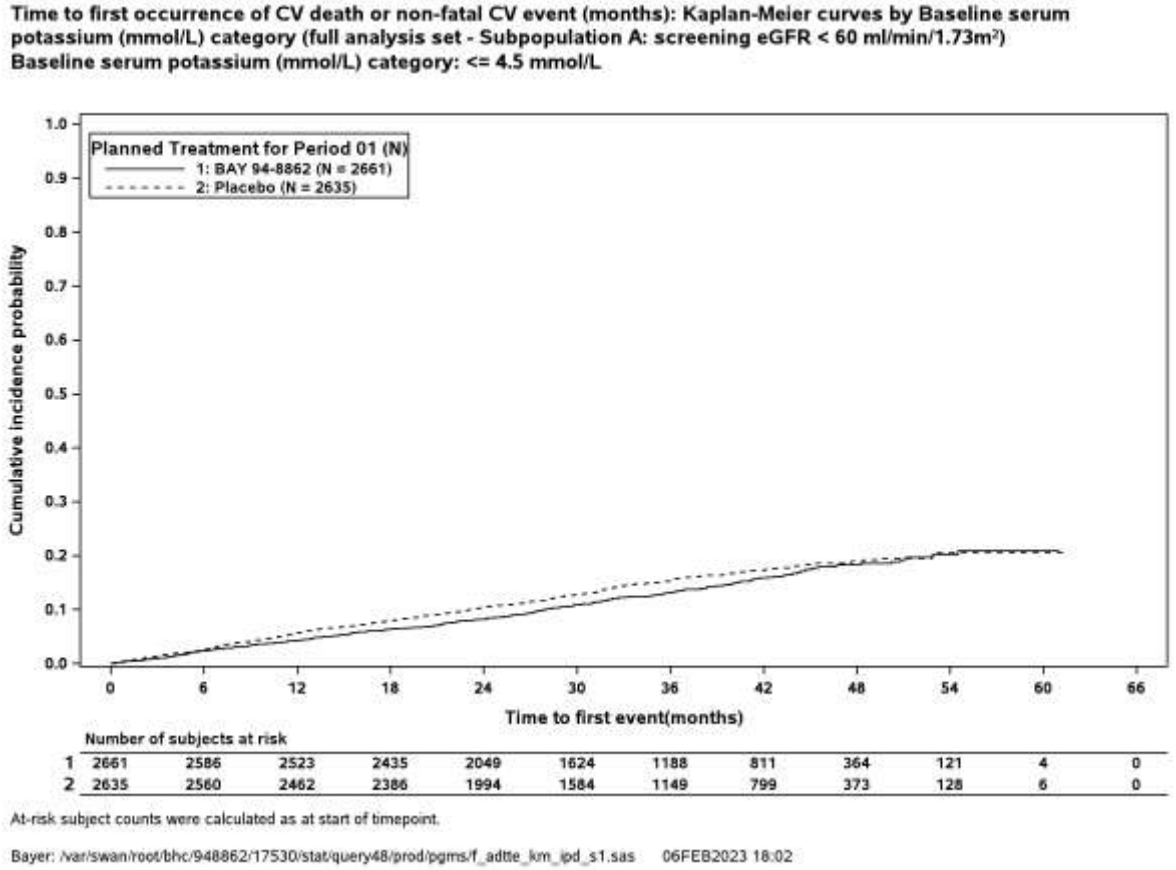


Figure 1.2.1 / 42: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

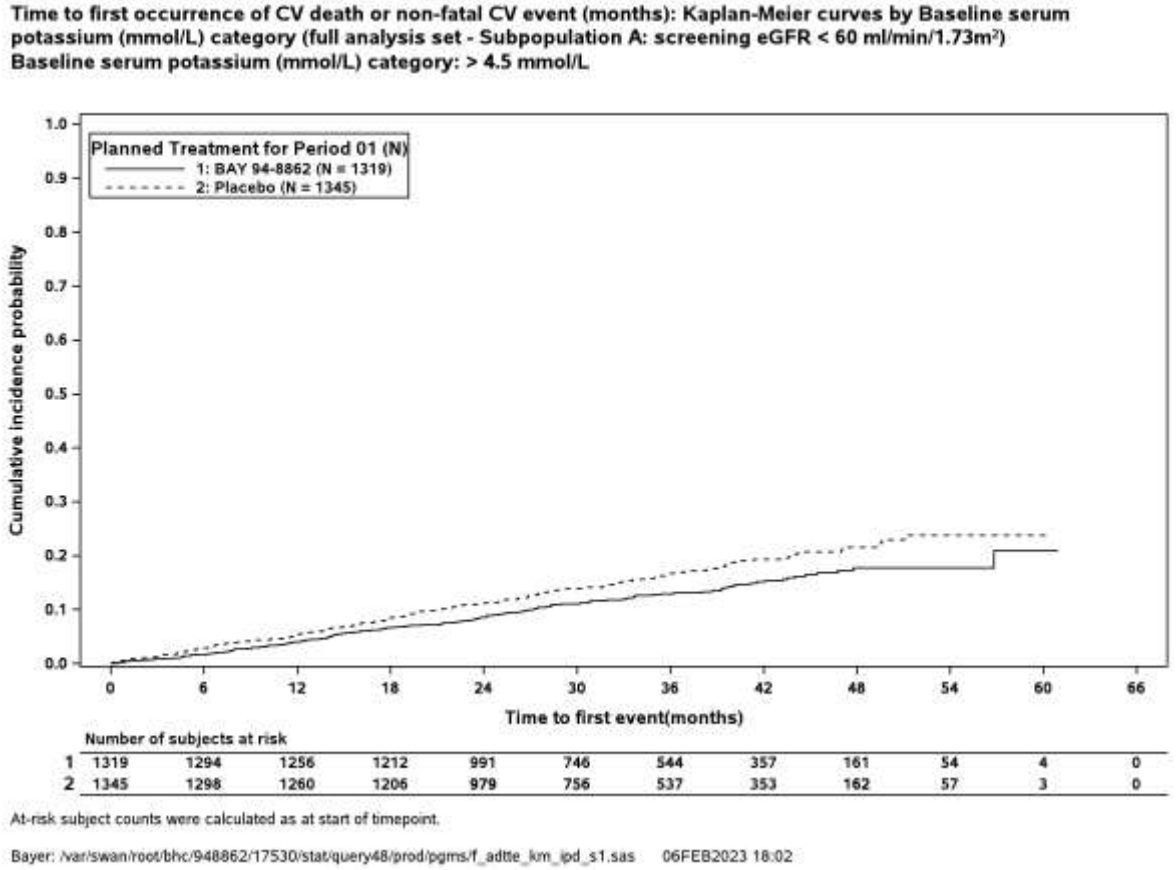


Figure 1.2.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

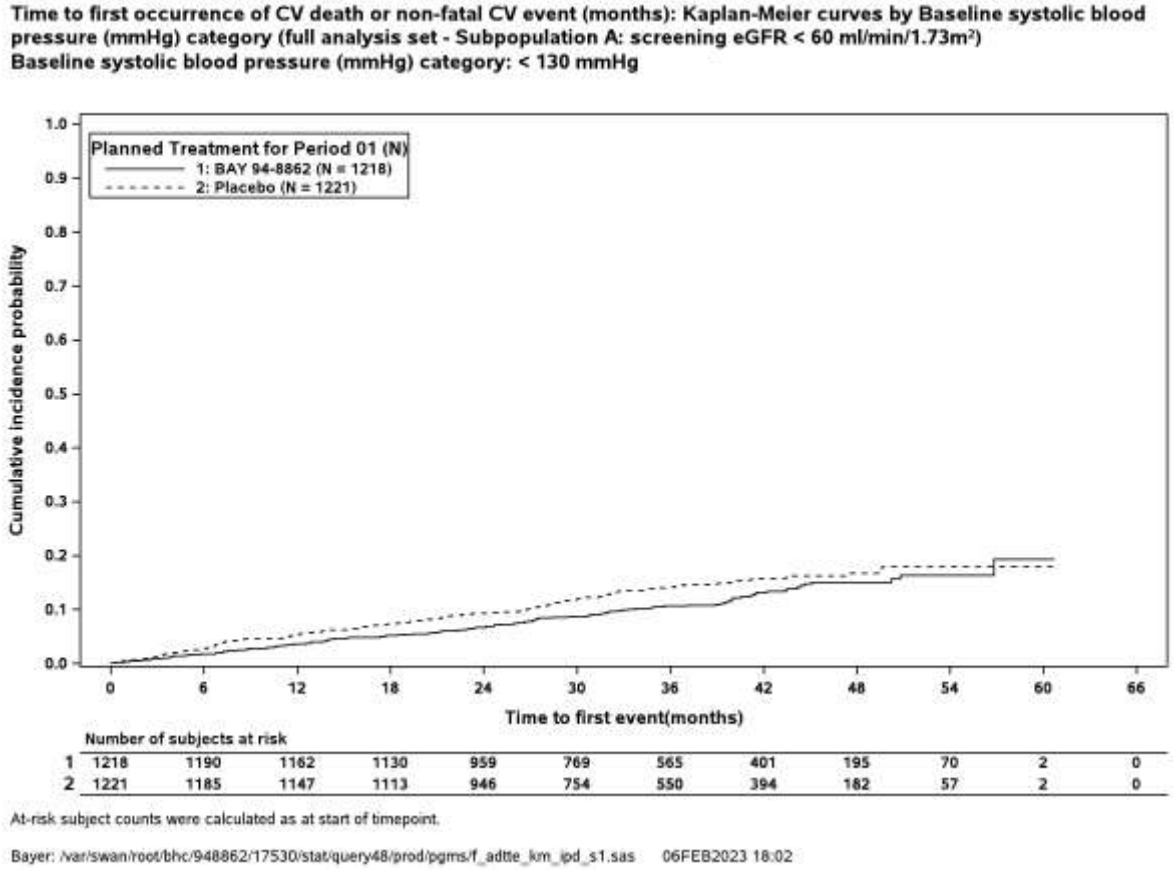


Figure 1.2.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

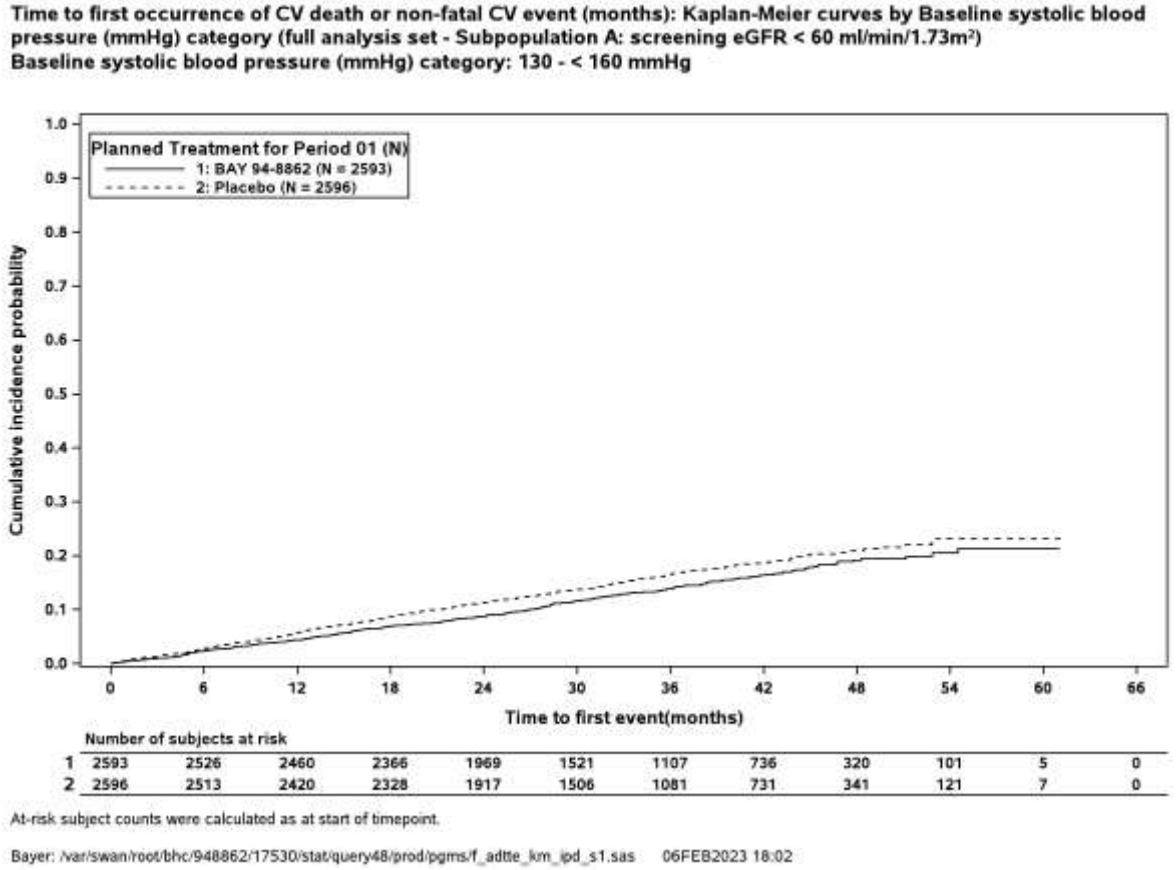
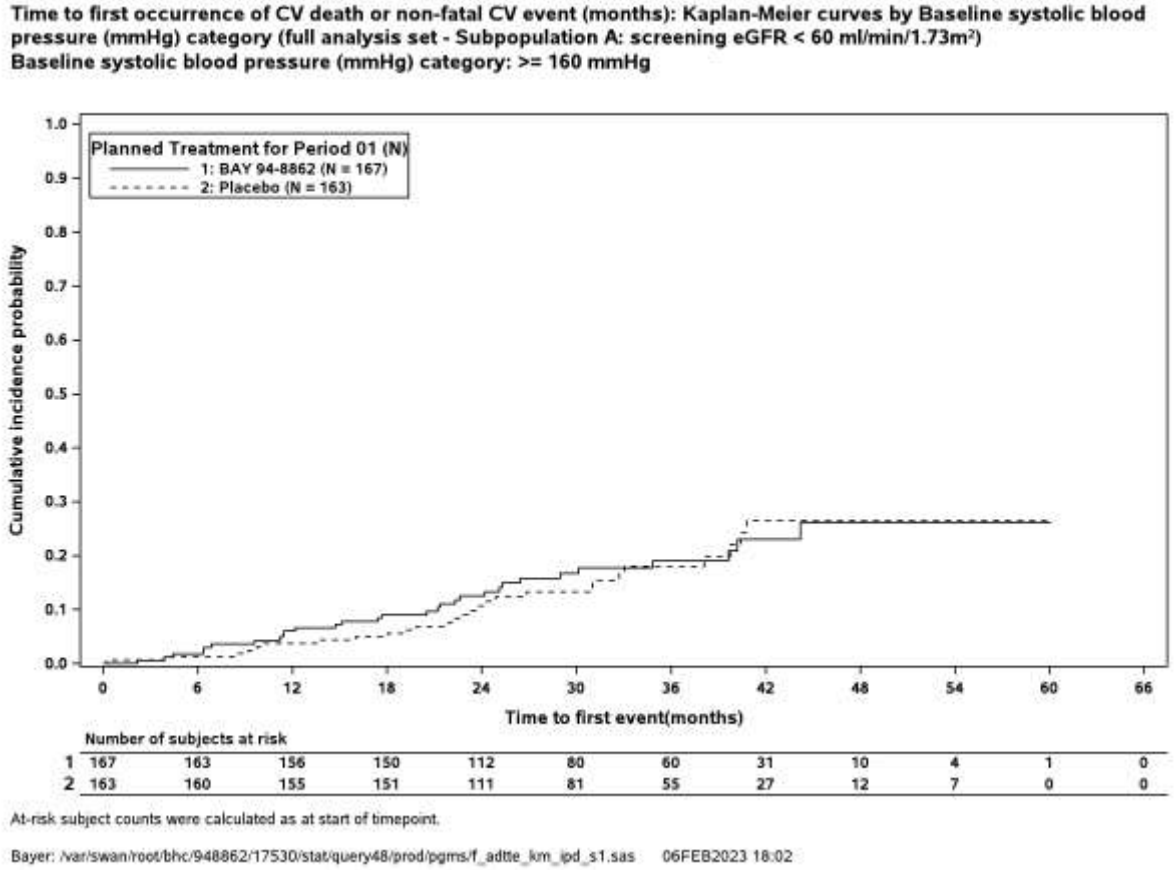


Figure 1.2.1 / 43: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

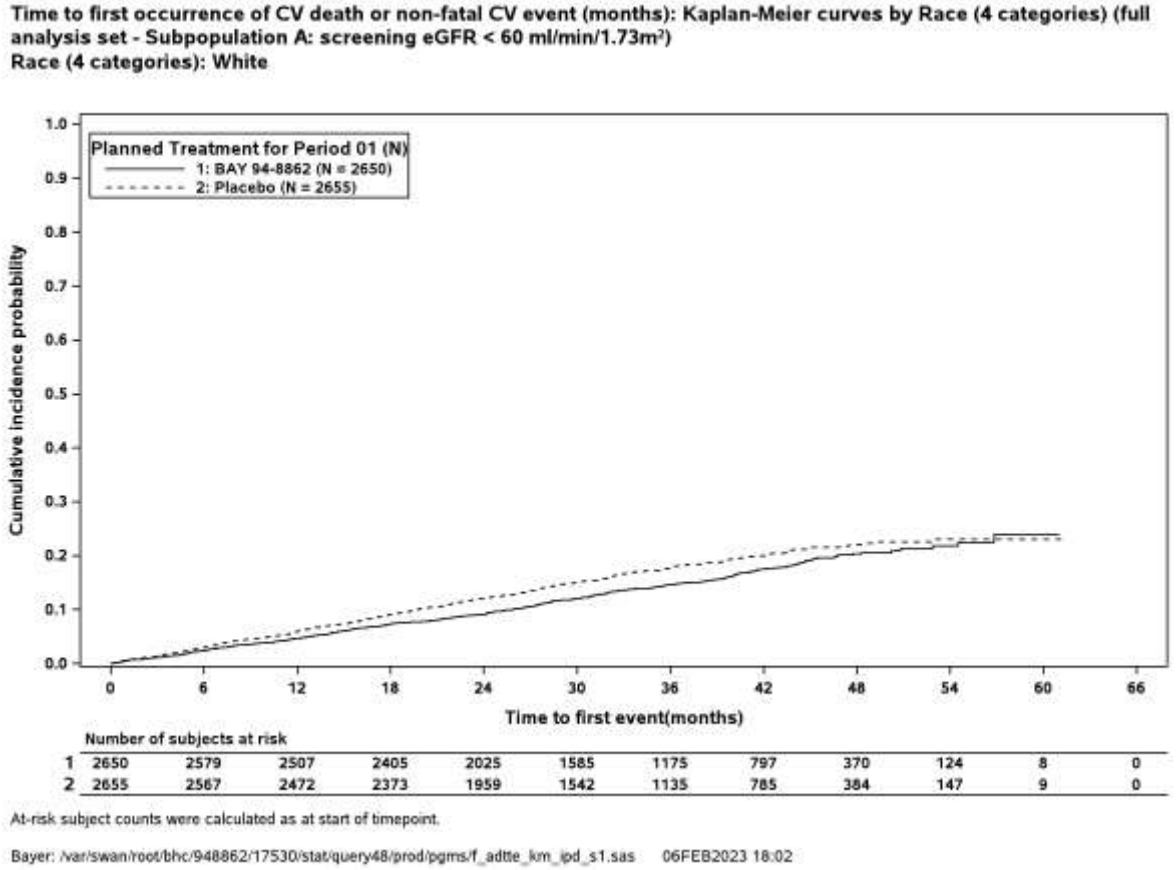


Figure 1.2.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

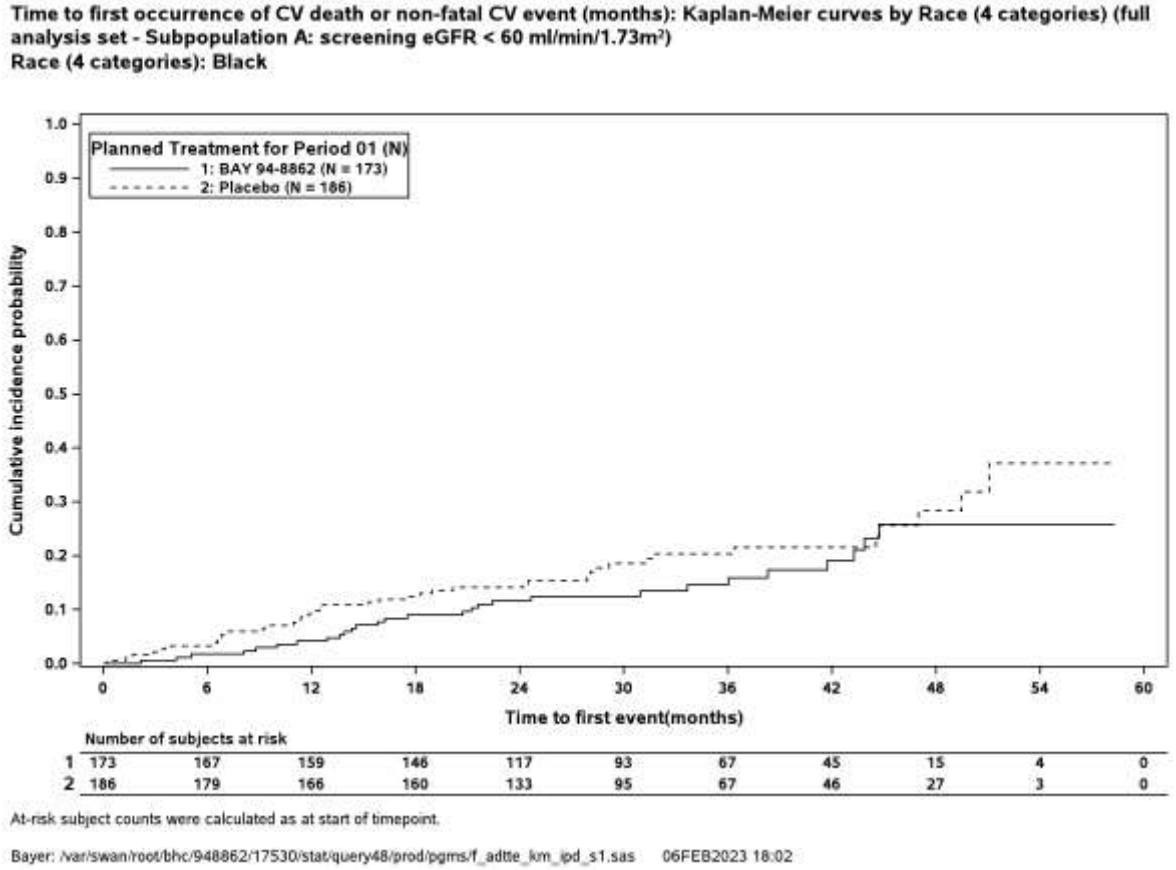


Figure 1.2.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

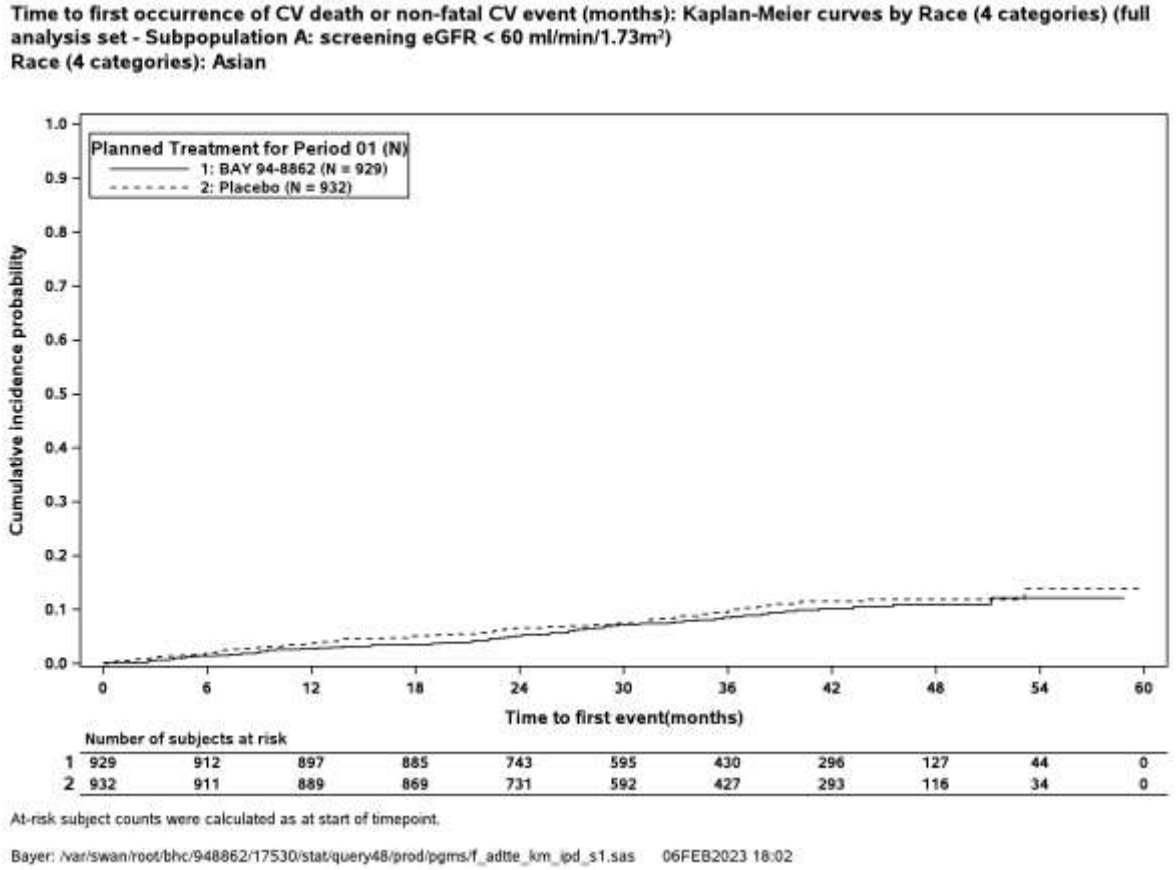


Figure 1.2.1 / 44: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

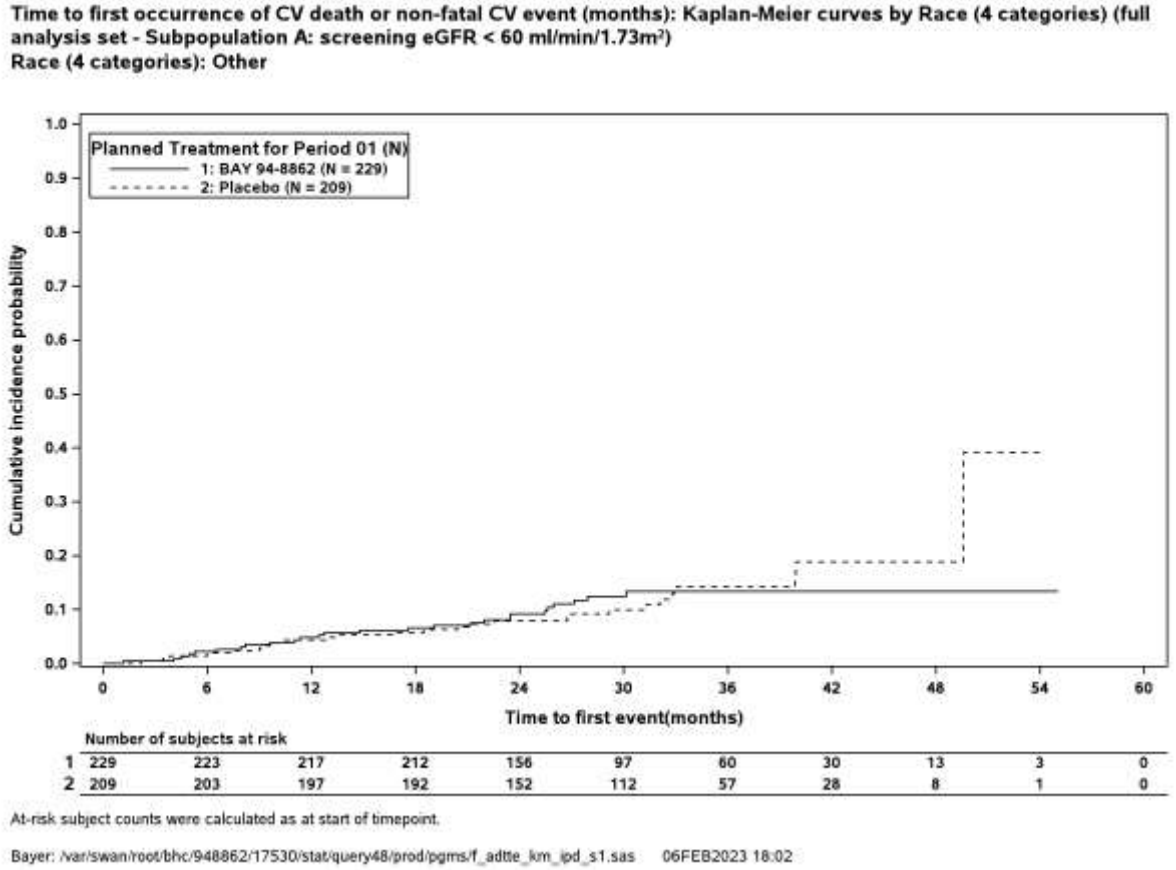


Figure 1.2.1 / 45: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

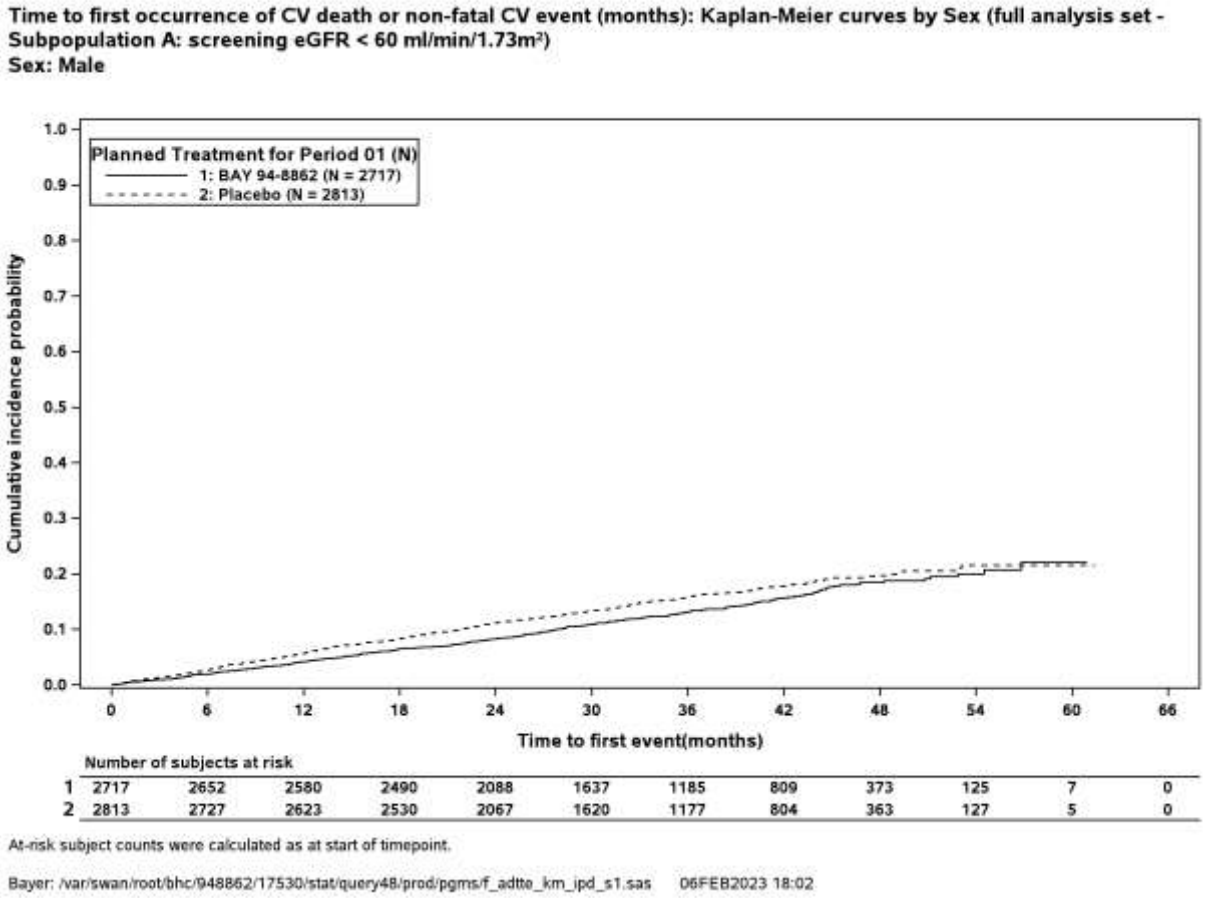


Figure 1.2.1 / 45: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

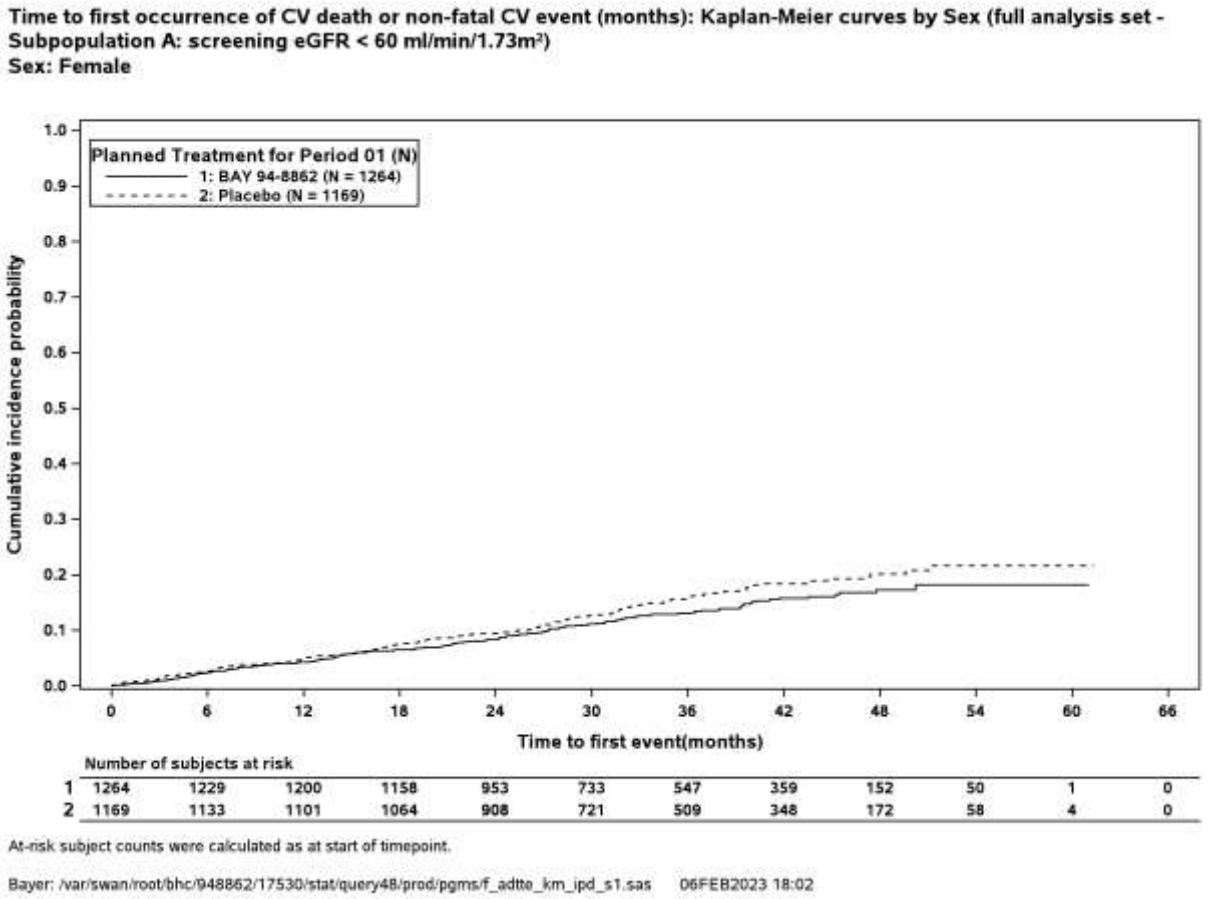


Figure 1.2.1 / 46: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

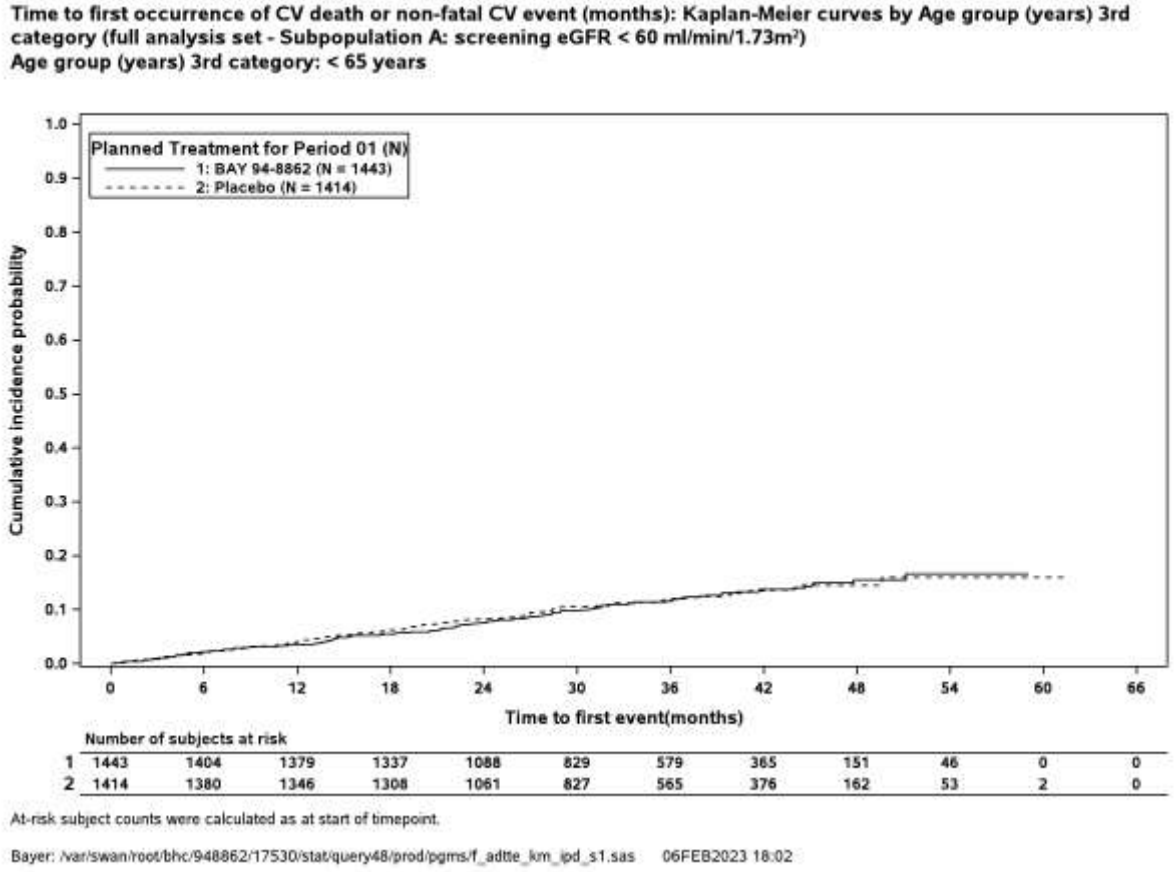


Figure 1.2.1 / 46: Time to first occurrence of CV death or non-fatal CV event (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

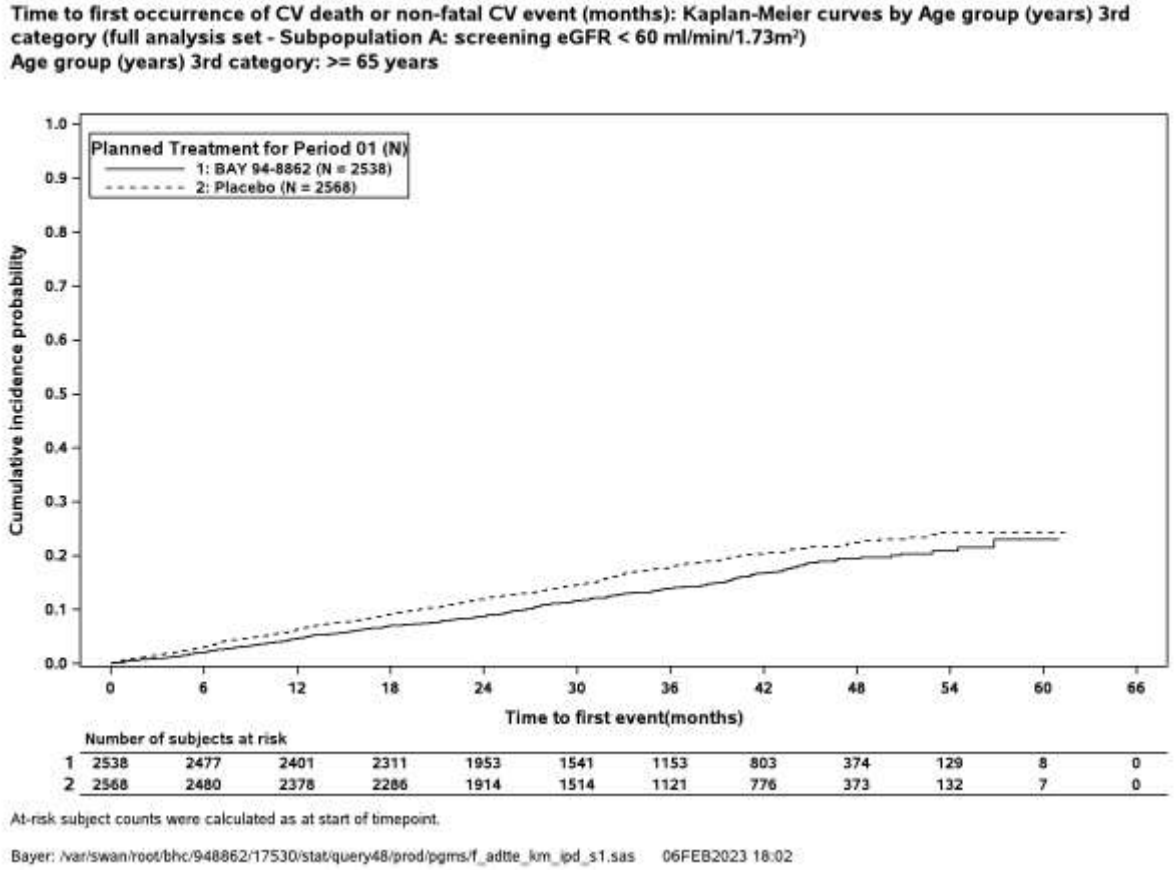


Figure 1.2.1 / 47: Time to CV death (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

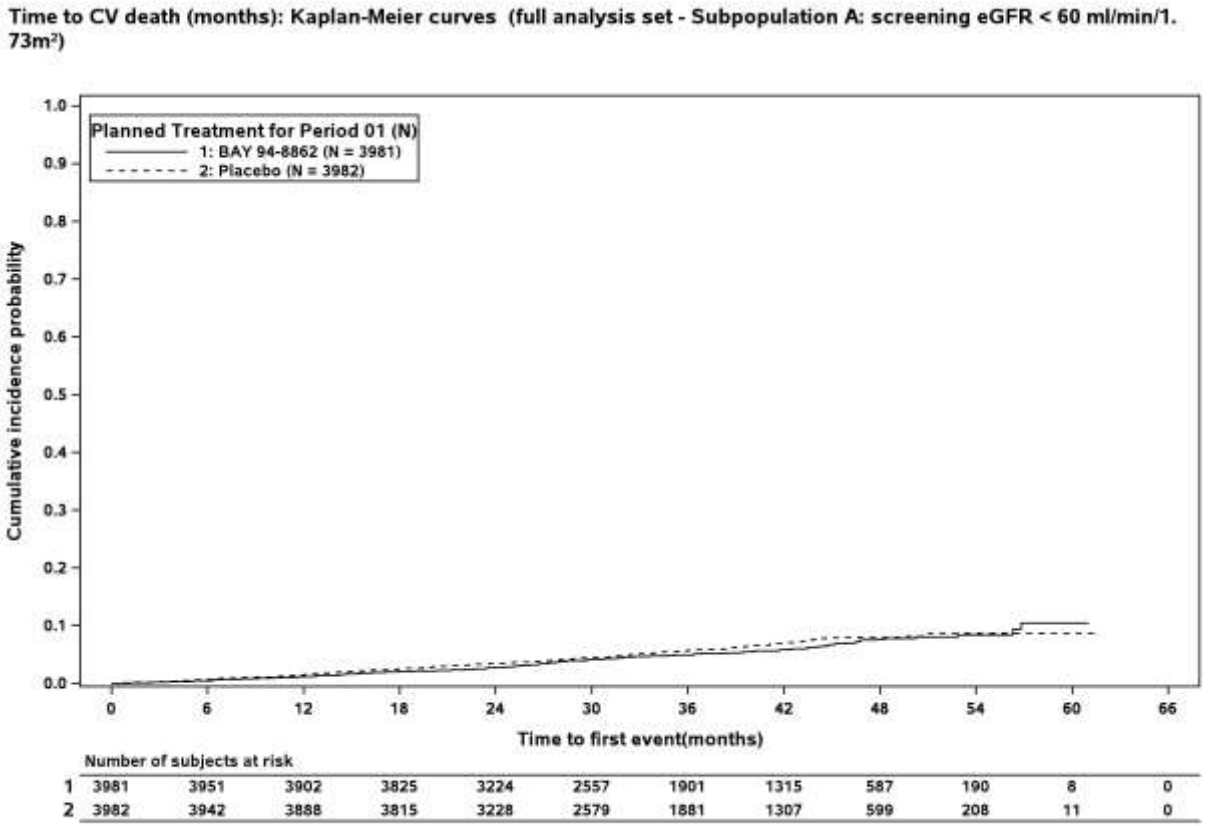


Figure 1.2.1 / 48: Time to first occurrence of non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

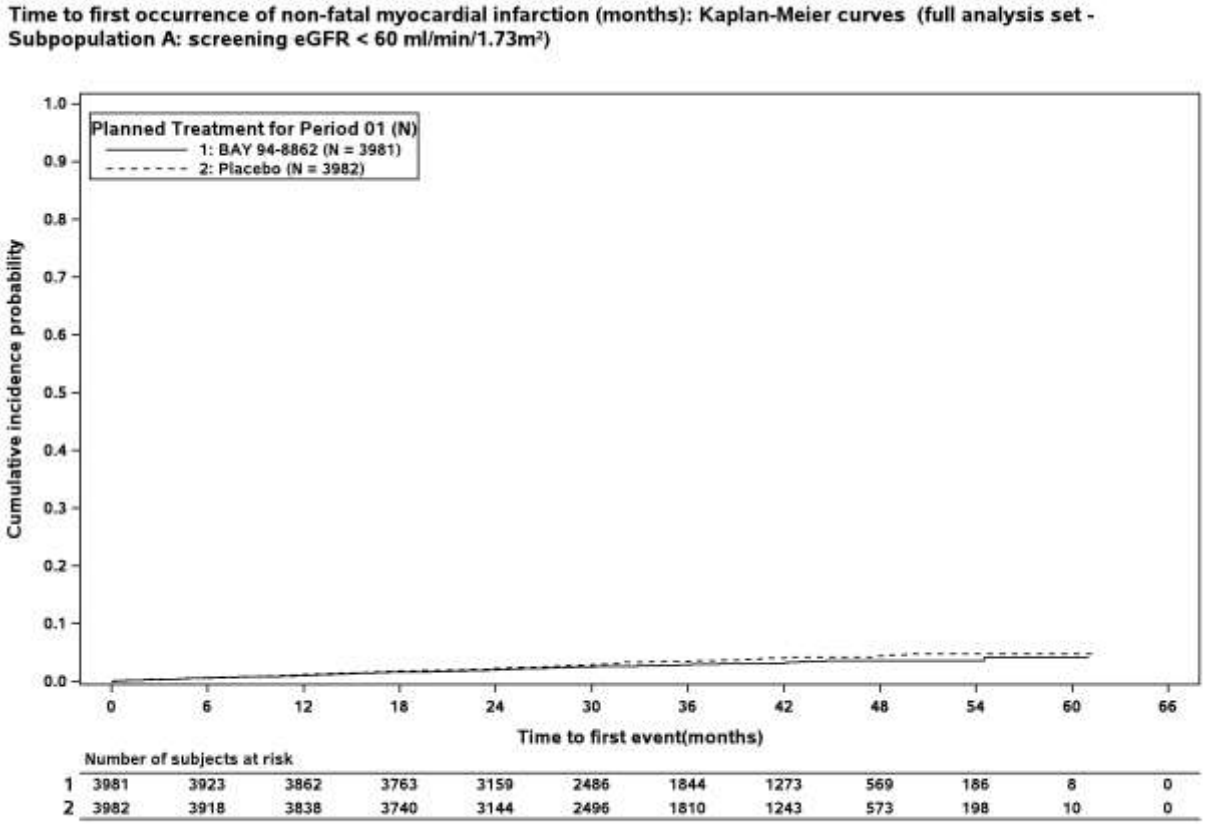


Figure 1.2.1 / 49: Time to first occurrence of non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

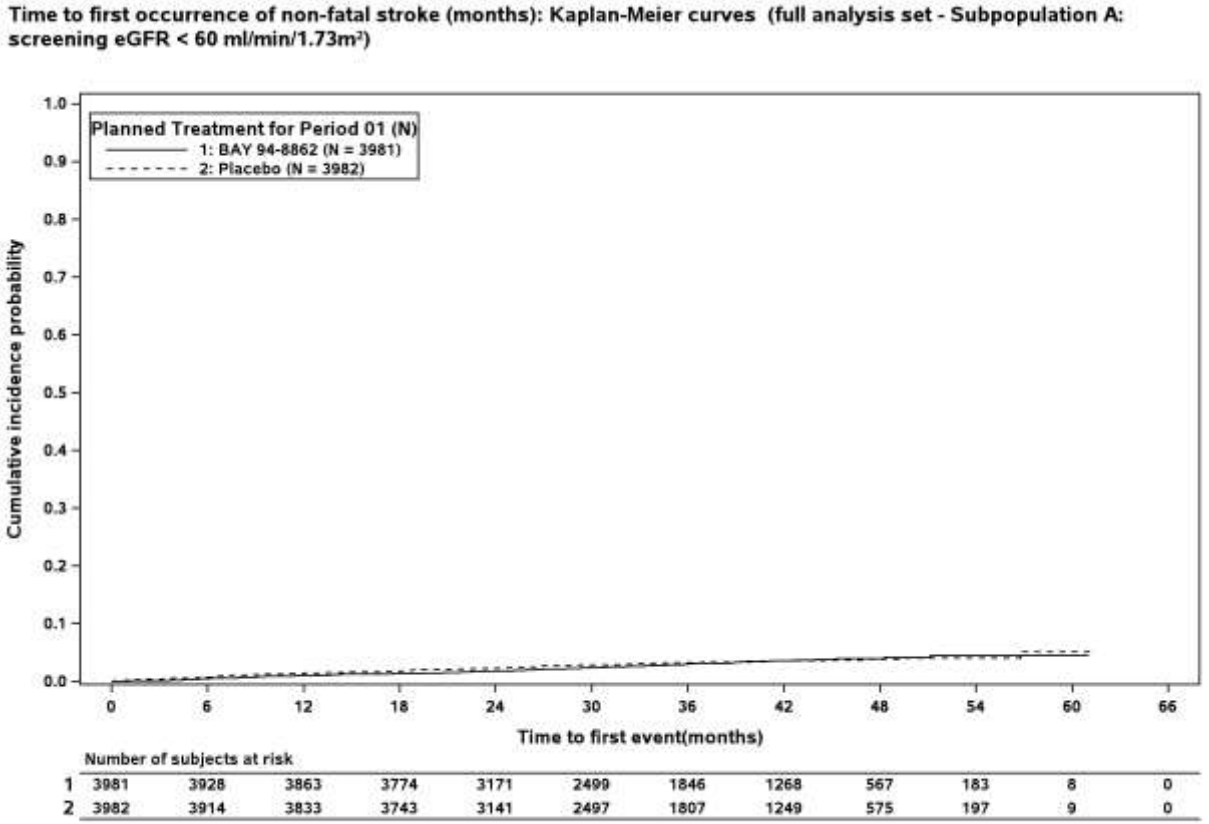


Figure 1.2.1 / 50: Time to hospitalization due to heart failure (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

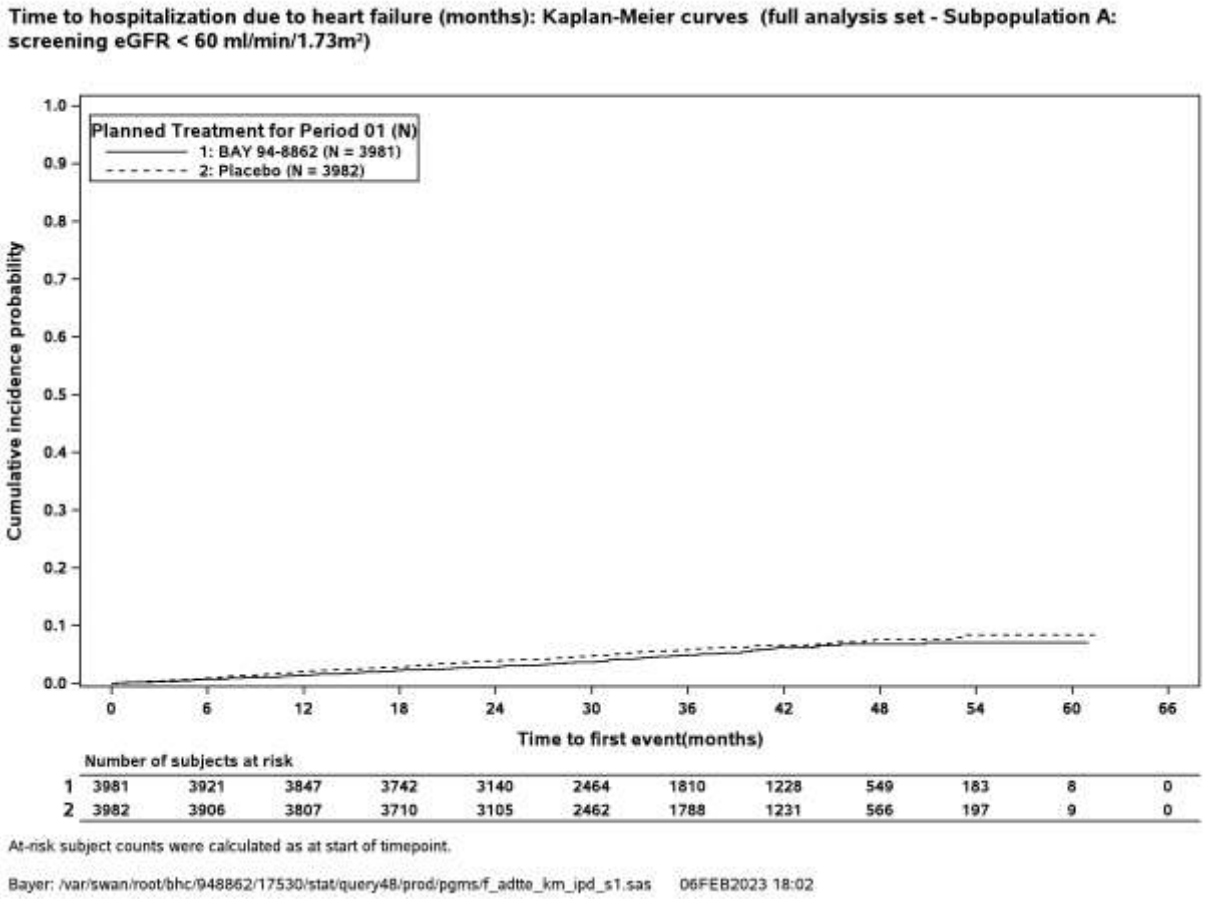


Figure 1.2.1 / 51: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

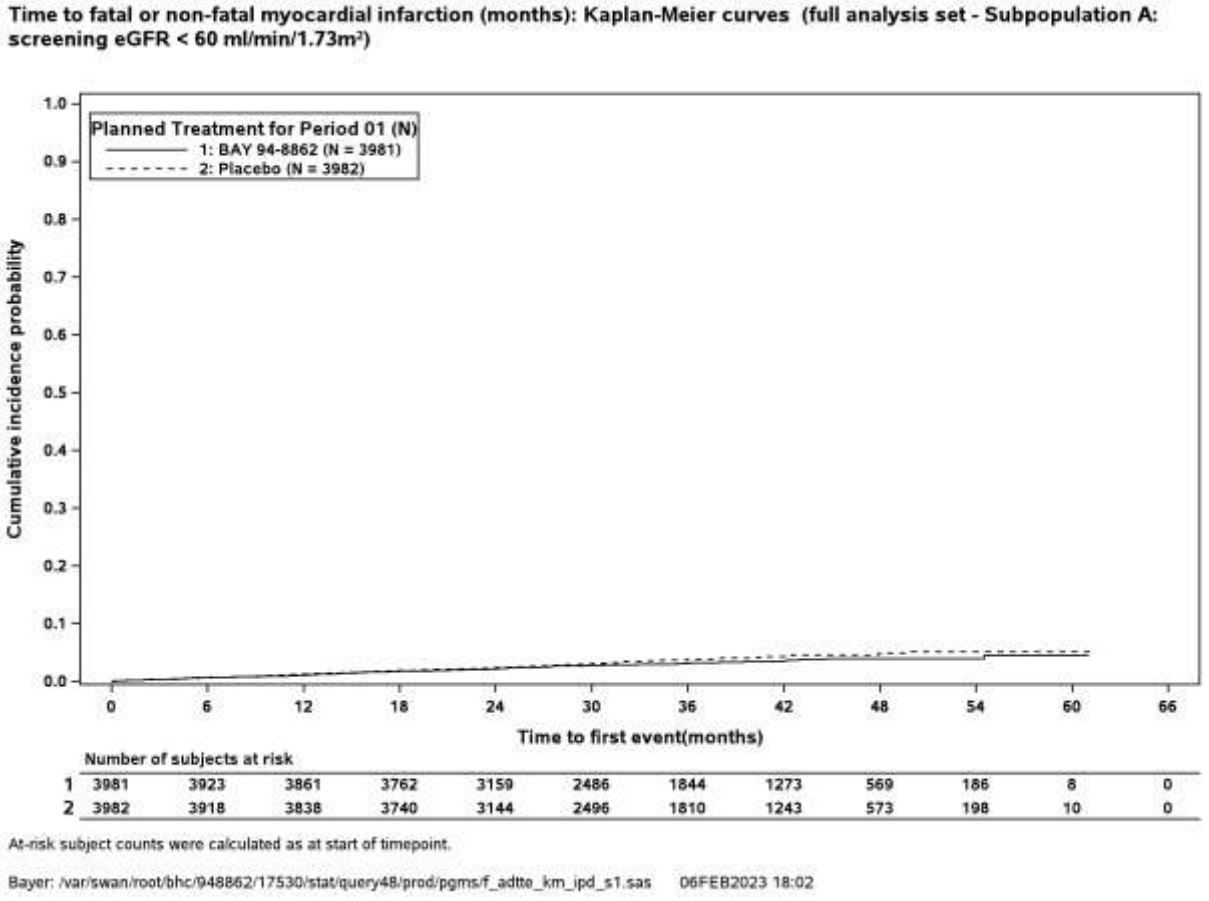


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

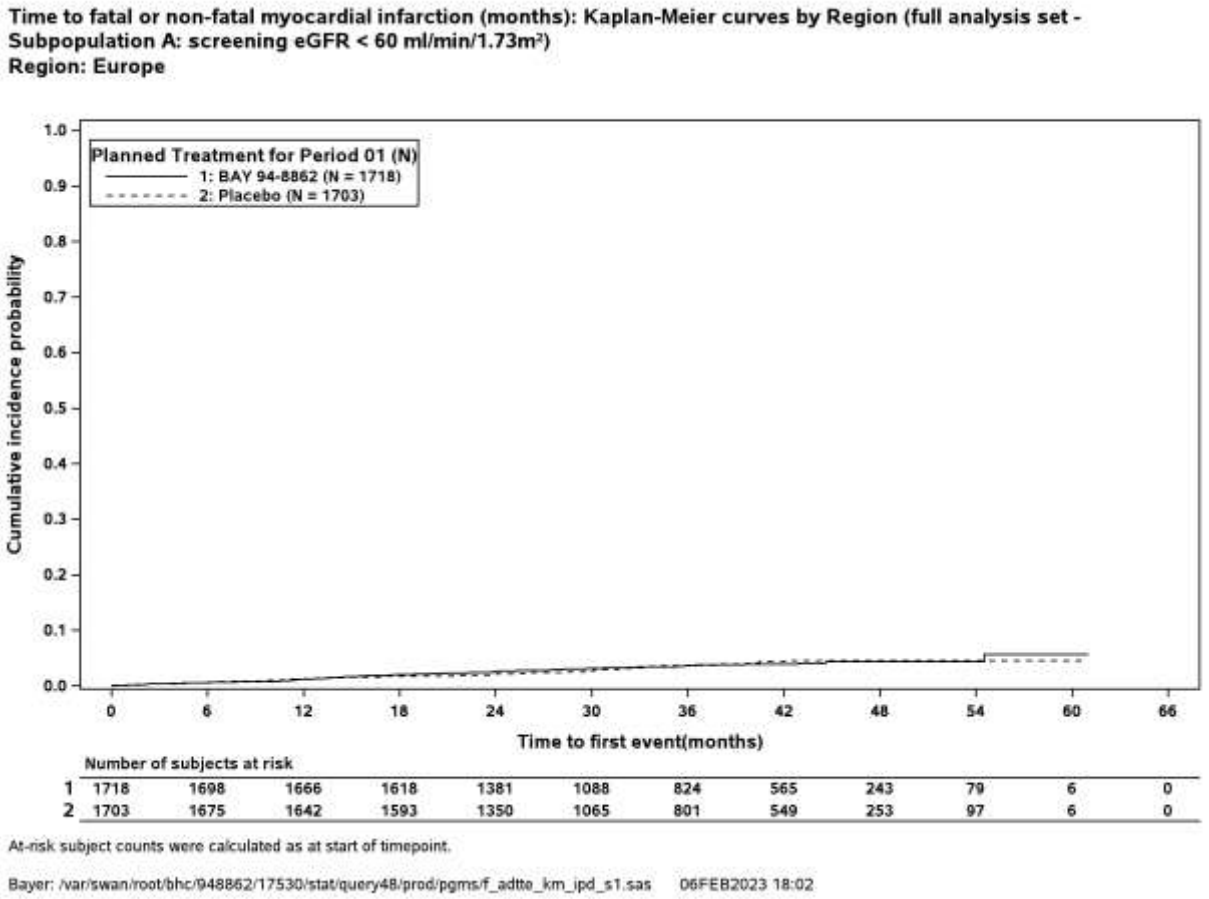


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

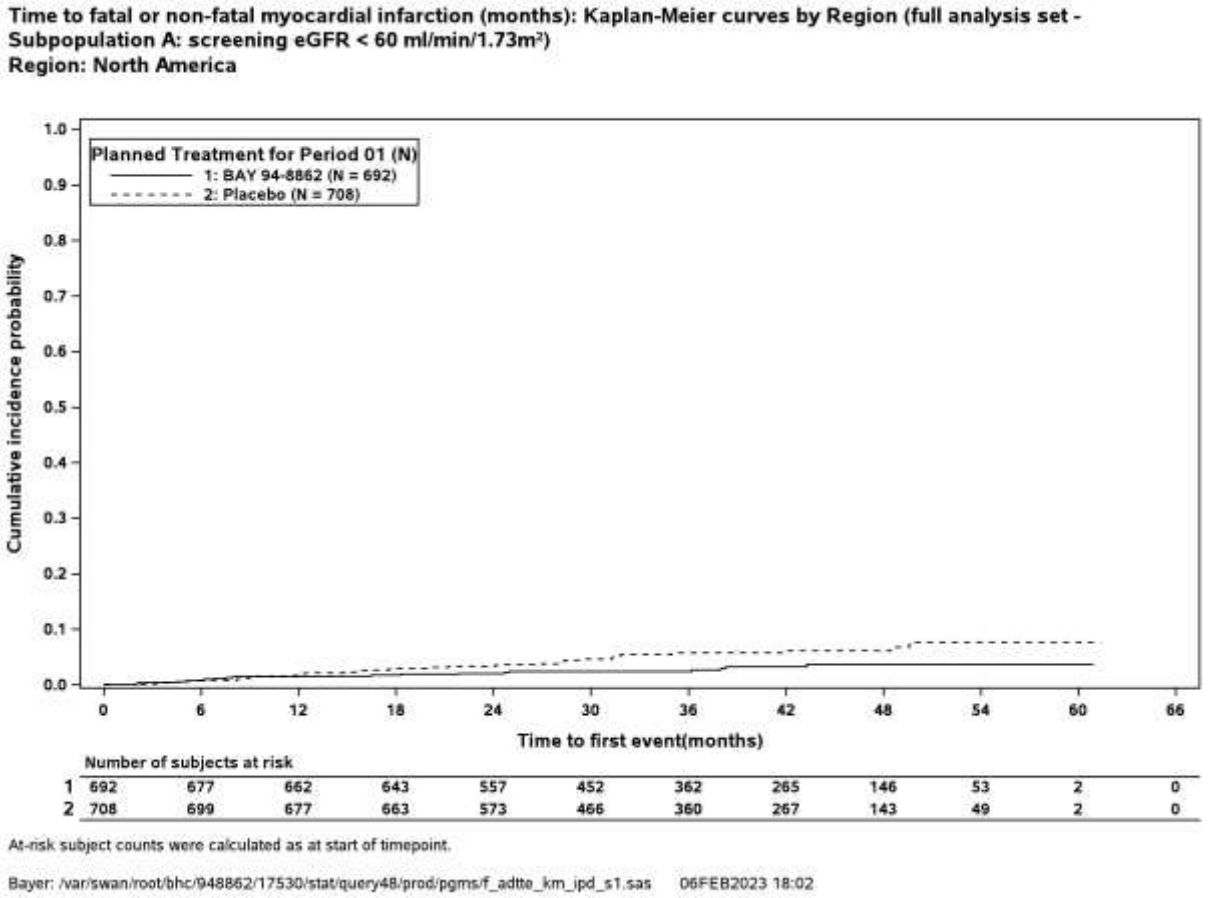


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

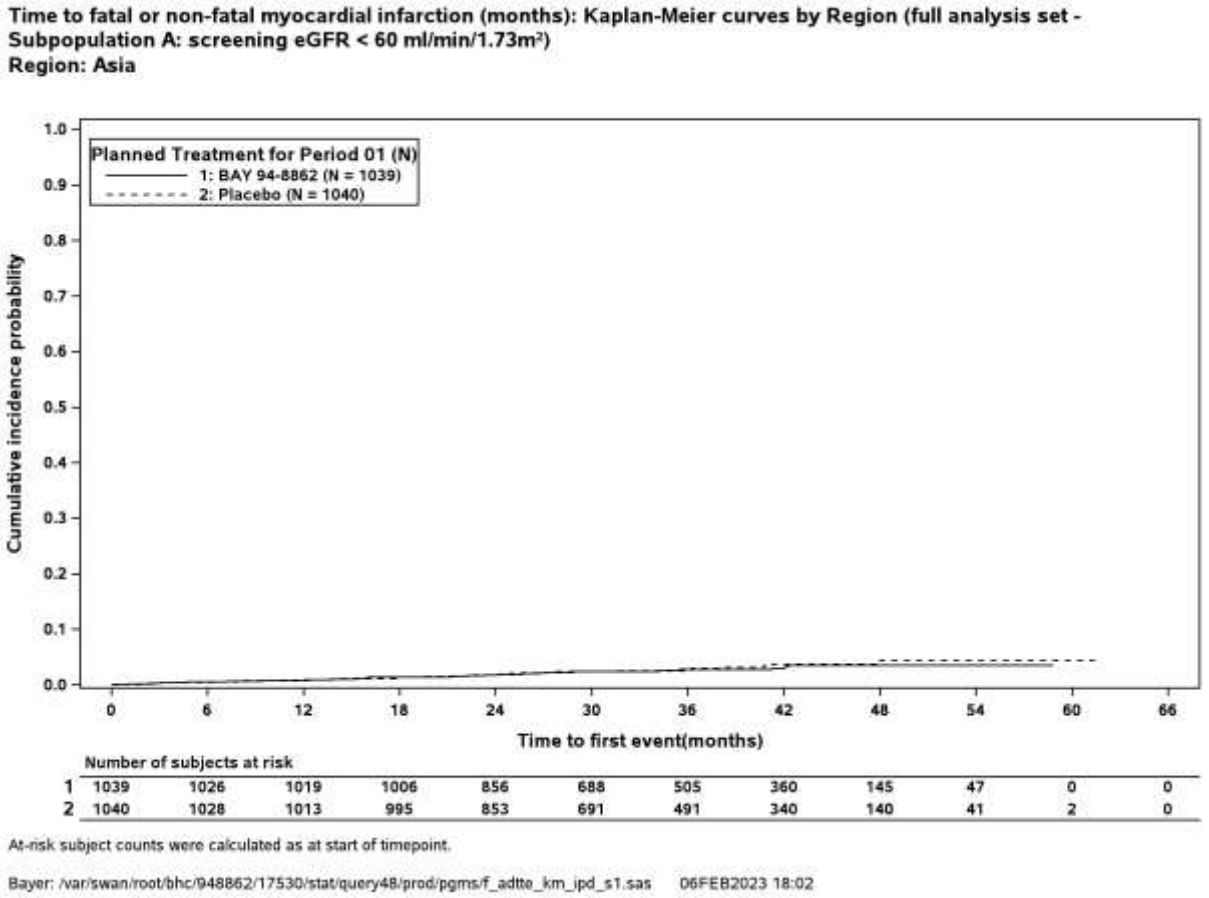


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

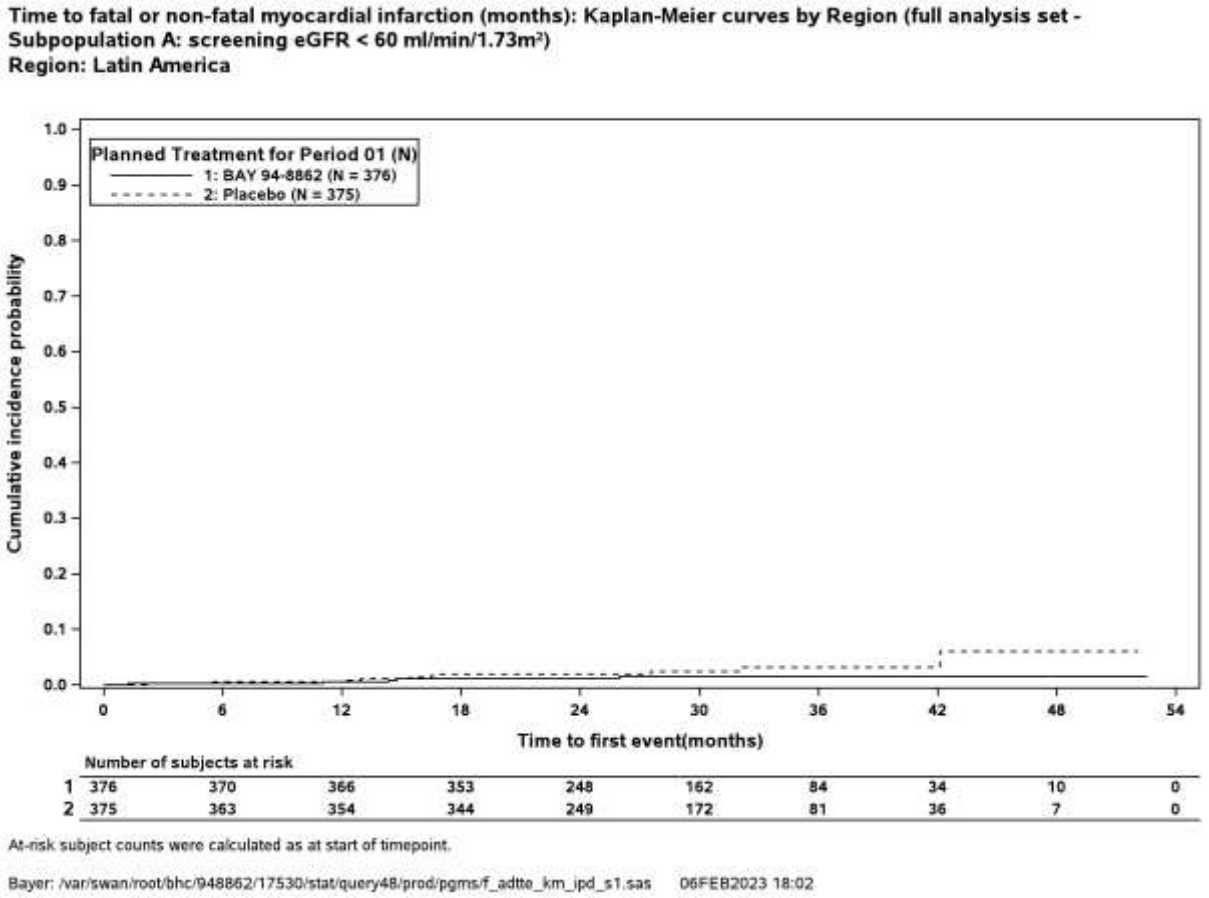


Figure 1.2.1 / 52: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

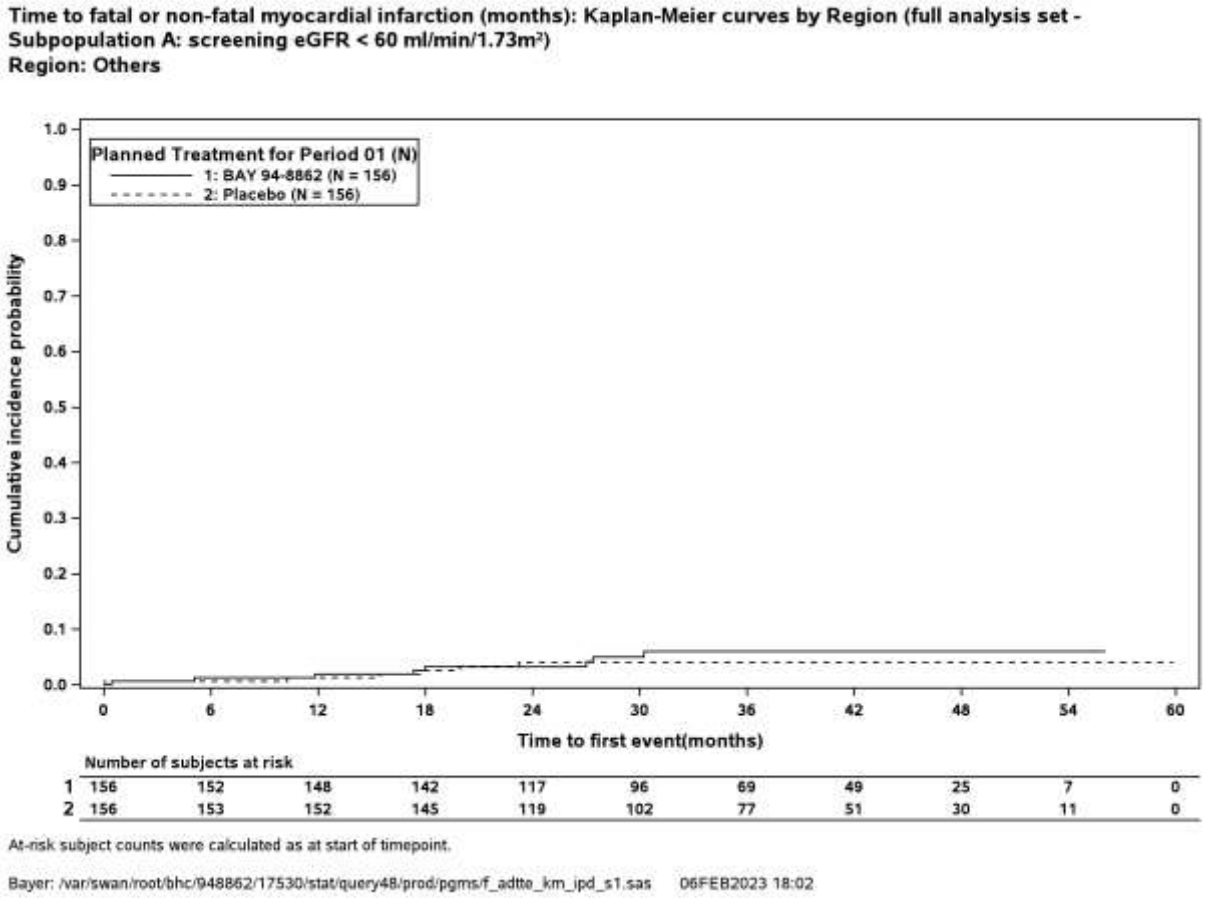


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

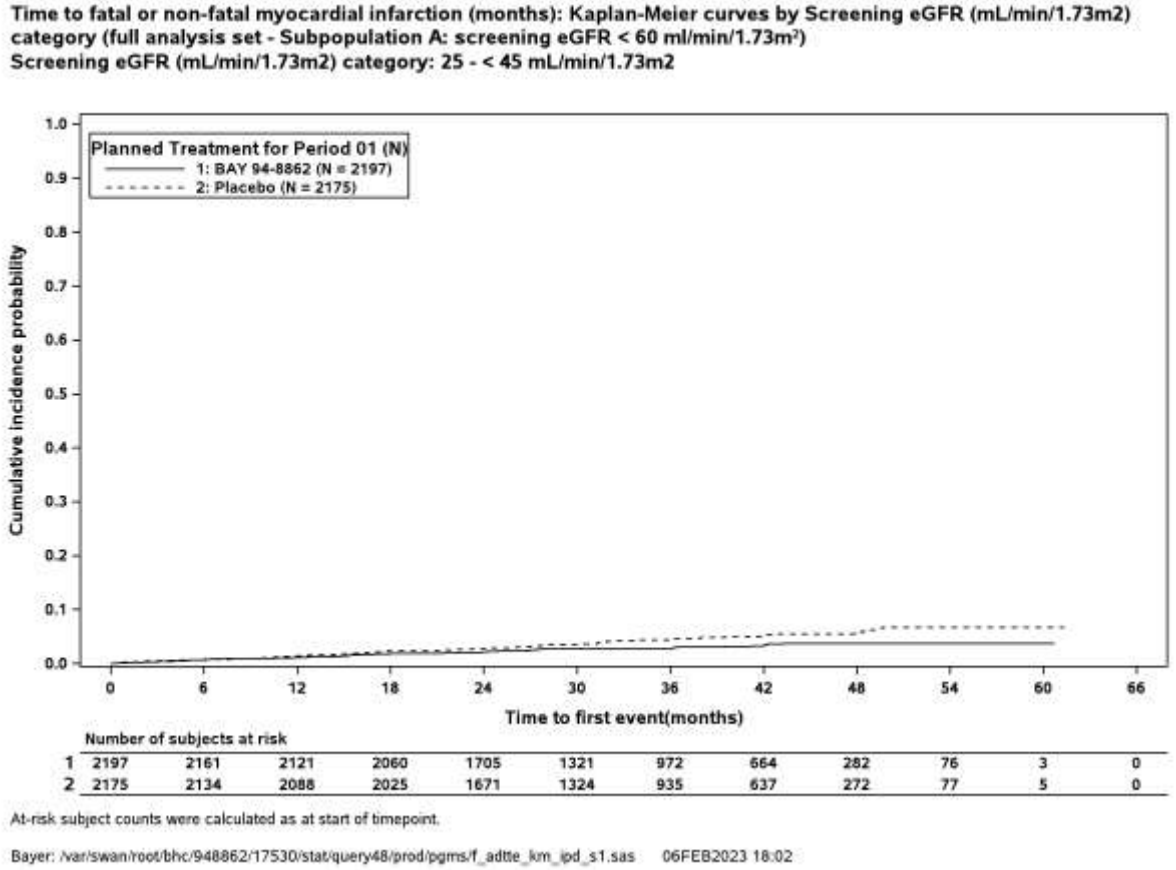


Figure 1.2.1 / 53: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

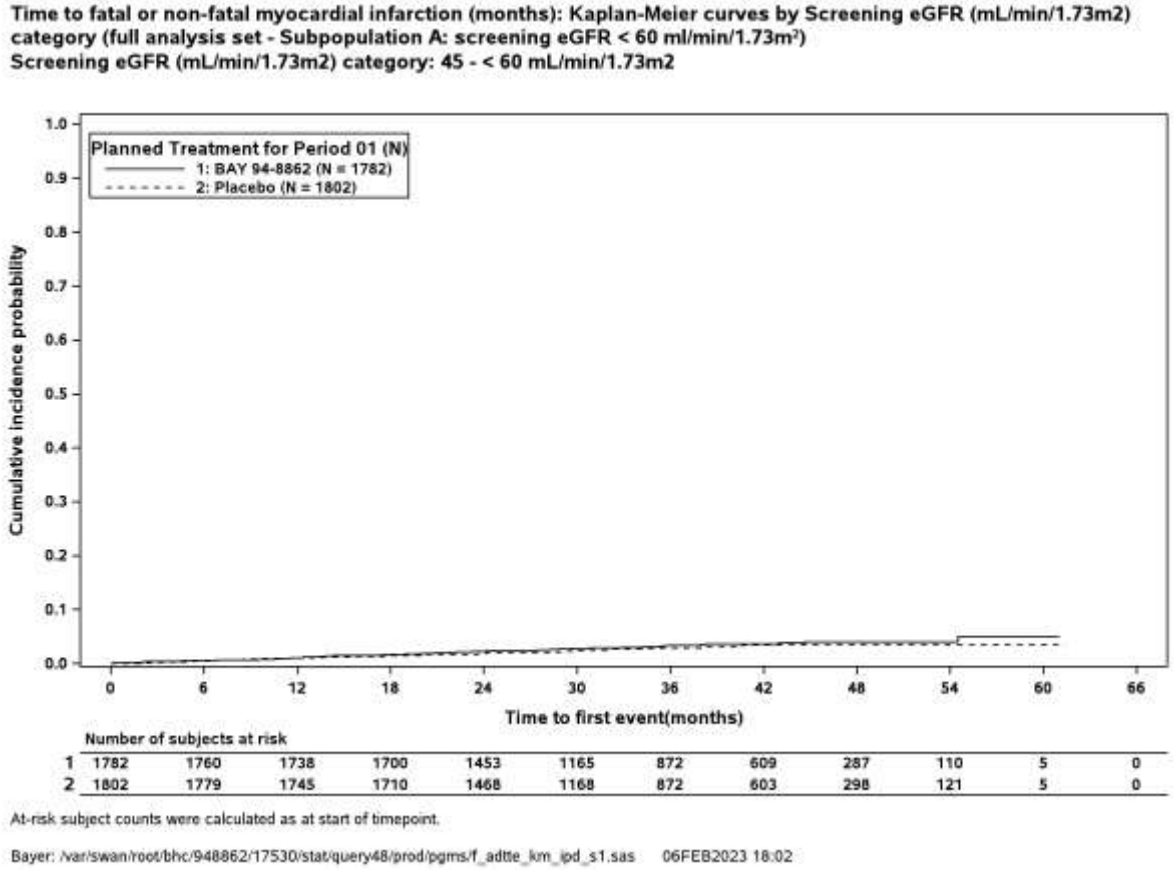


Figure 1.2.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

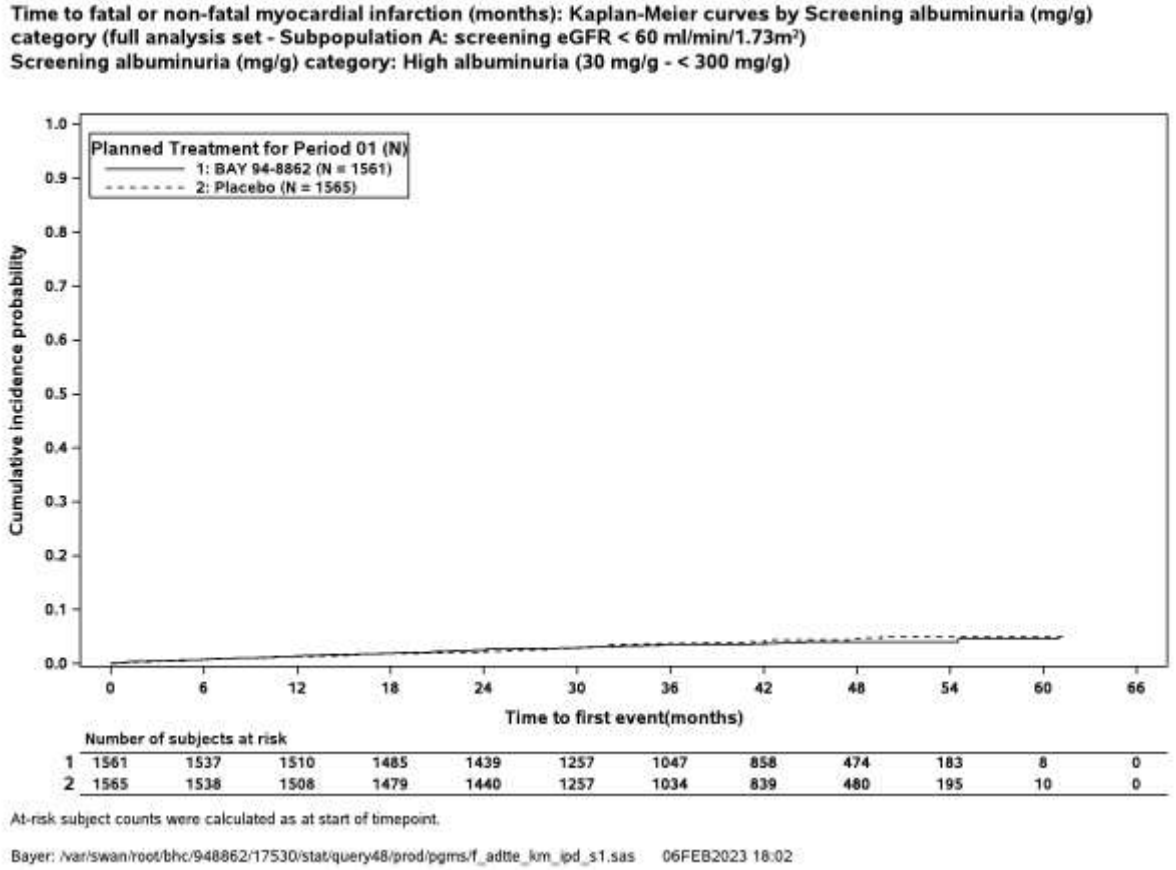


Figure 1.2.1 / 54: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

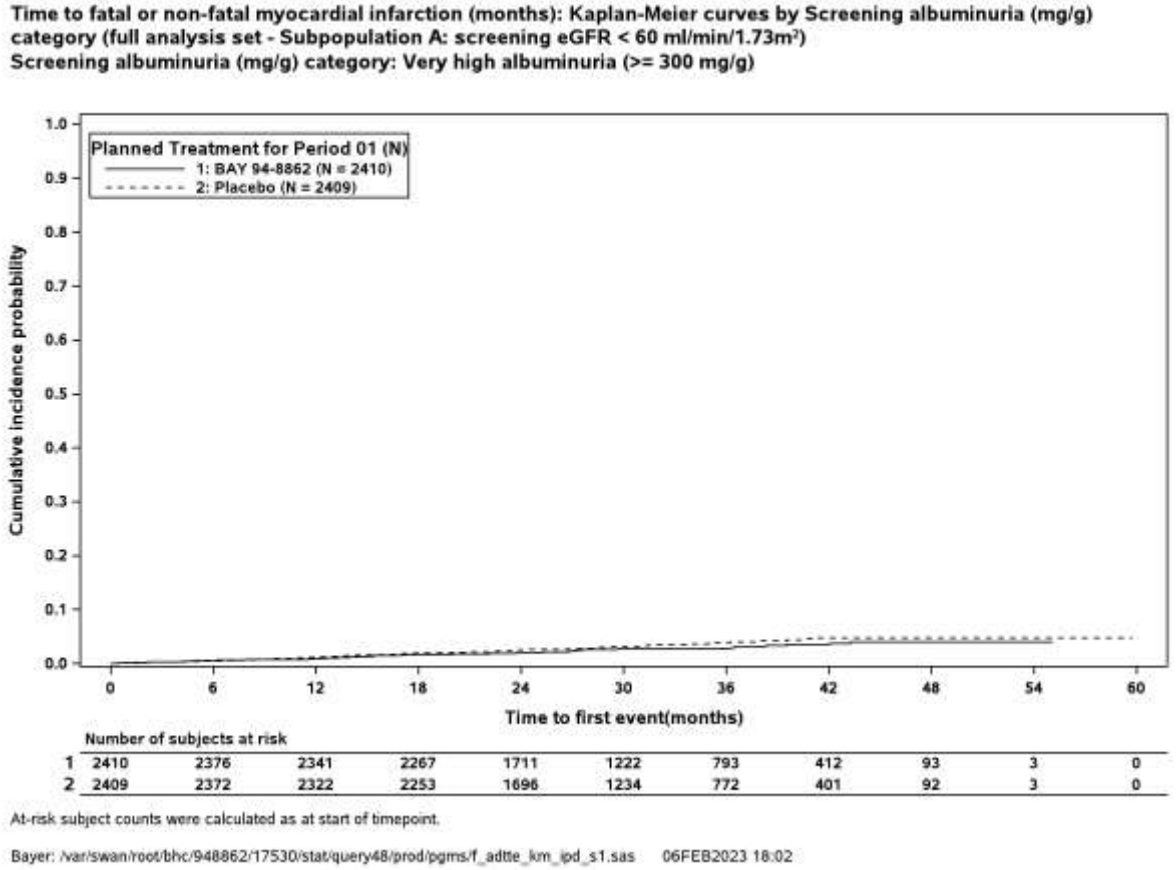


Figure 1.2.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

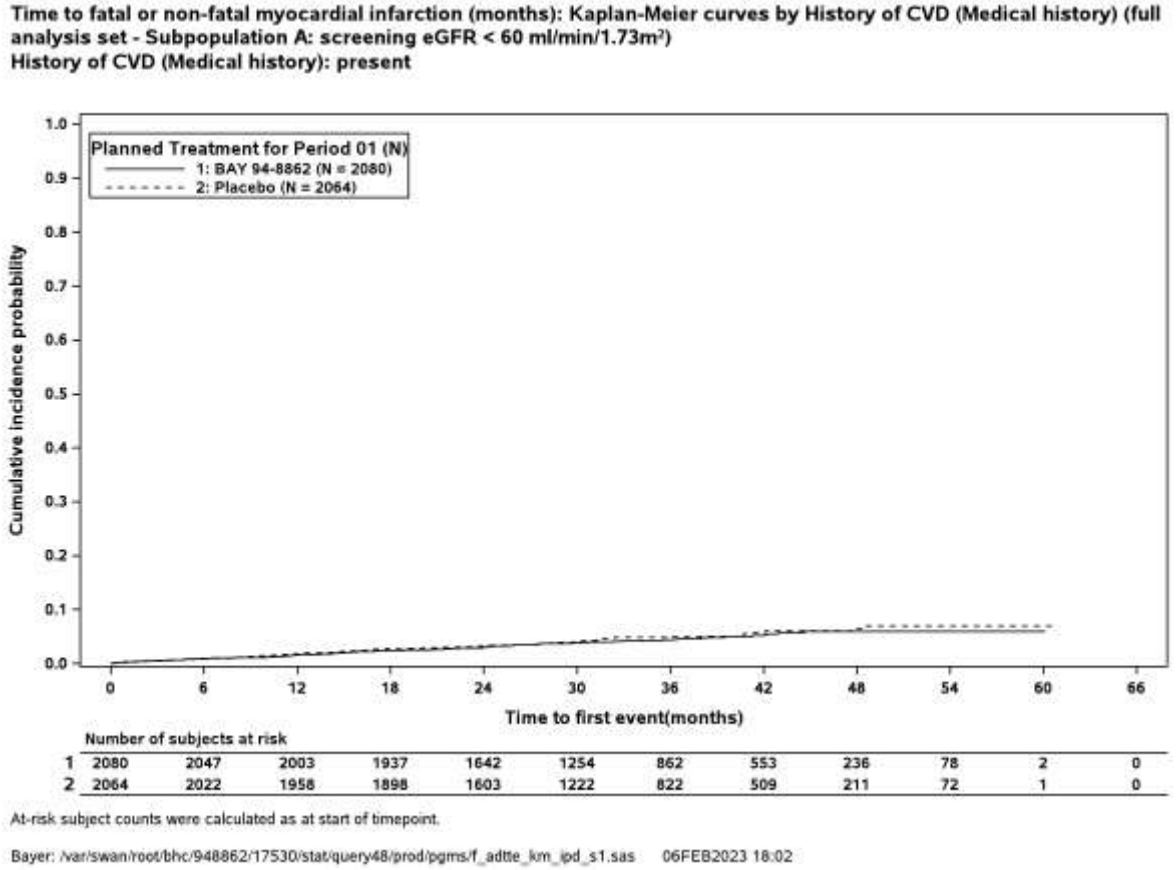


Figure 1.2.1 / 55: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

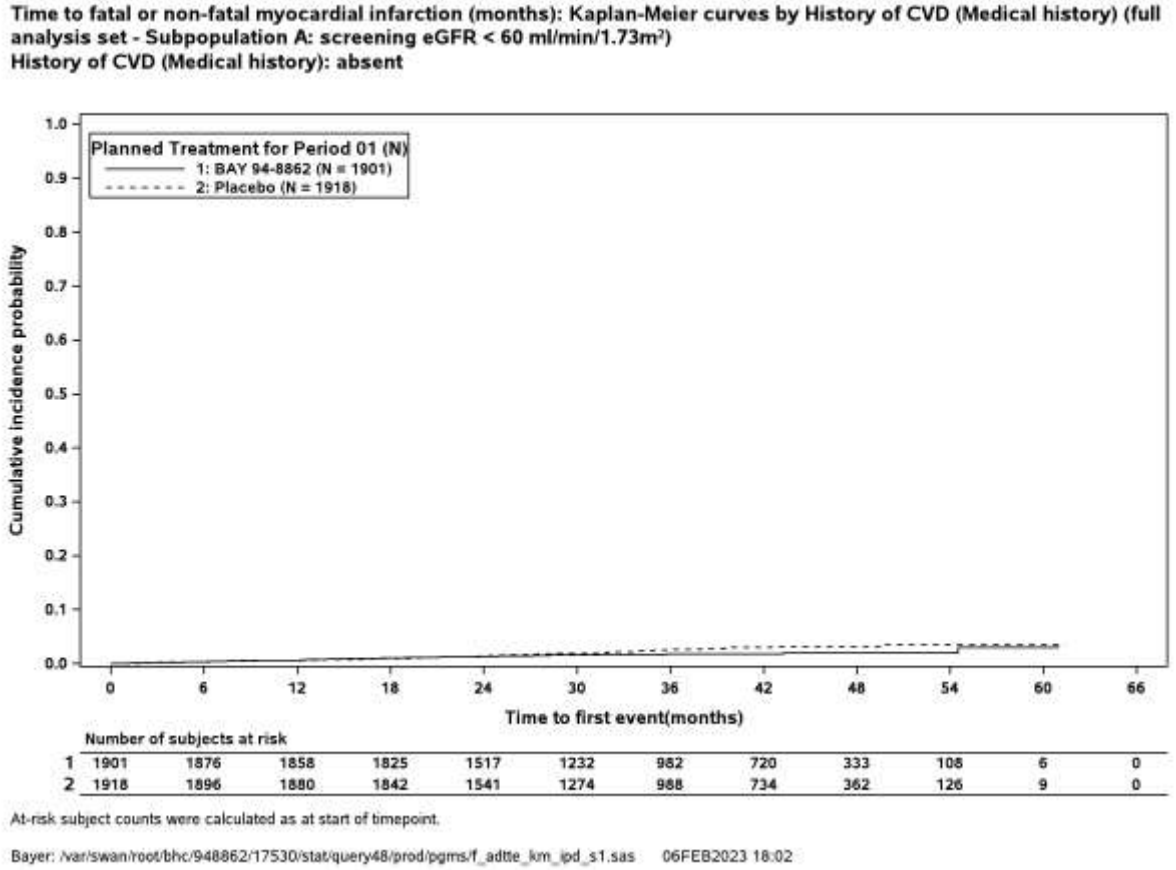


Figure 1.2.1 / 56: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

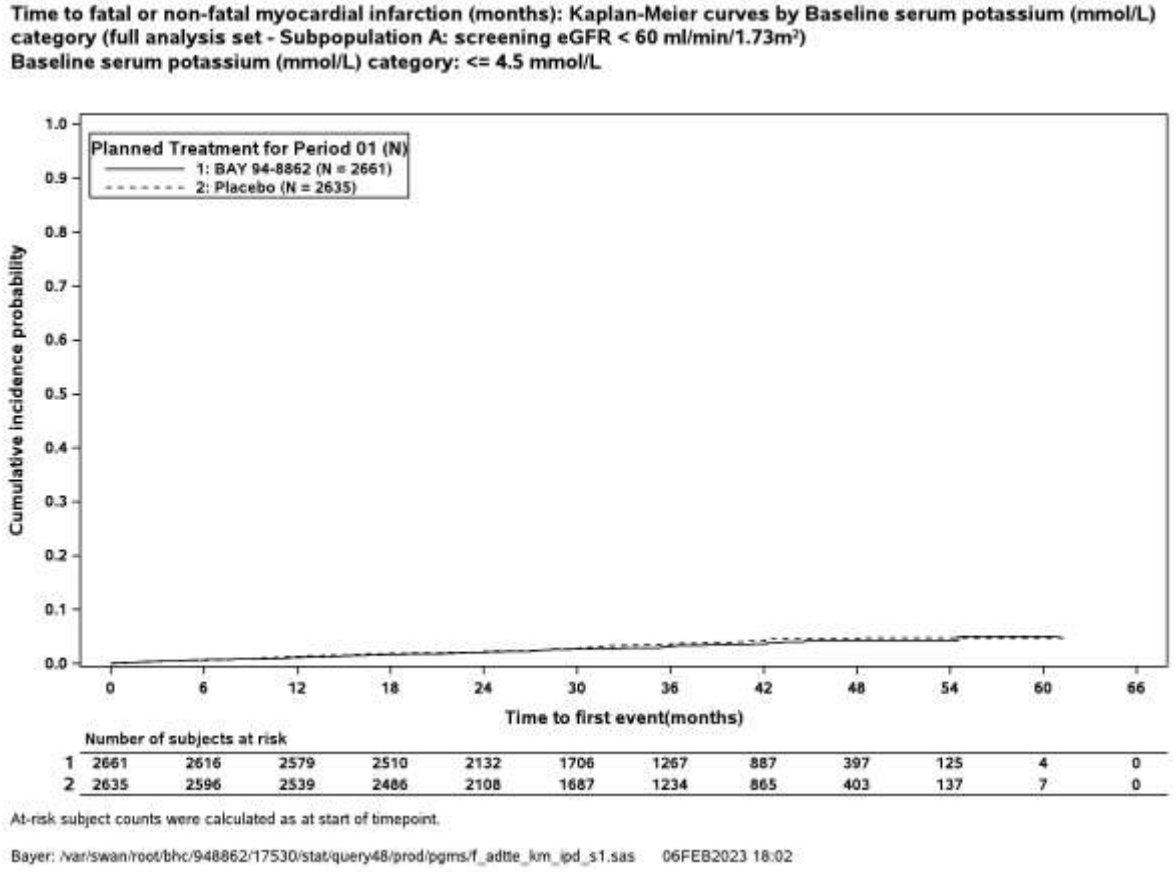


Figure 1.2.1 / 56: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

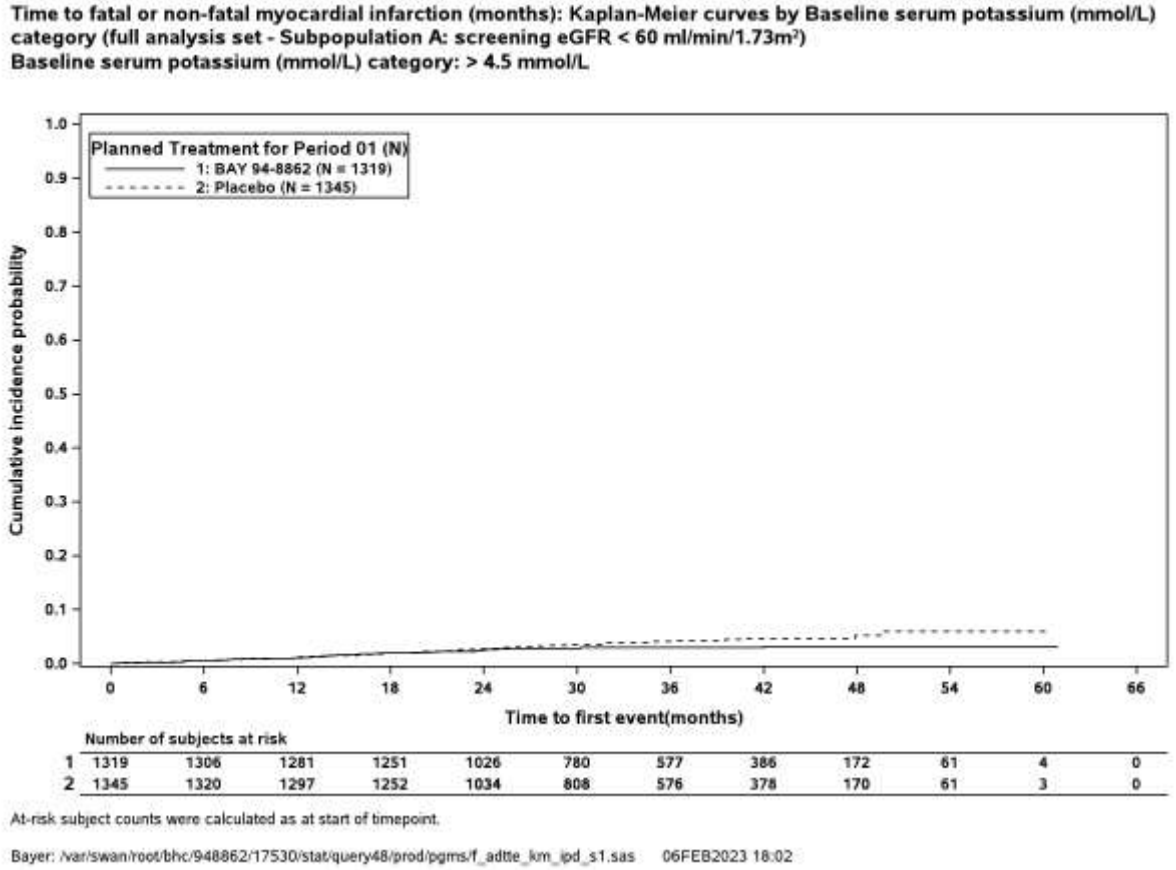


Figure 1.2.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

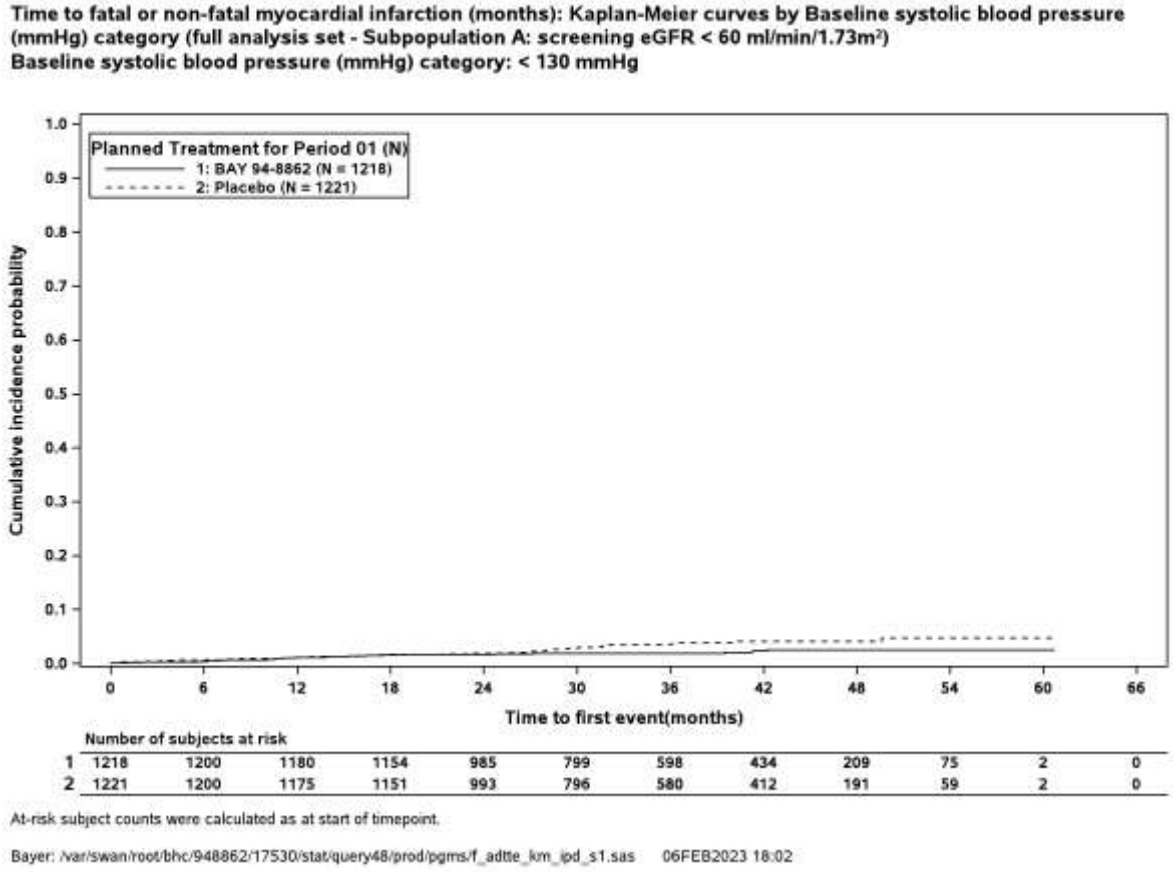
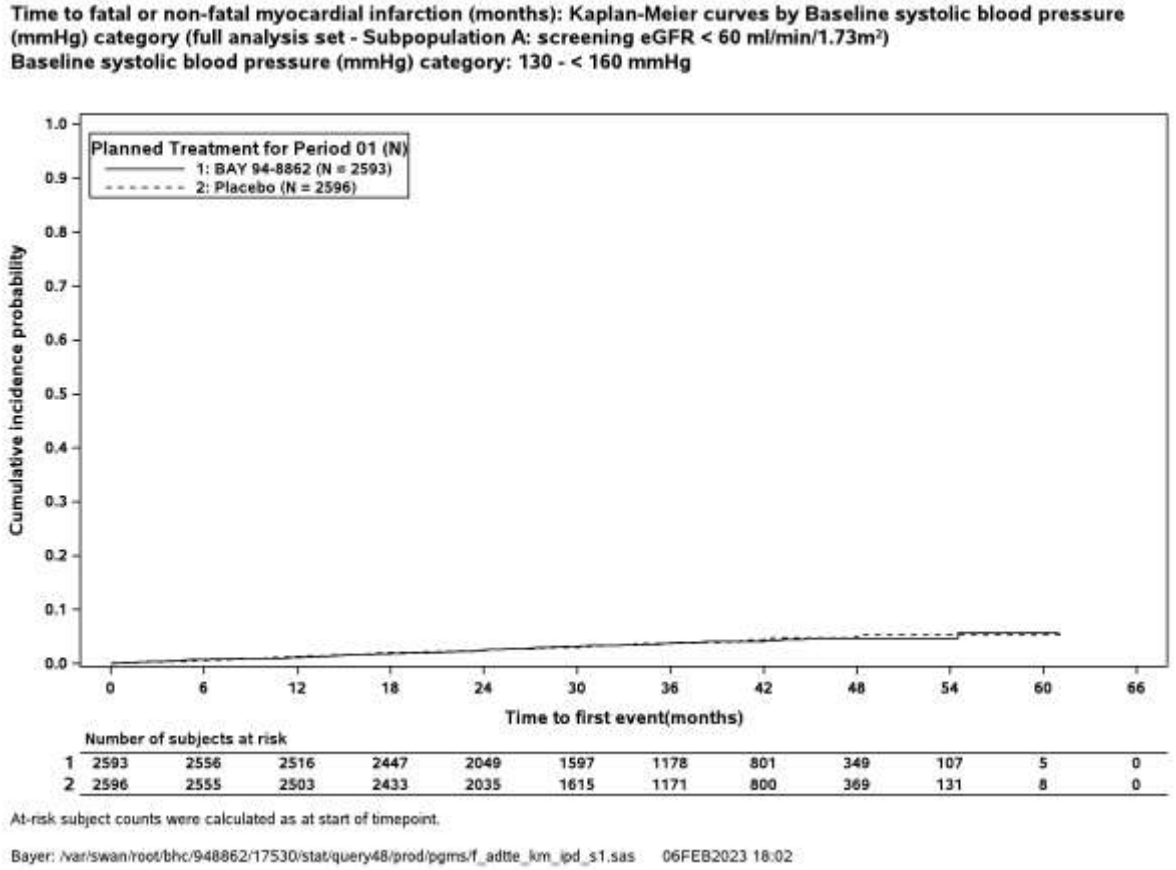


Figure 1.2.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

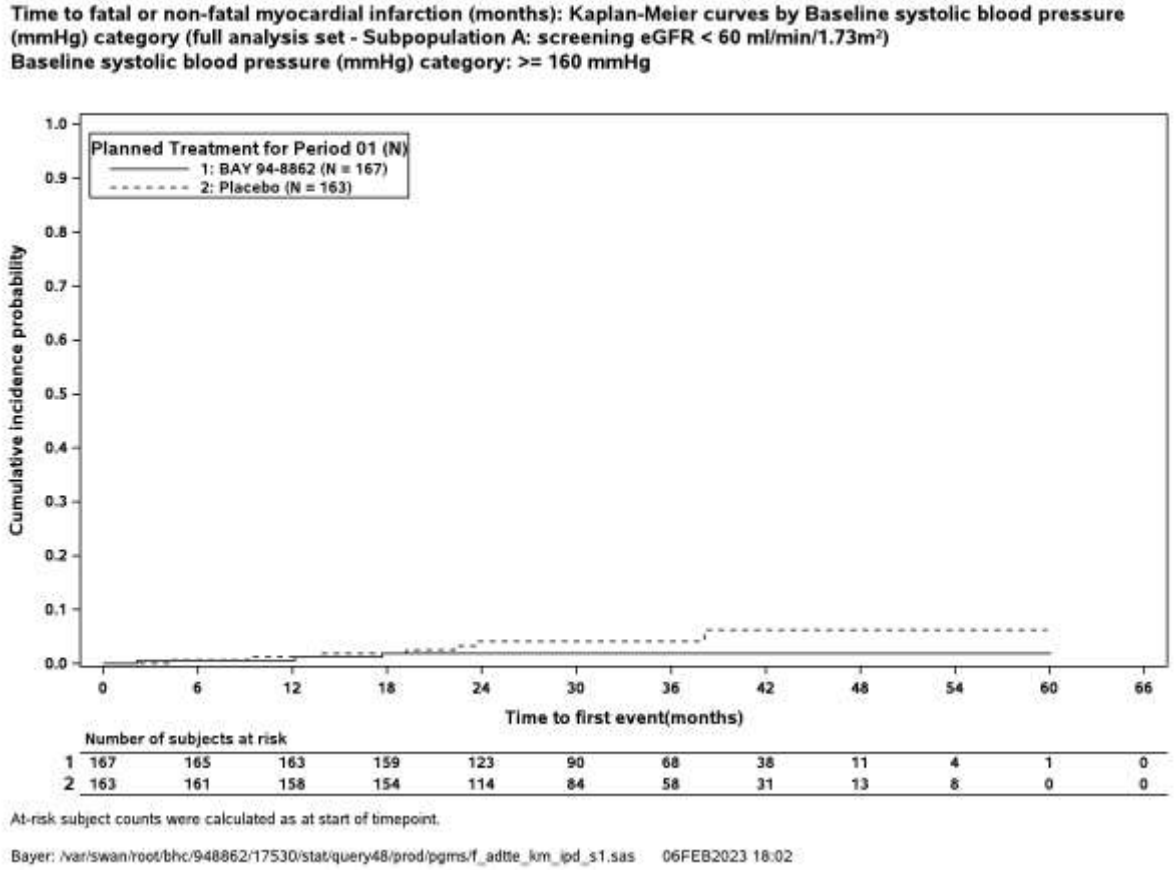


At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 57: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

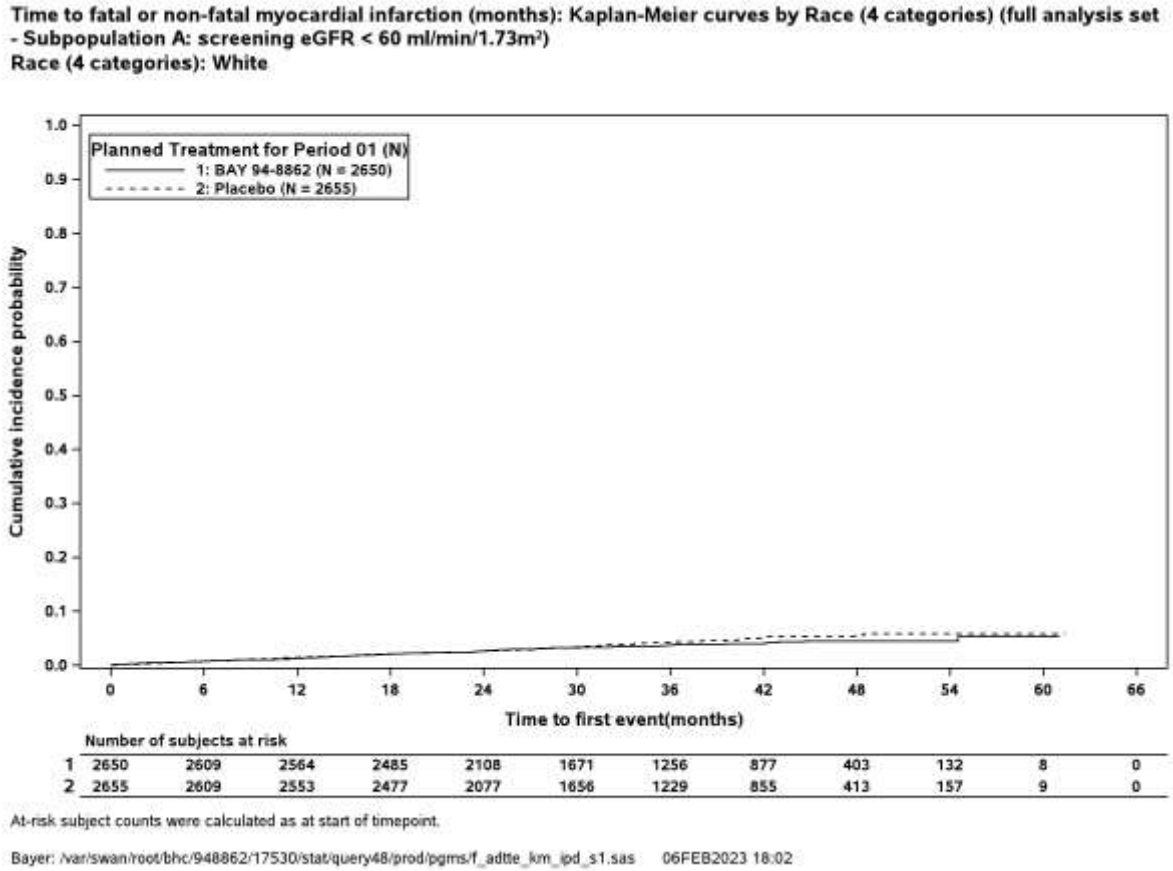


Figure 1.2.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

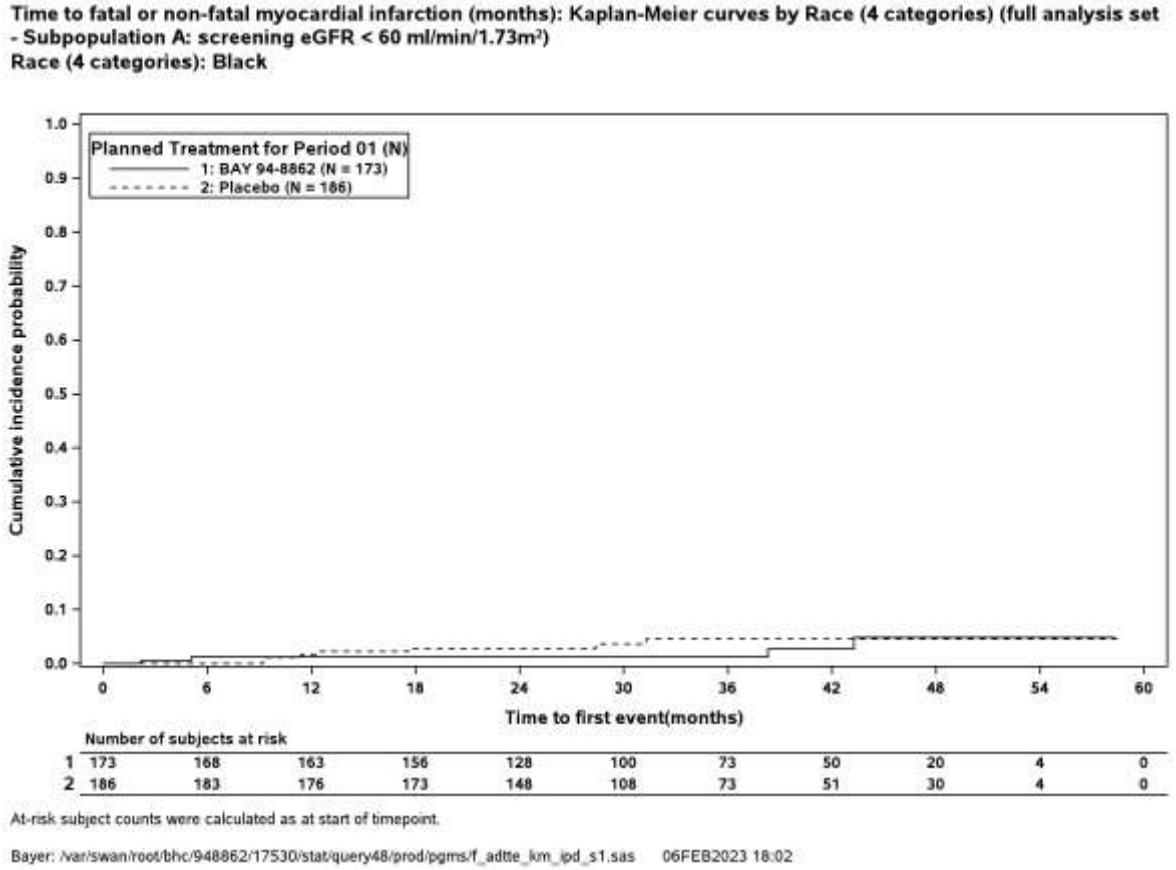


Figure 1.2.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

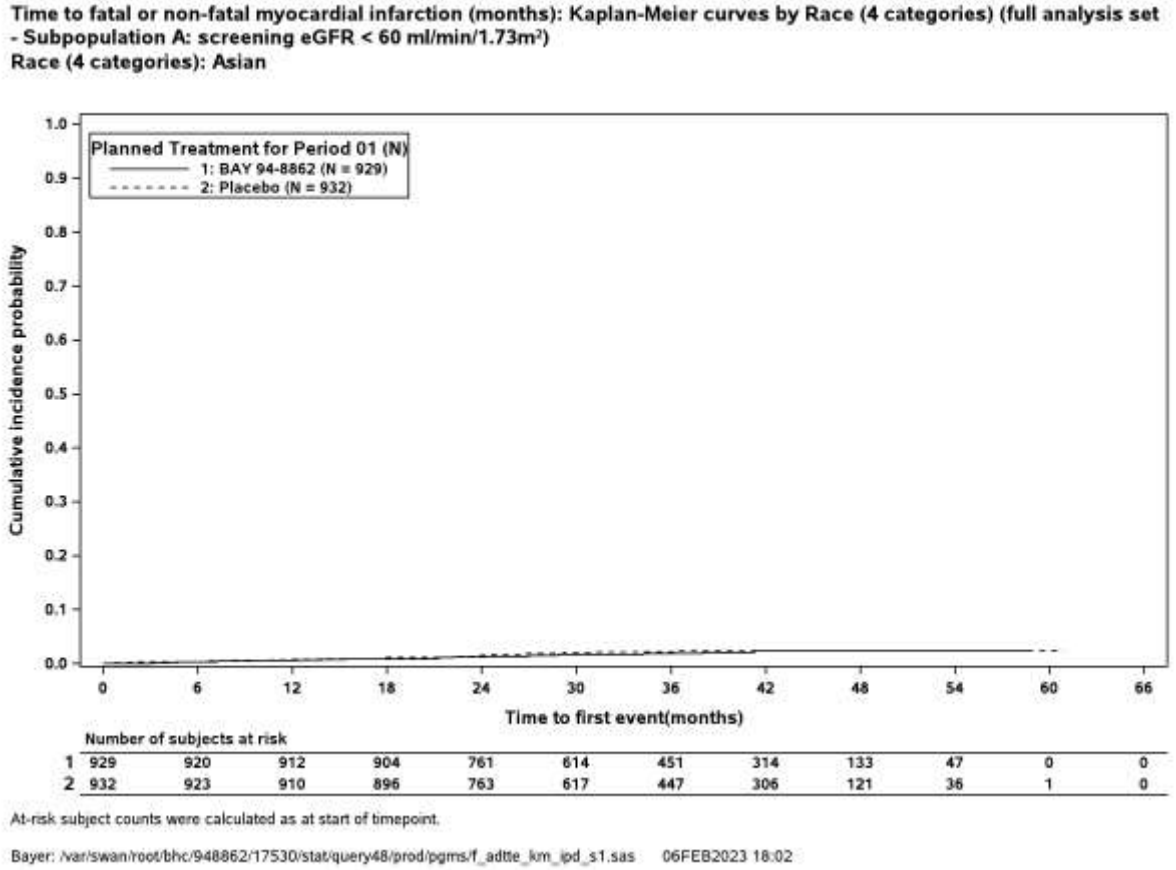


Figure 1.2.1 / 58: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

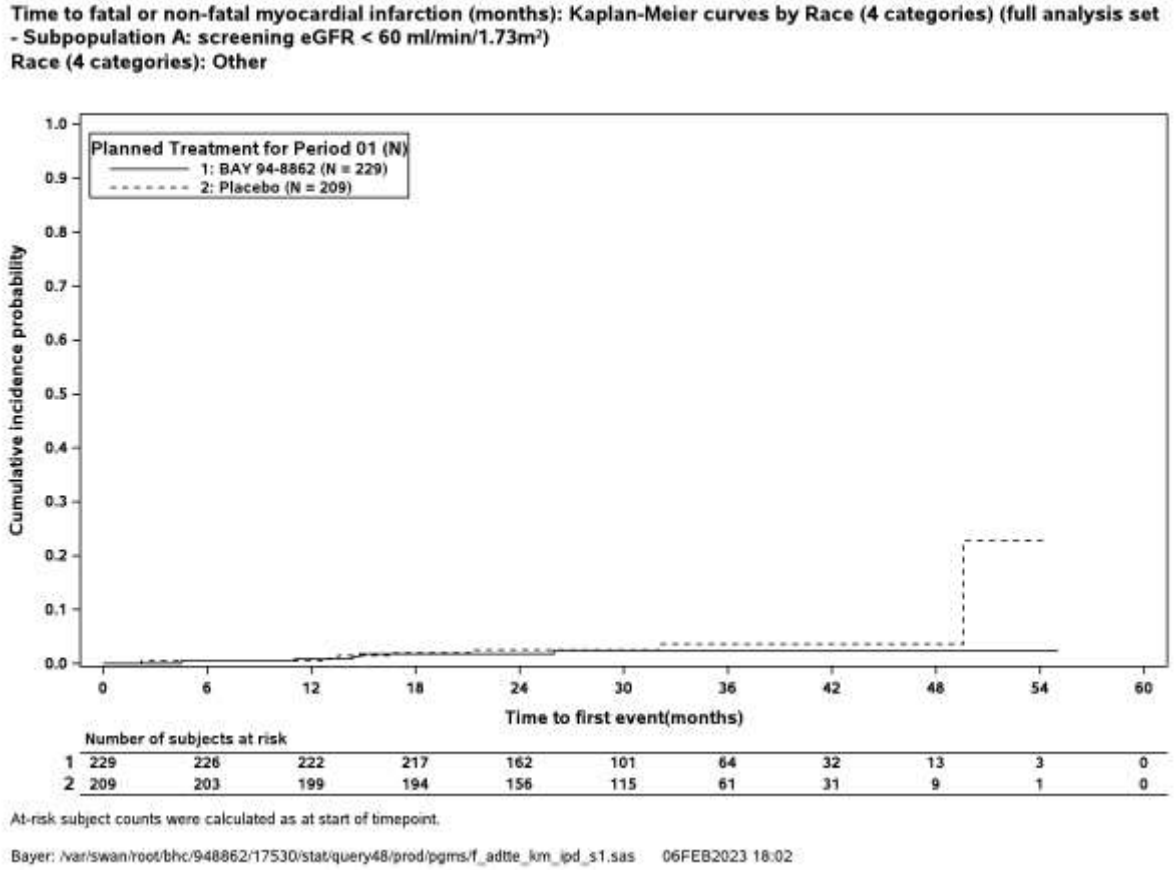


Figure 1.2.1 / 59: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

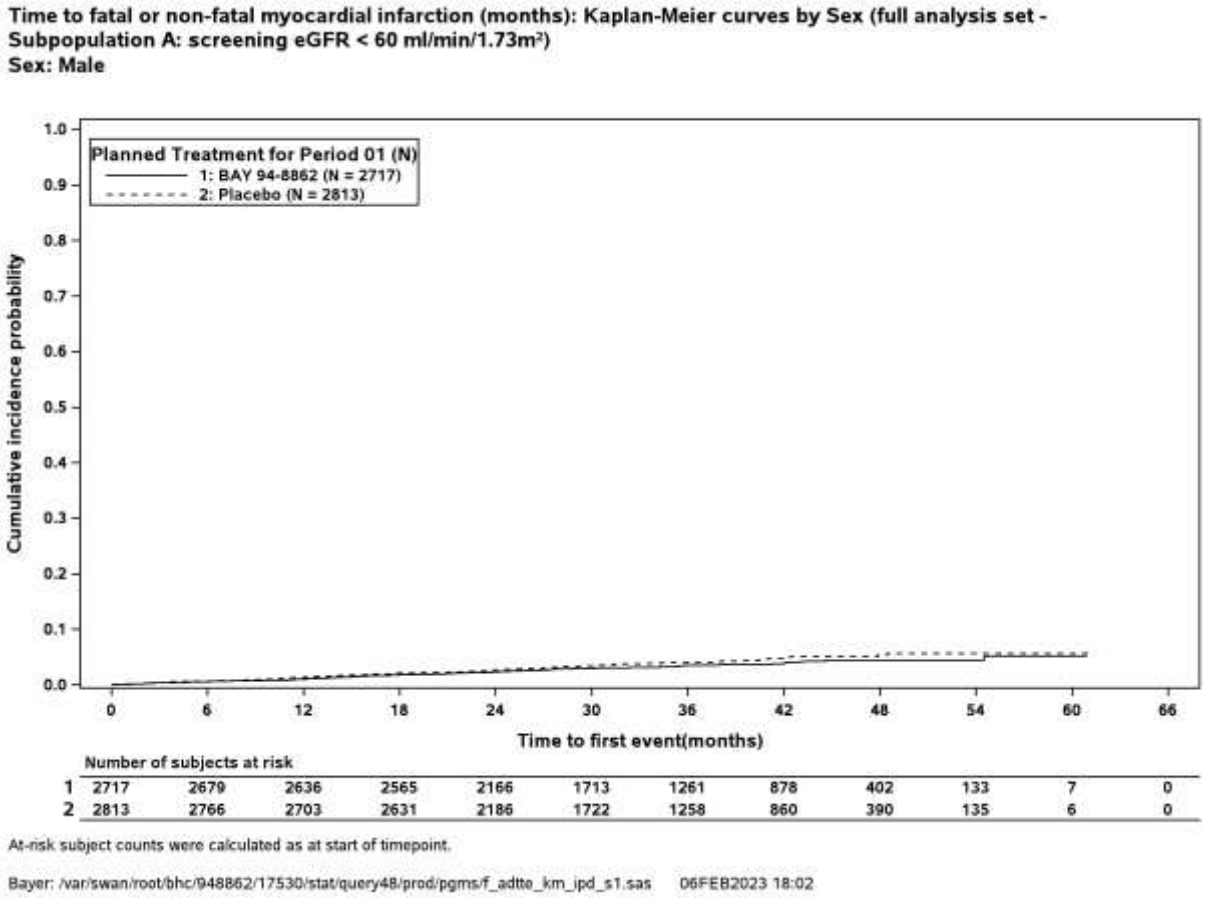


Figure 1.2.1 / 59: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

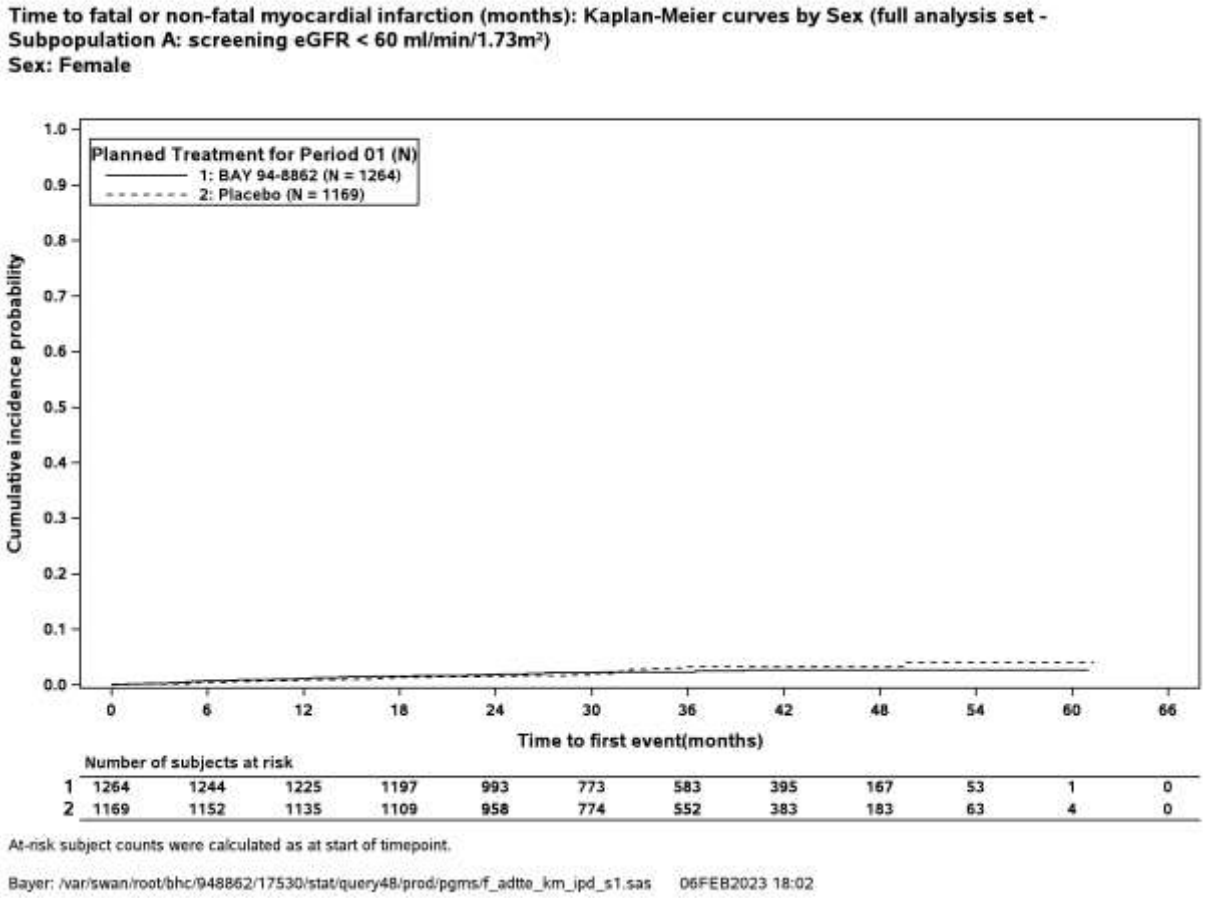


Figure 1.2.1 / 60: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

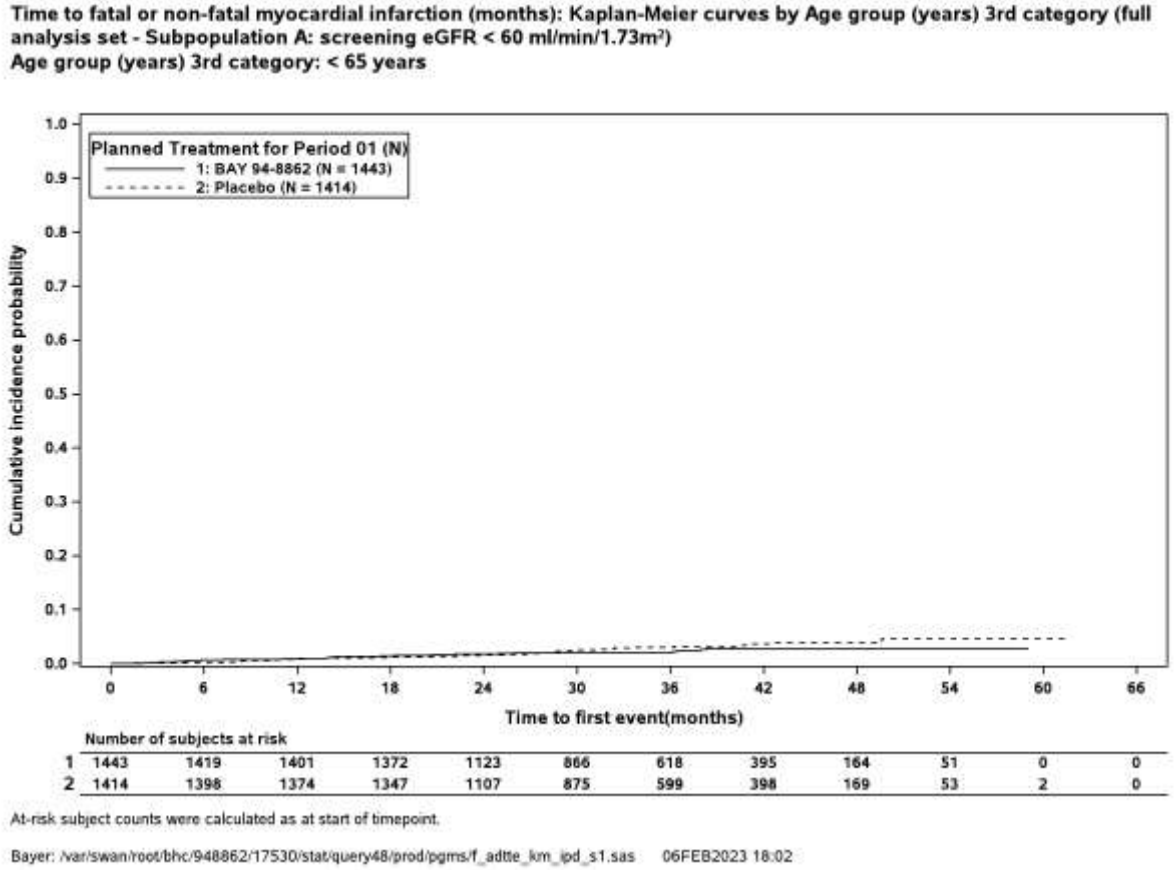


Figure 1.2.1 / 60: Time to fatal or non-fatal myocardial infarction (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

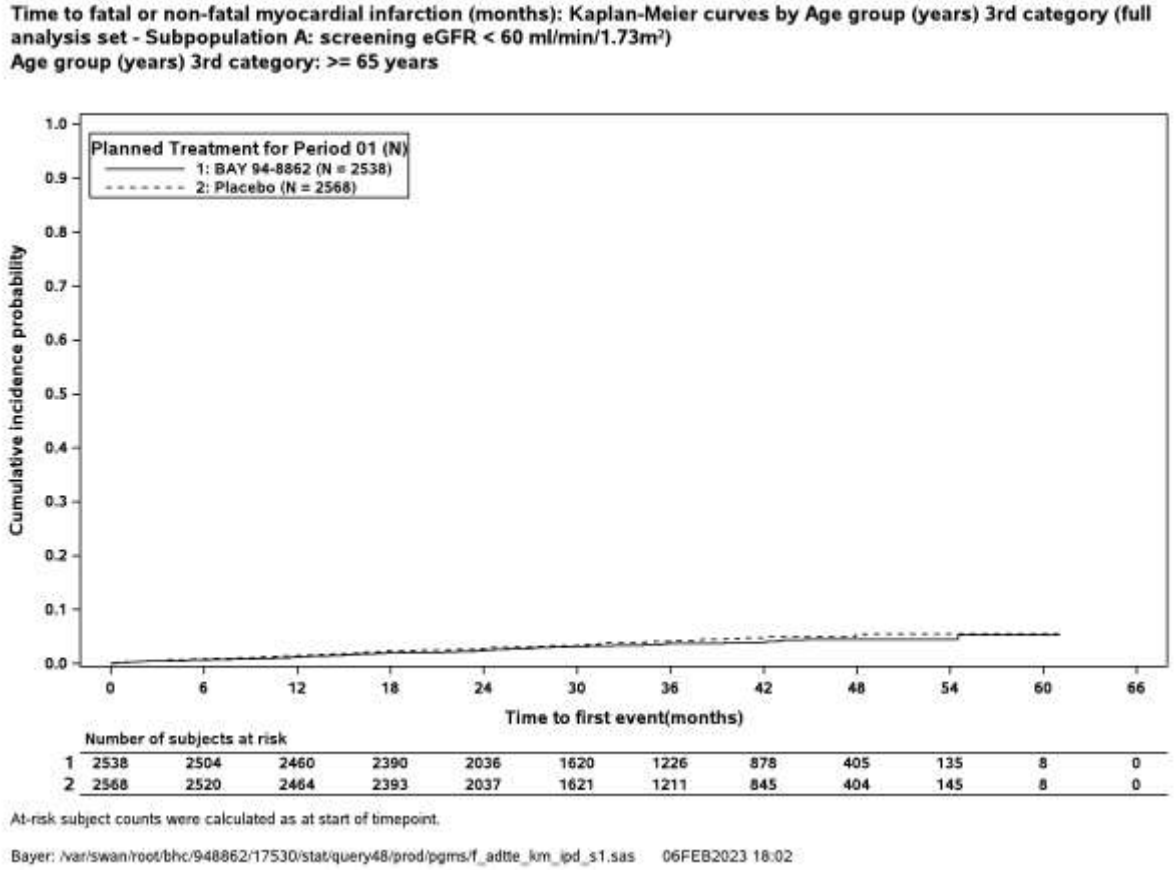


Figure 1.2.1 / 61: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

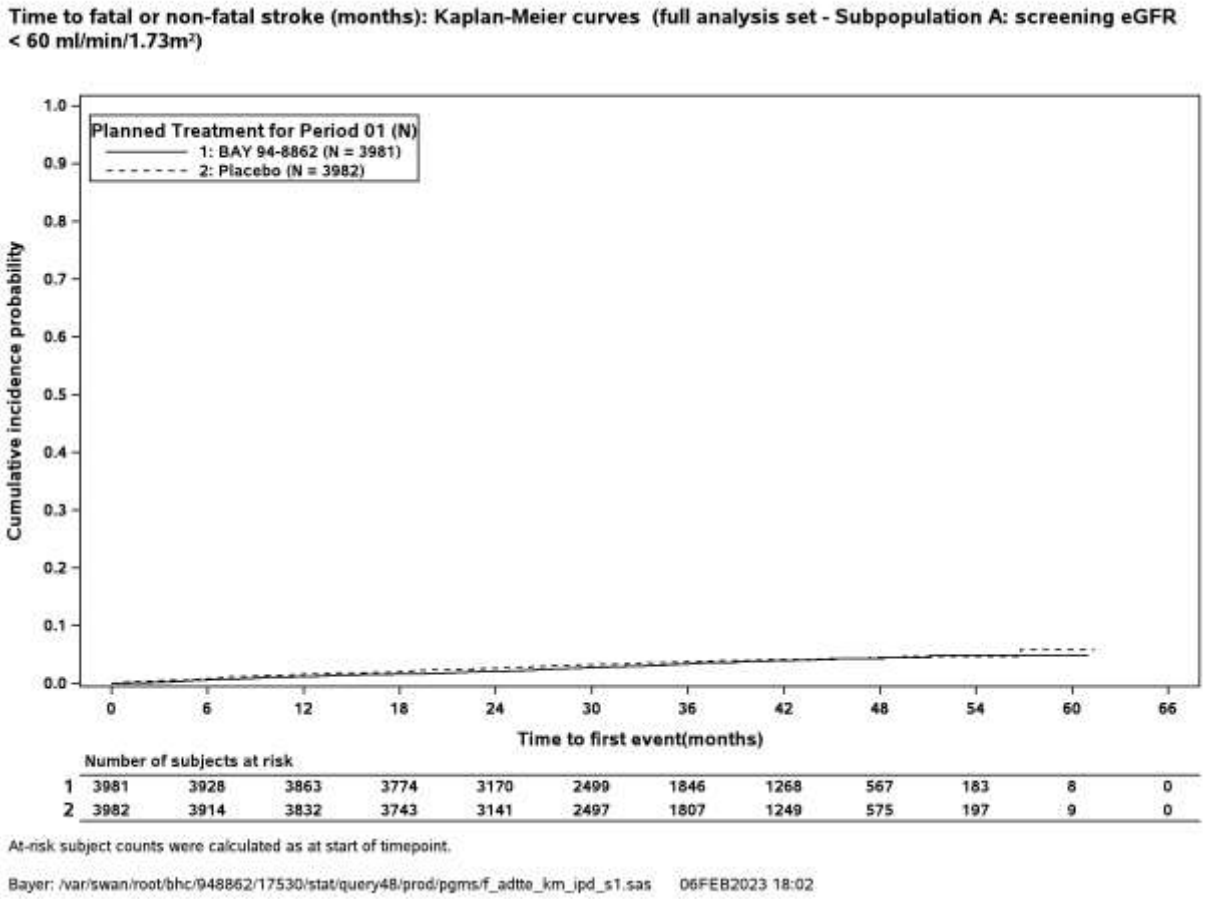


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

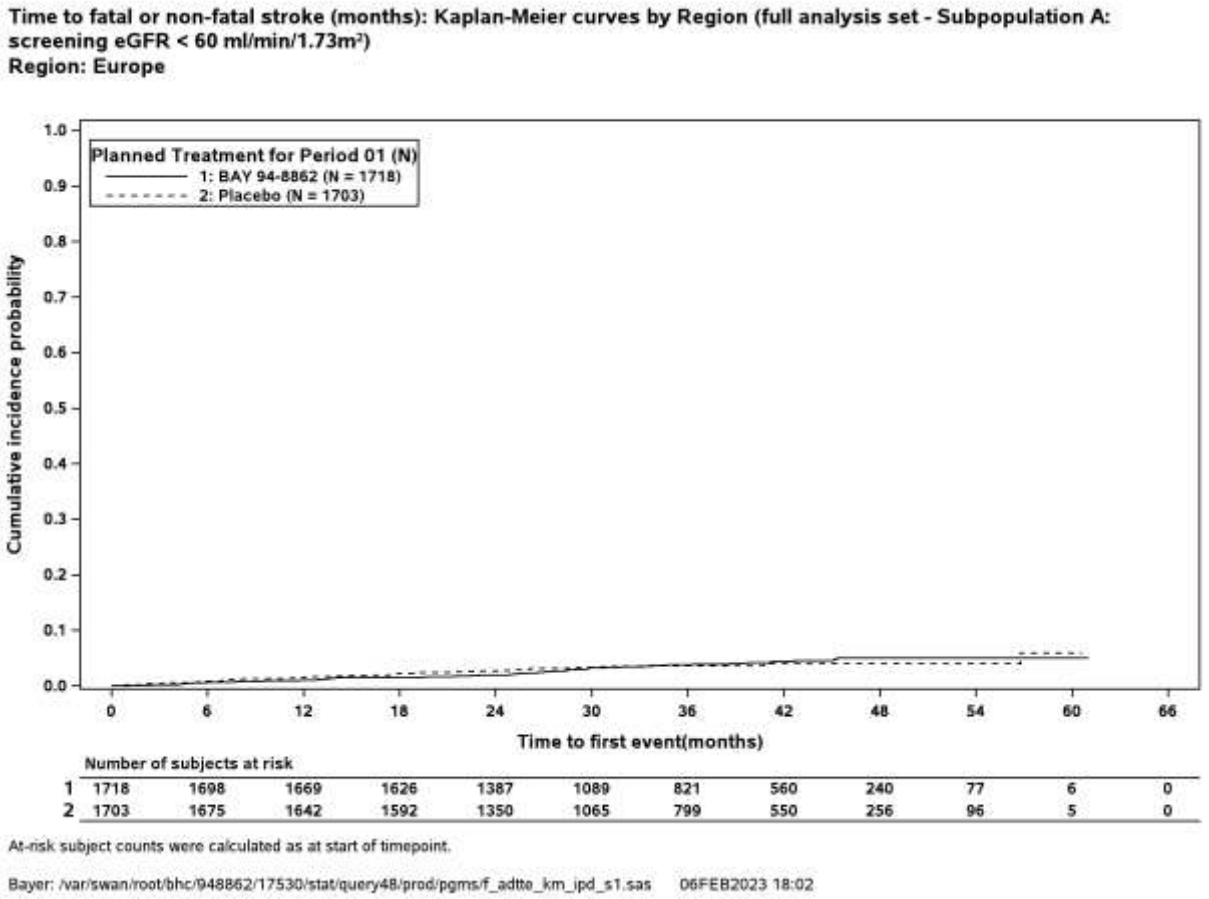


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

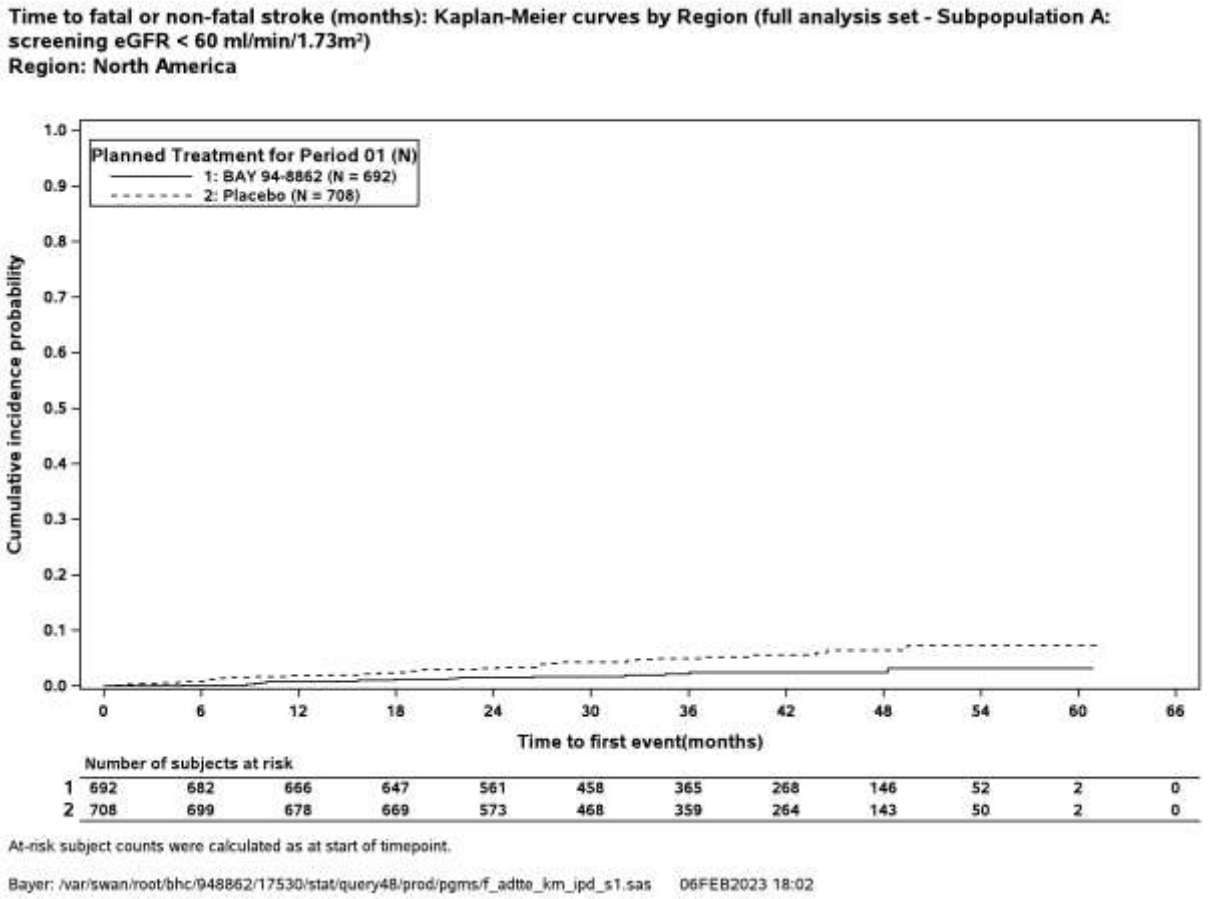


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

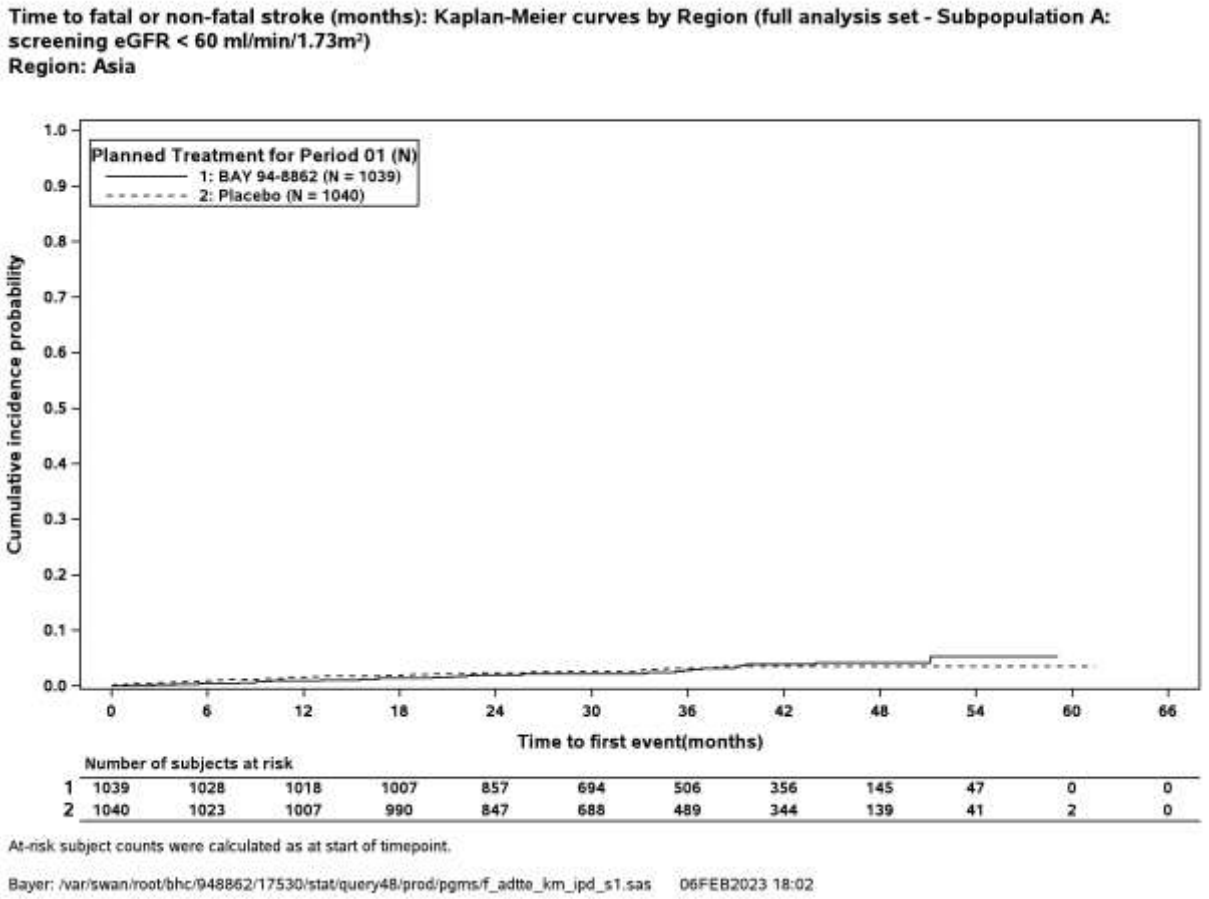


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

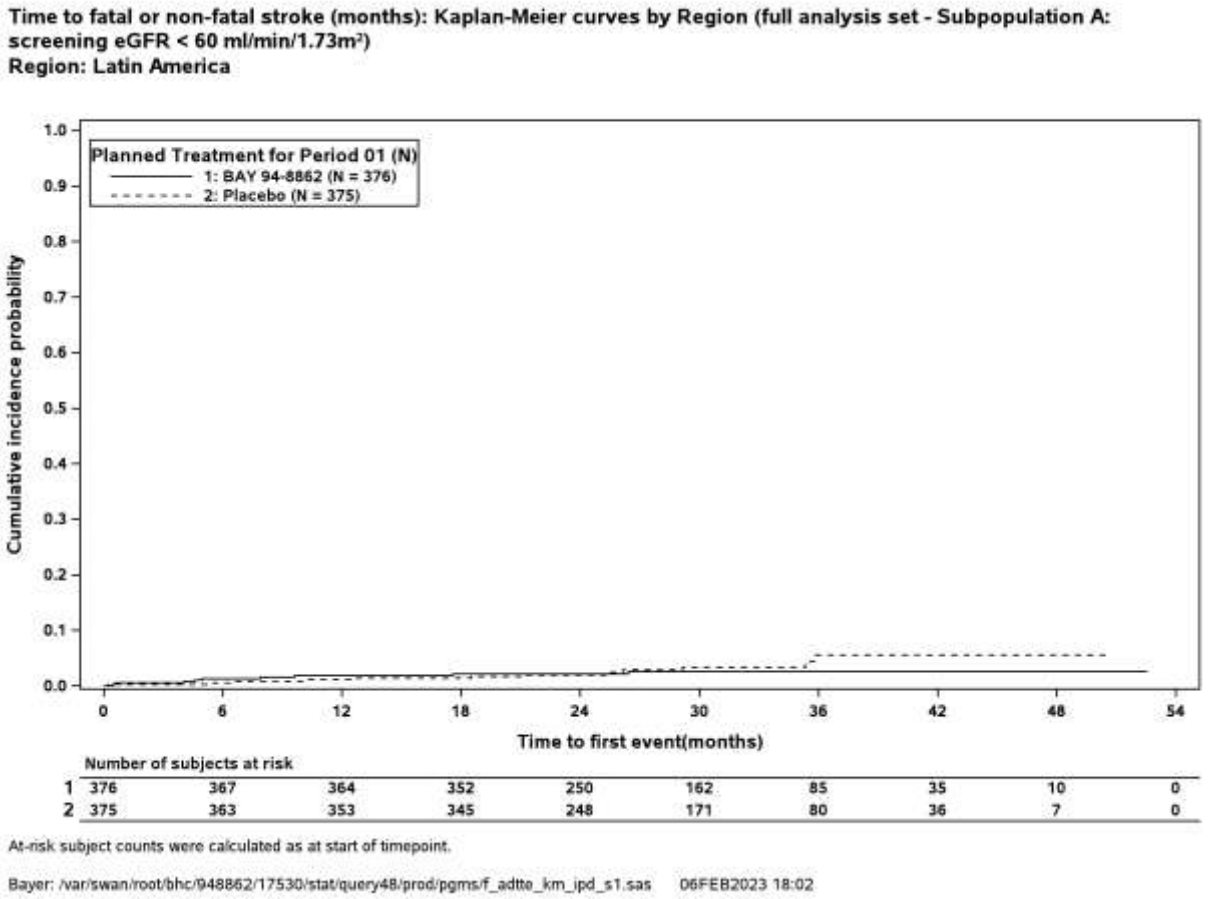


Figure 1.2.1 / 62: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

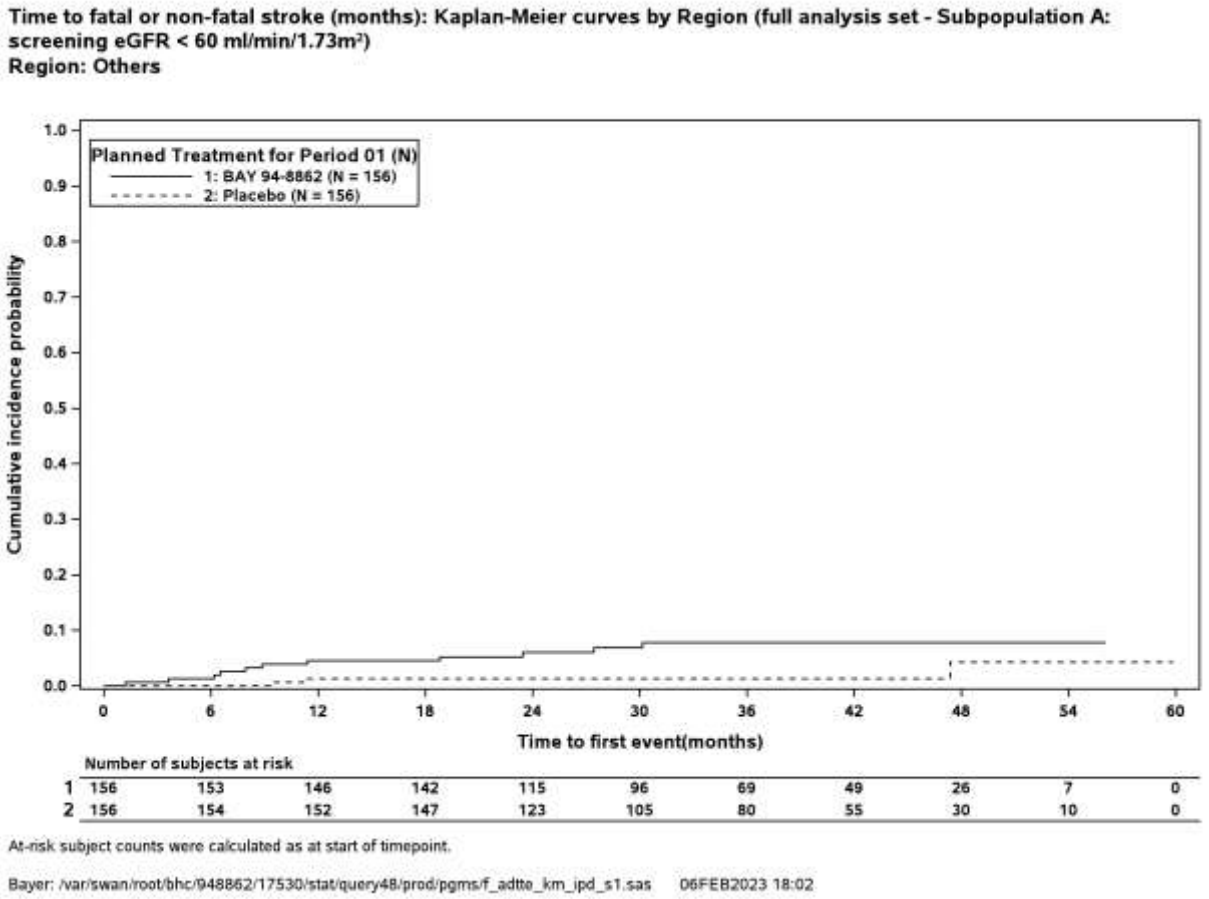


Figure 1.2.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

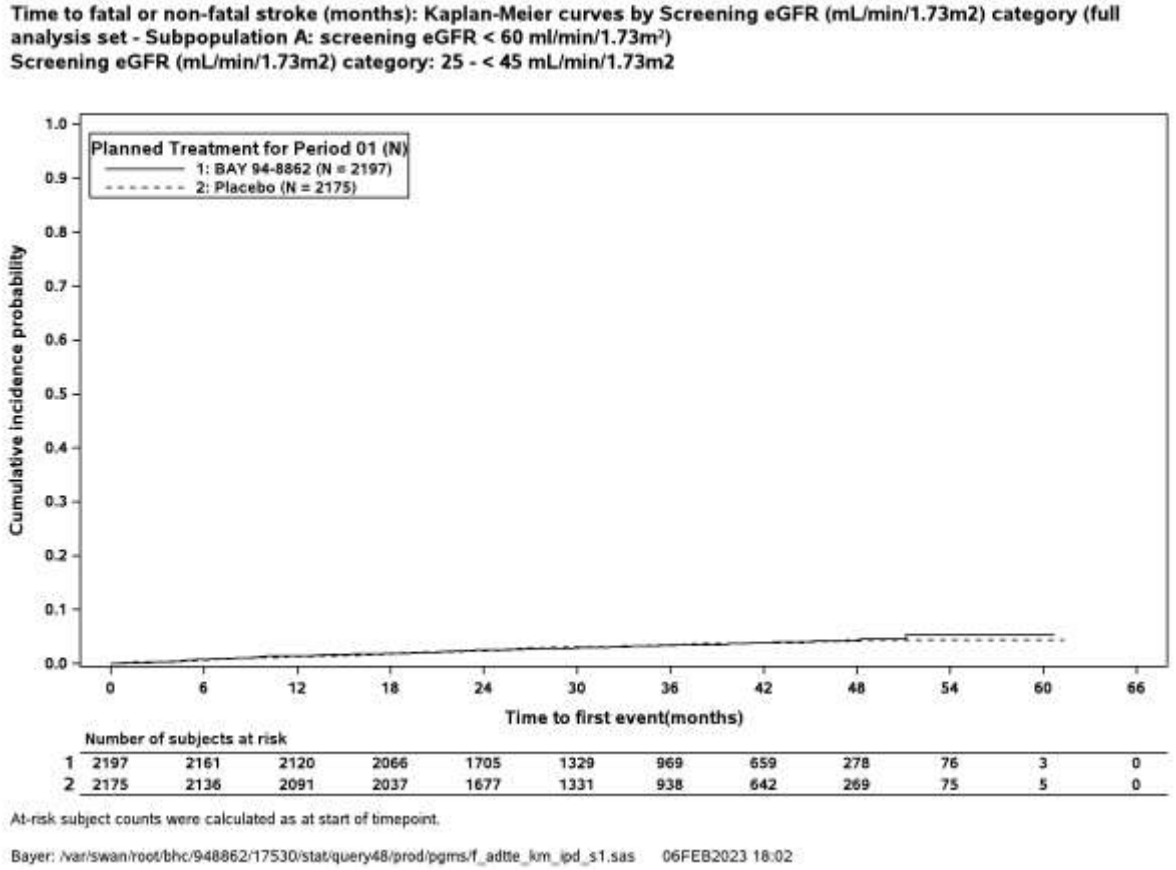


Figure 1.2.1 / 63: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

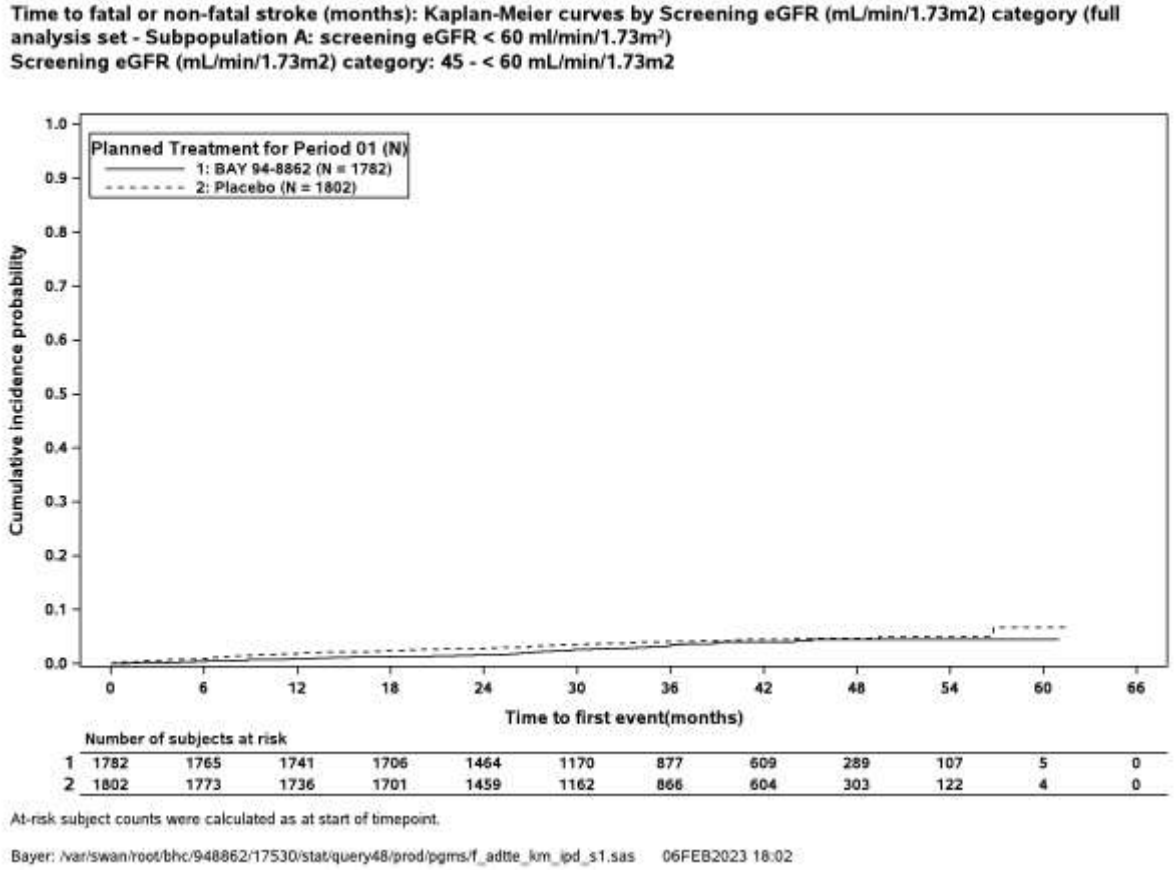


Figure 1.2.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

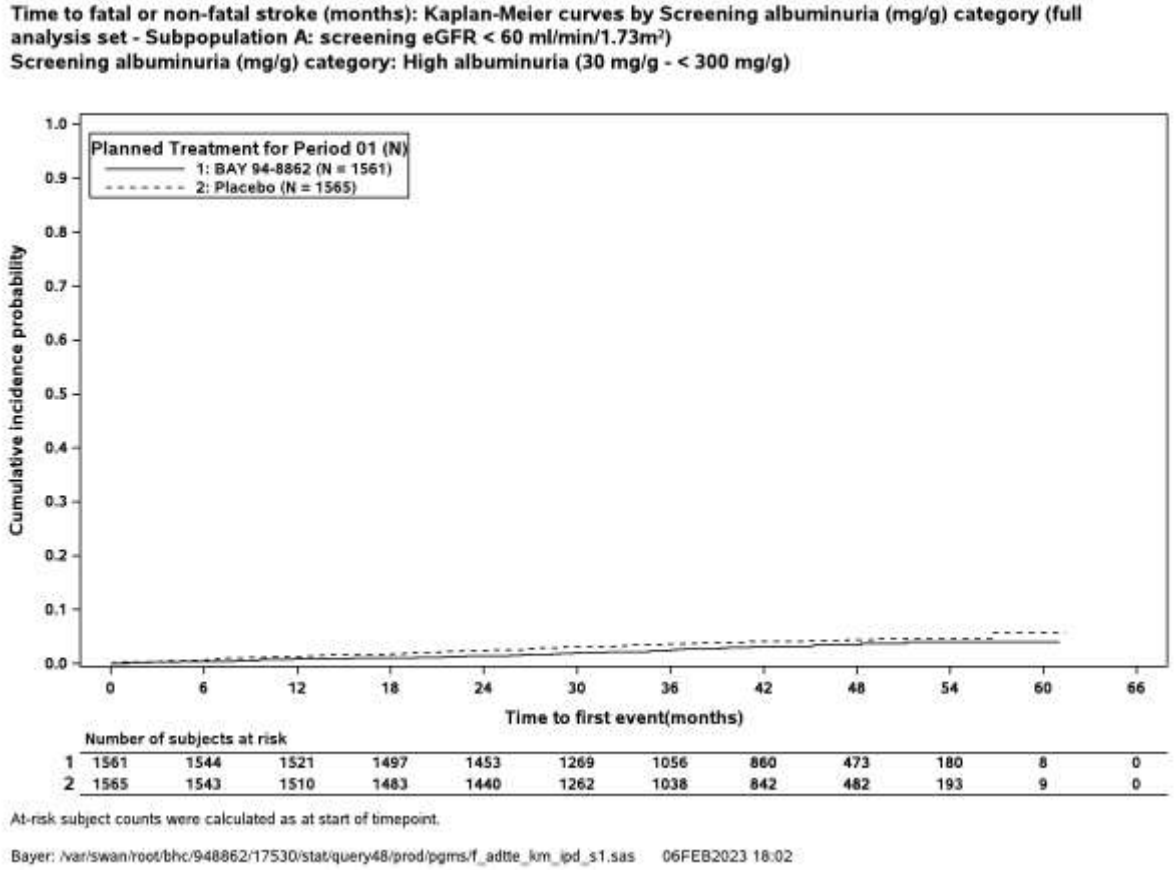


Figure 1.2.1 / 64: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

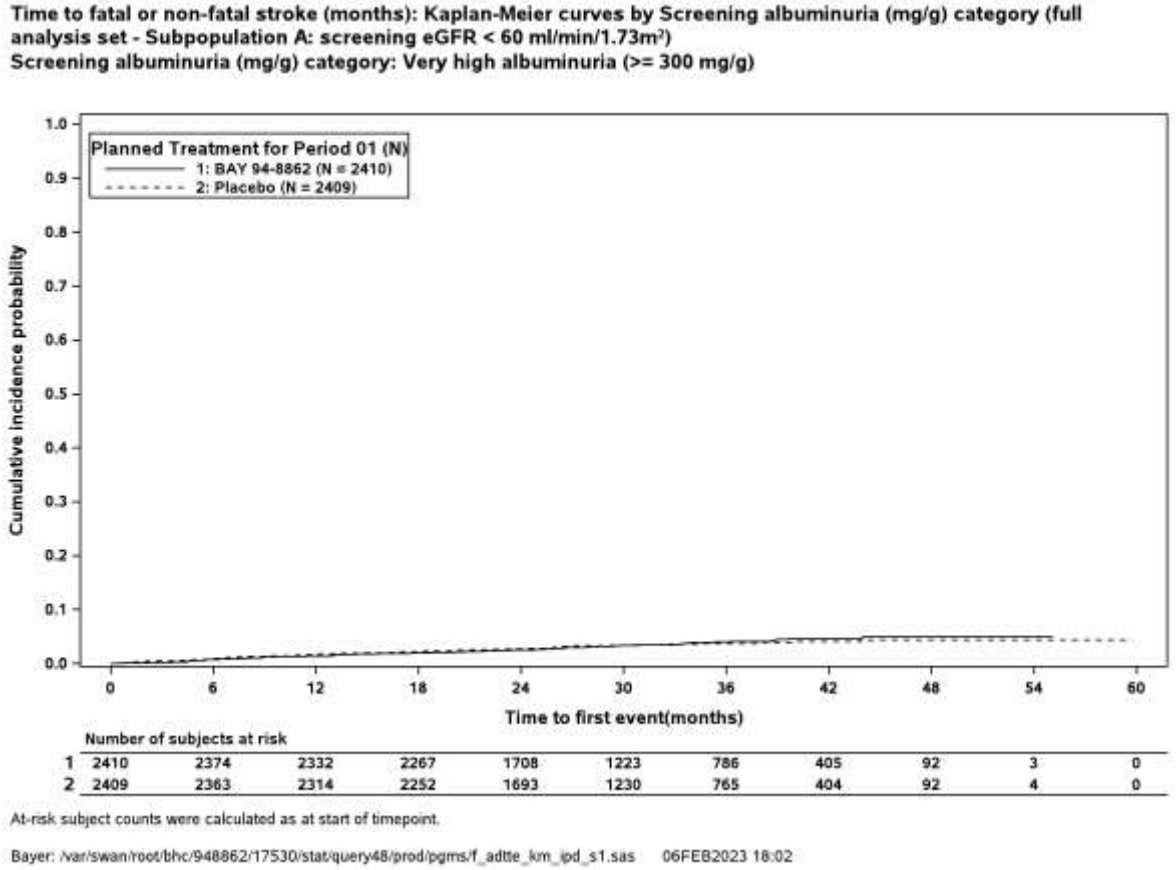


Figure 1.2.1 / 65: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

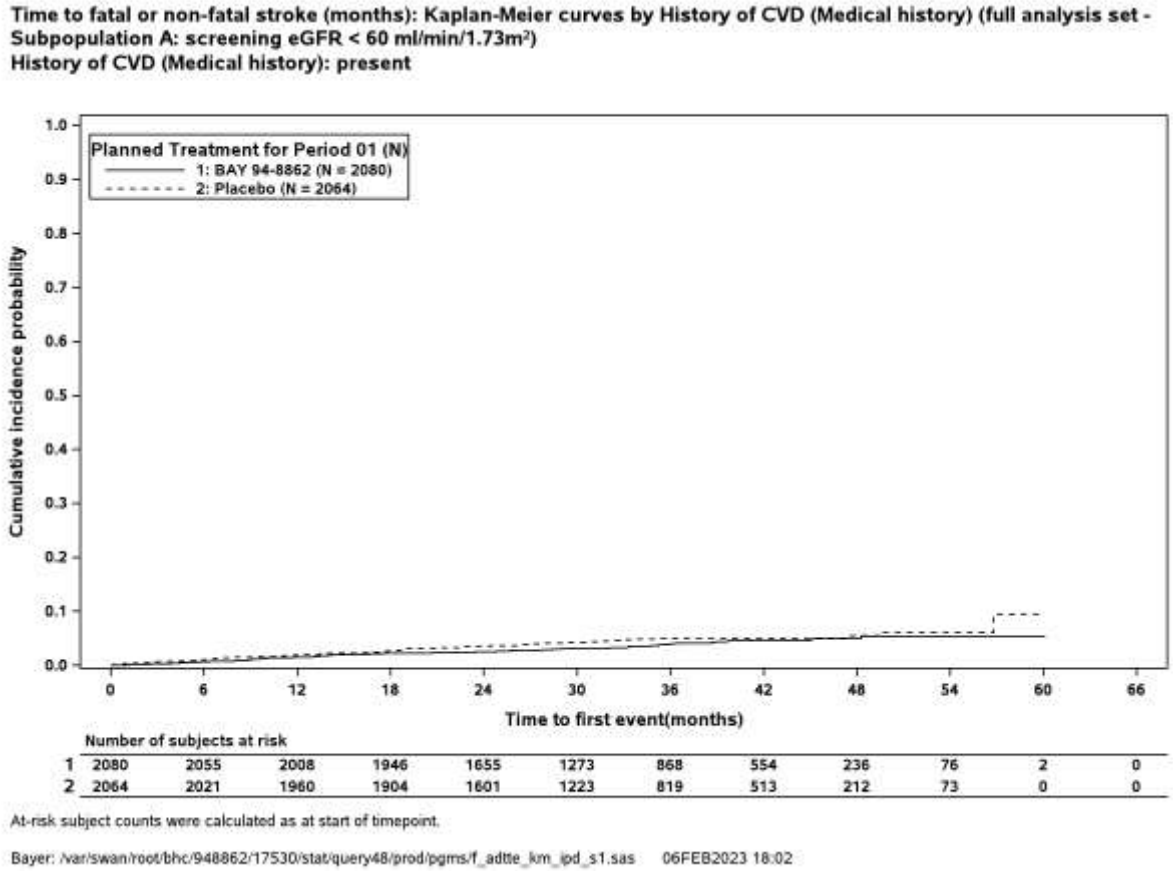


Figure 1.2.1 / 65: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

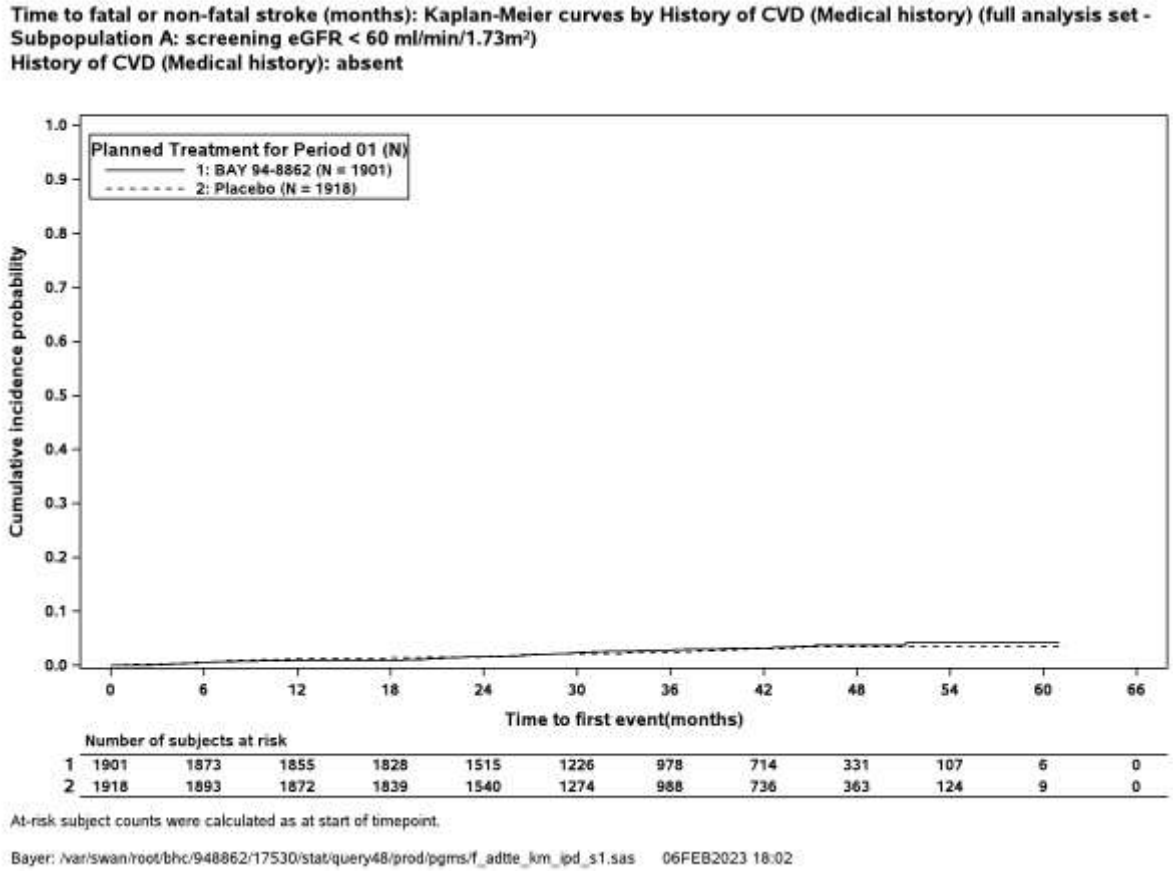


Figure 1.2.1 / 66: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

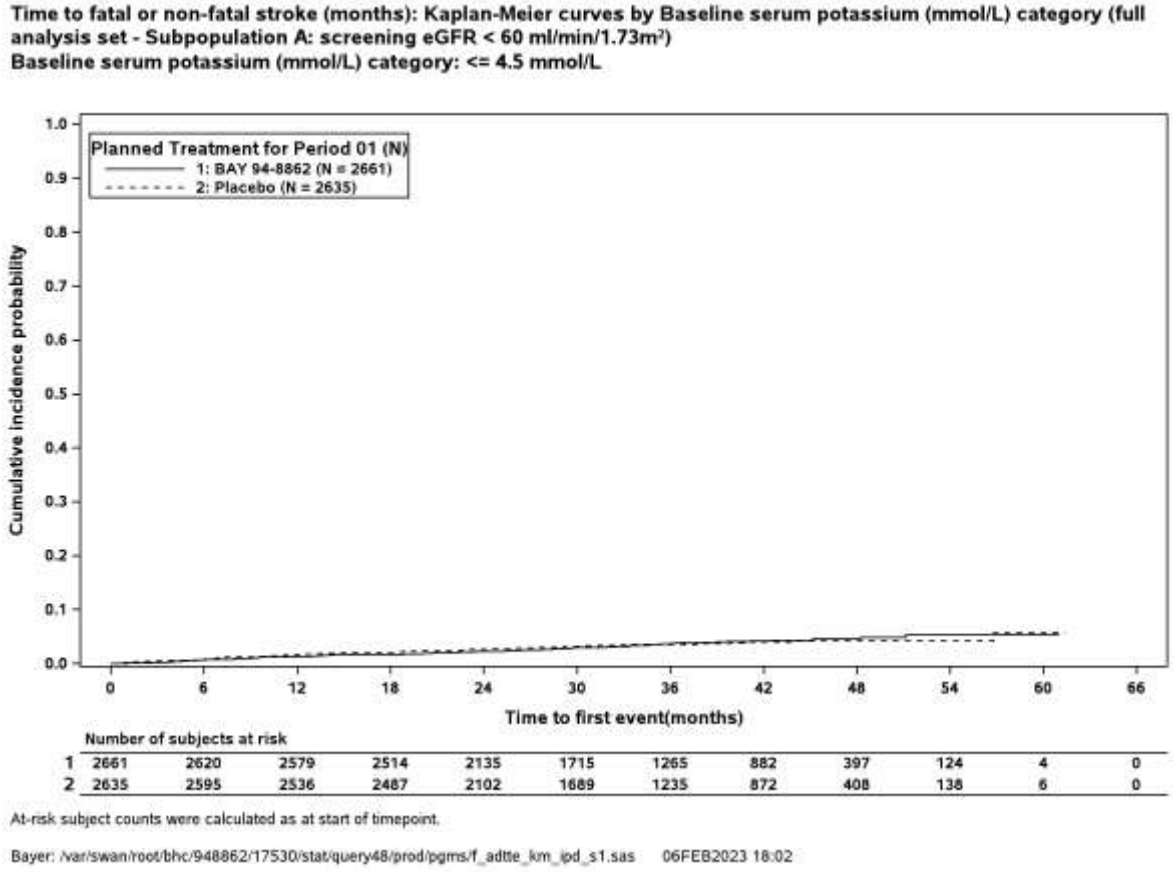


Figure 1.2.1 / 66: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

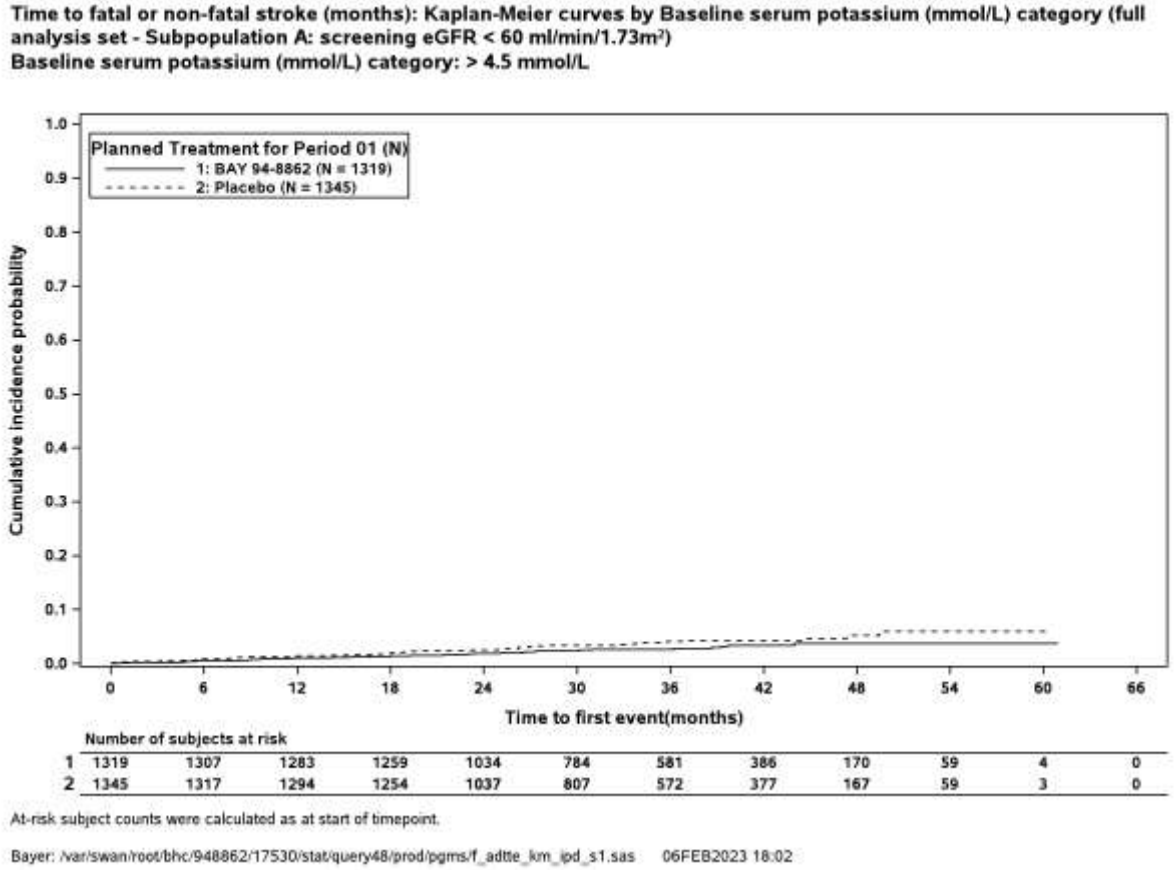


Figure 1.2.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

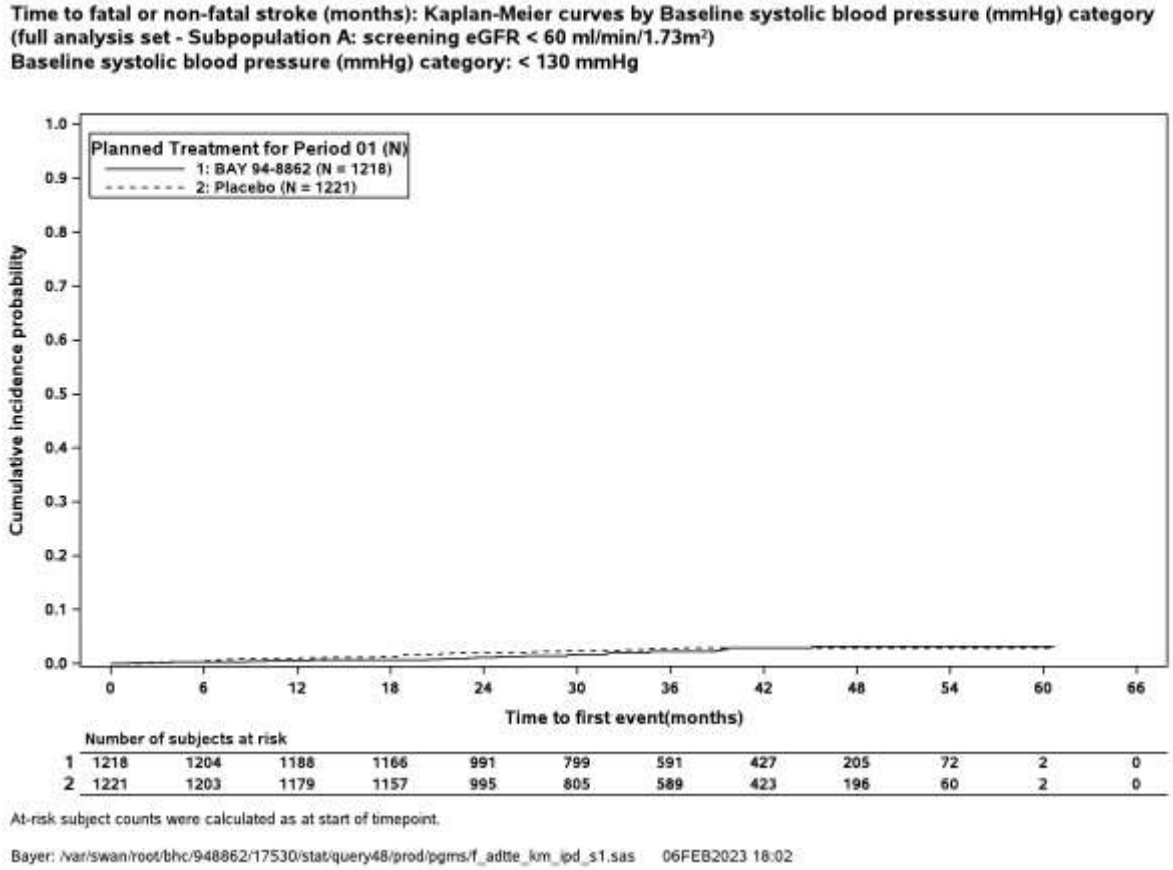


Figure 1.2.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

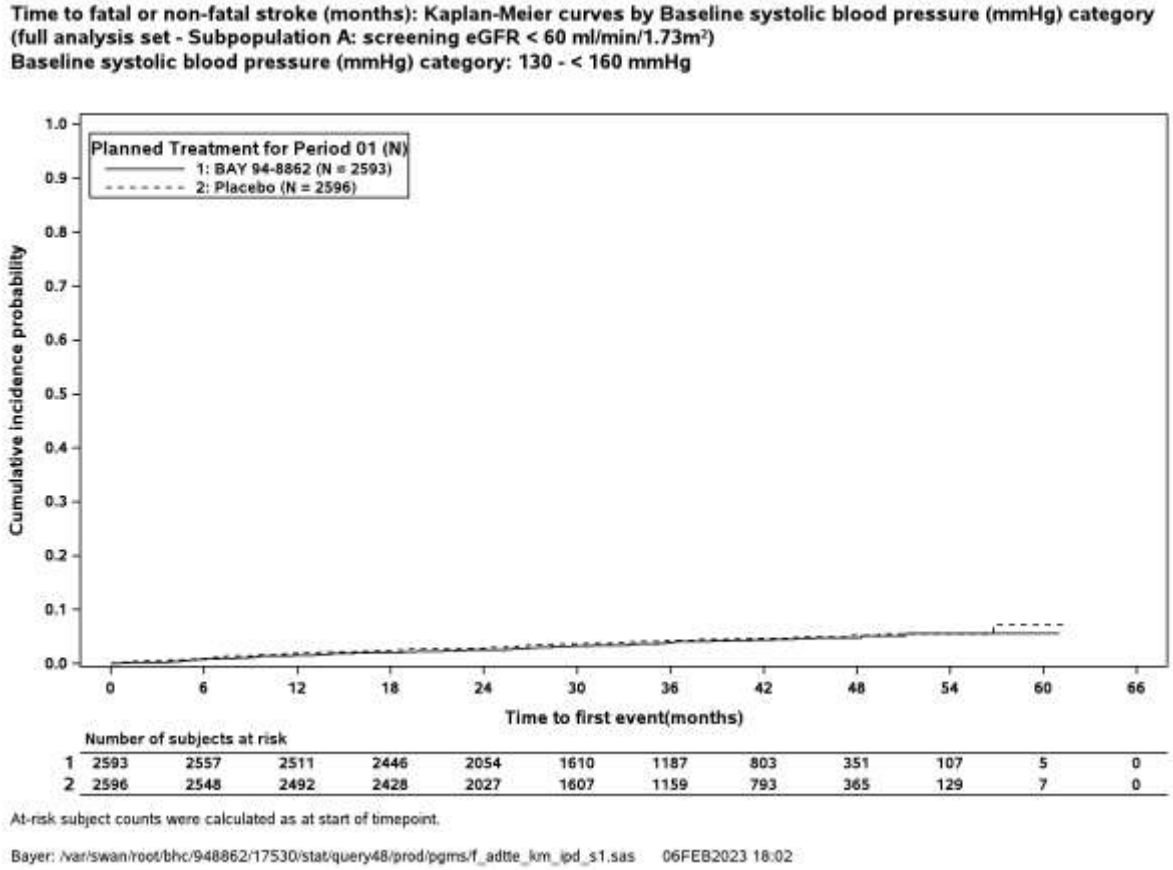


Figure 1.2.1 / 67: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

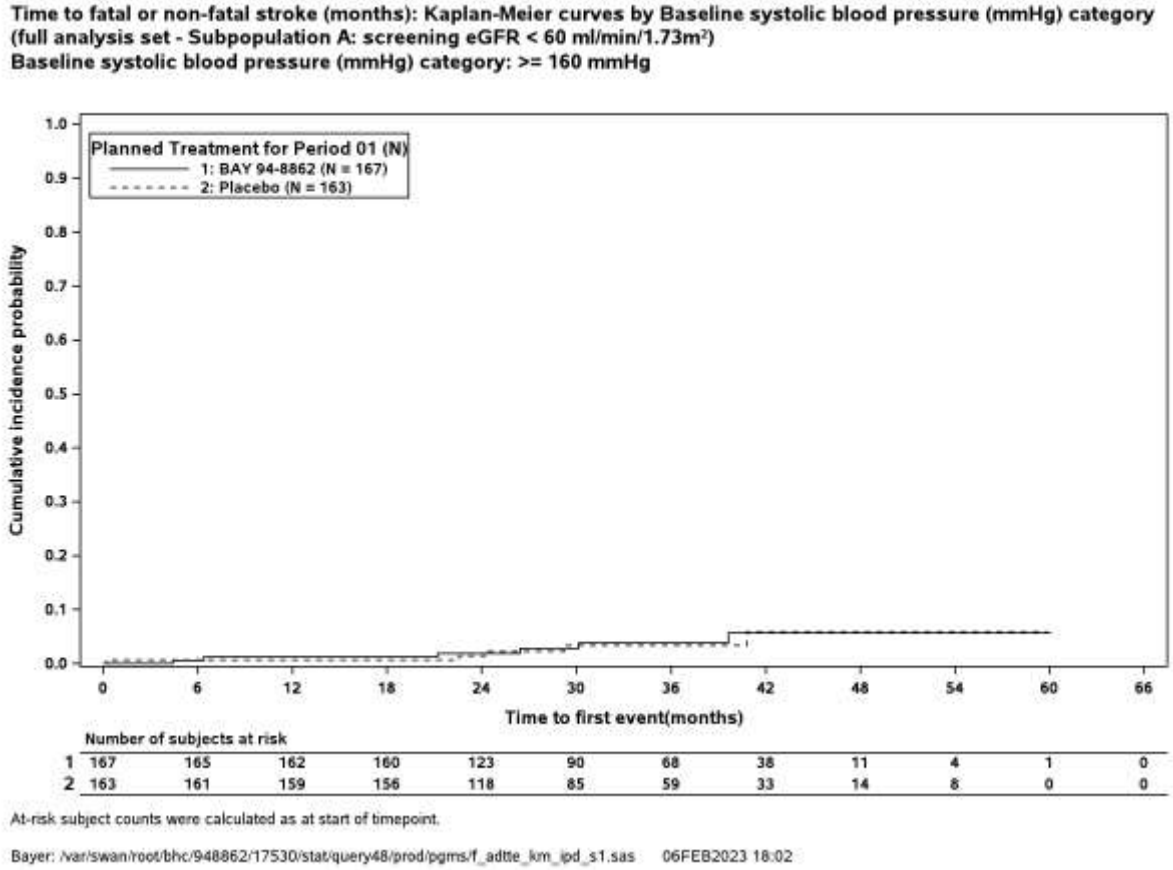


Figure 1.2.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

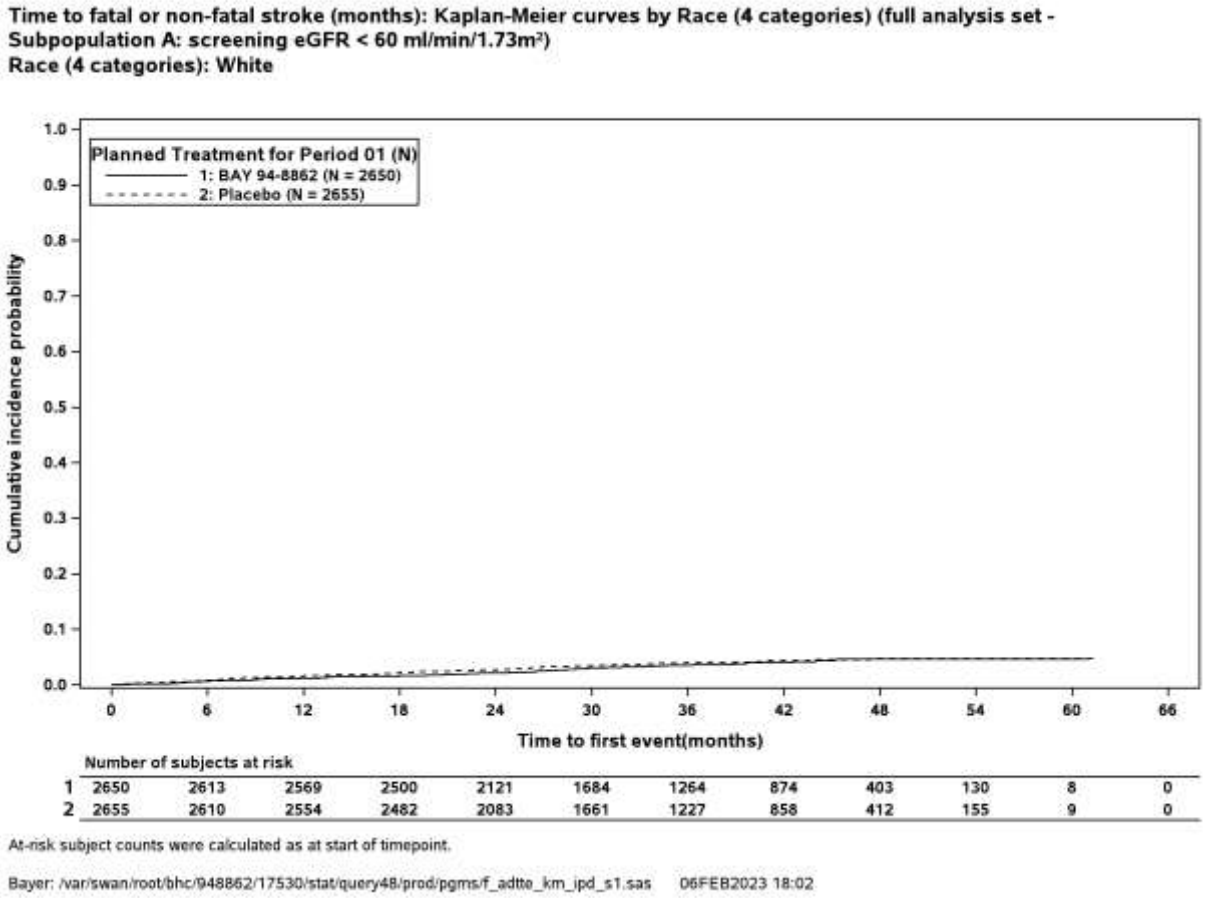


Figure 1.2.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

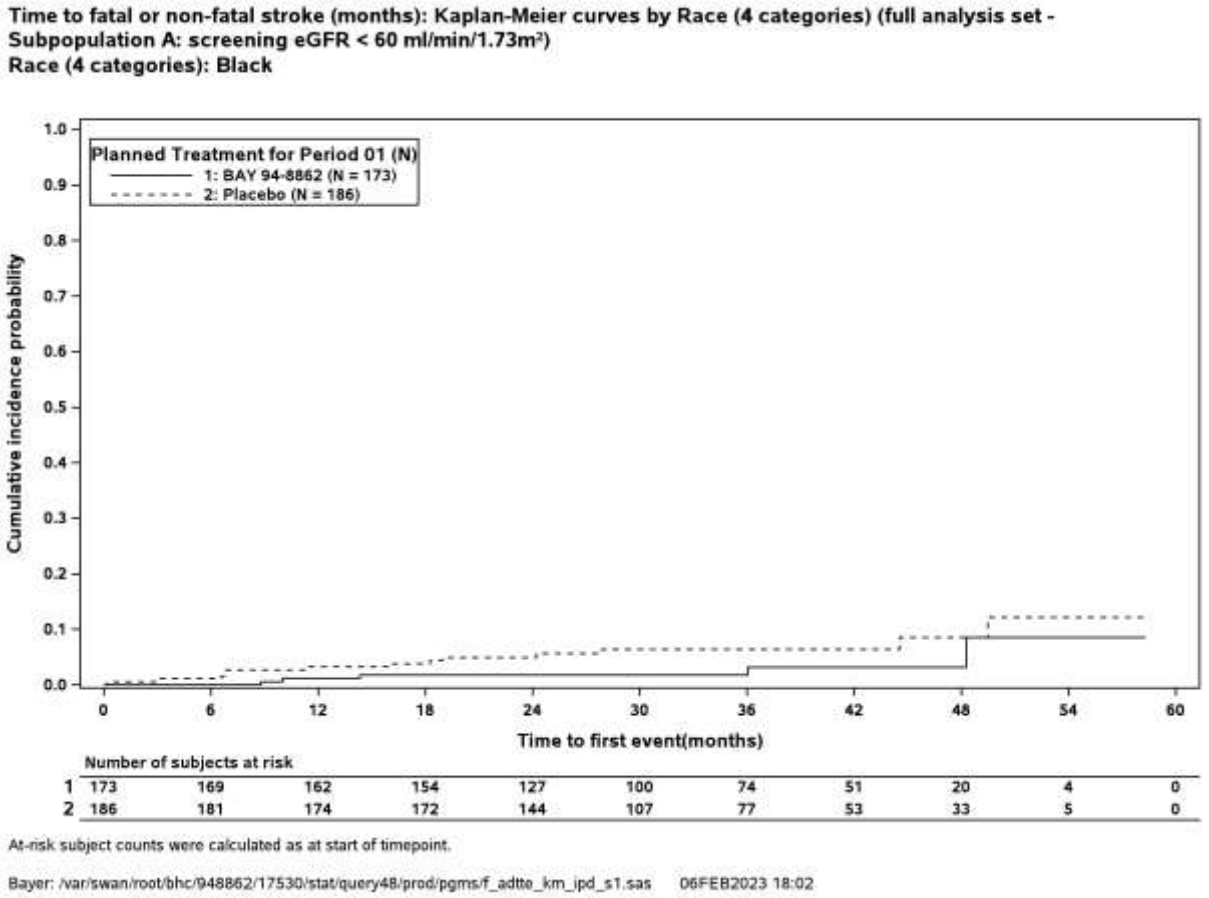


Figure 1.2.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

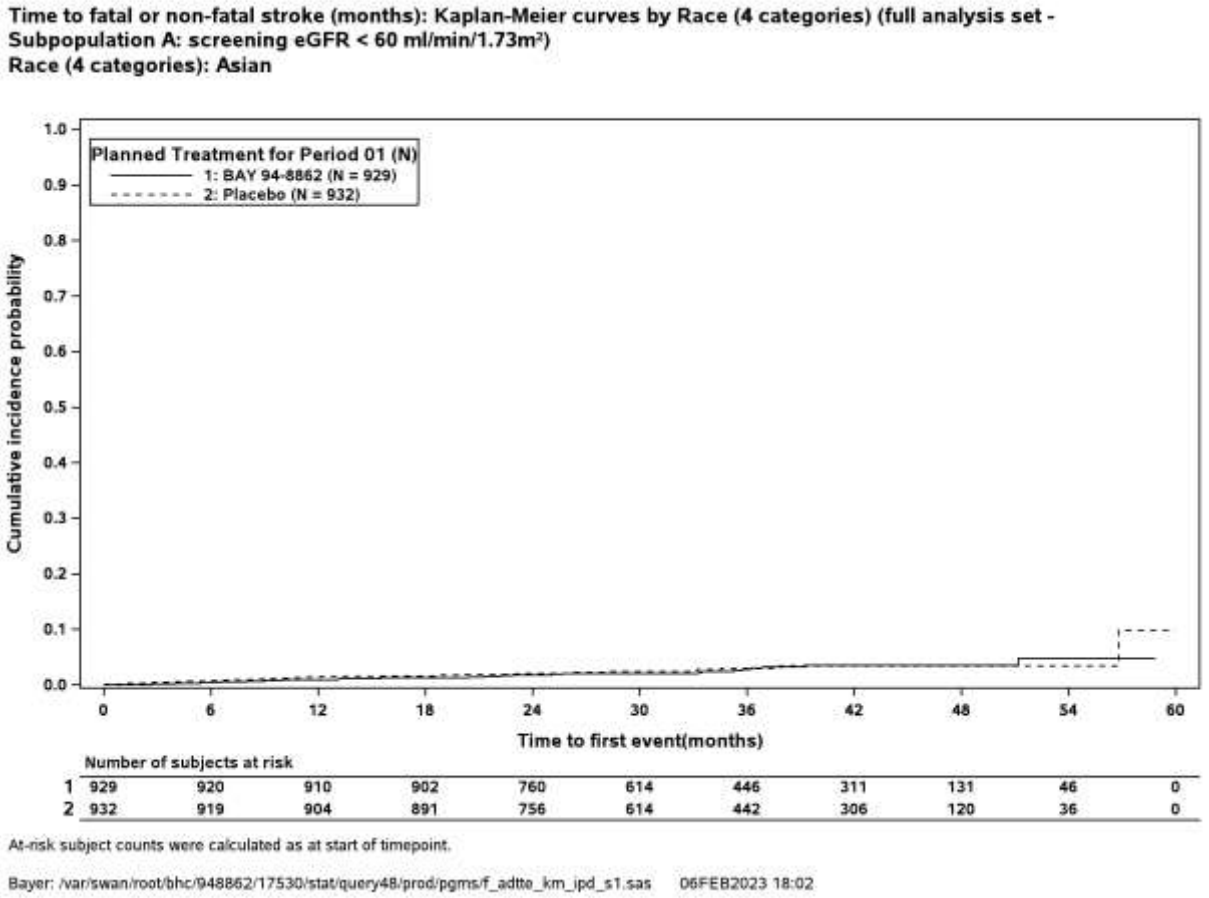


Figure 1.2.1 / 68: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

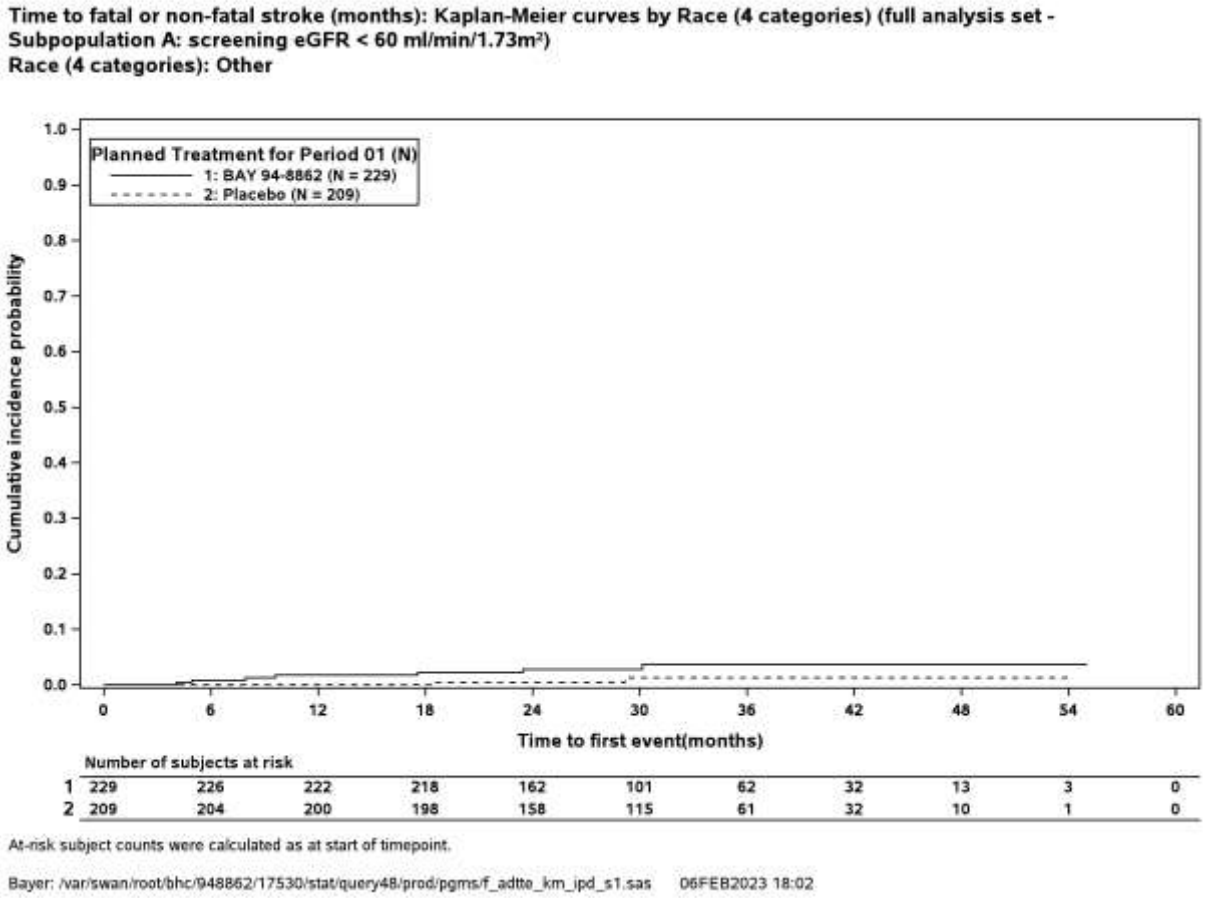


Figure 1.2.1 / 69: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

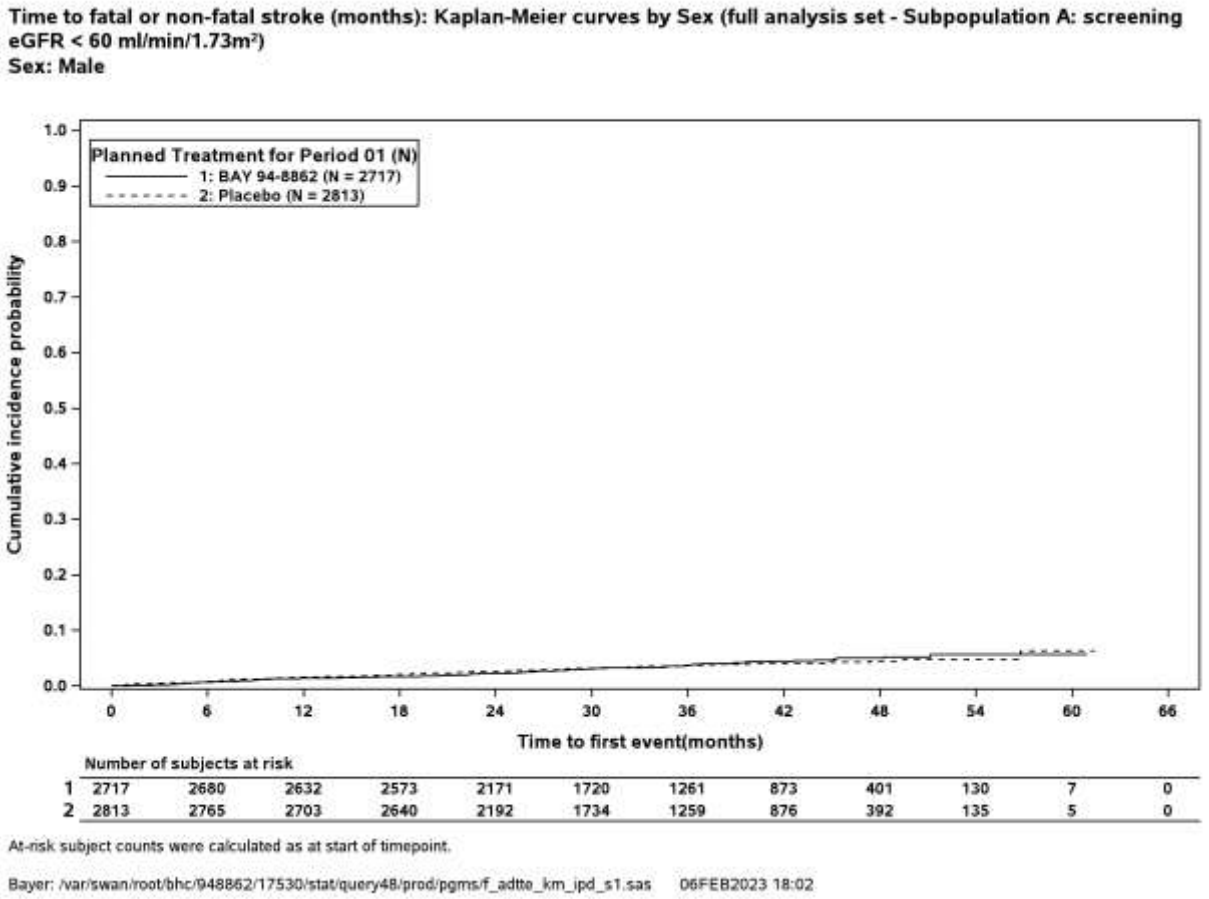


Figure 1.2.1 / 69: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

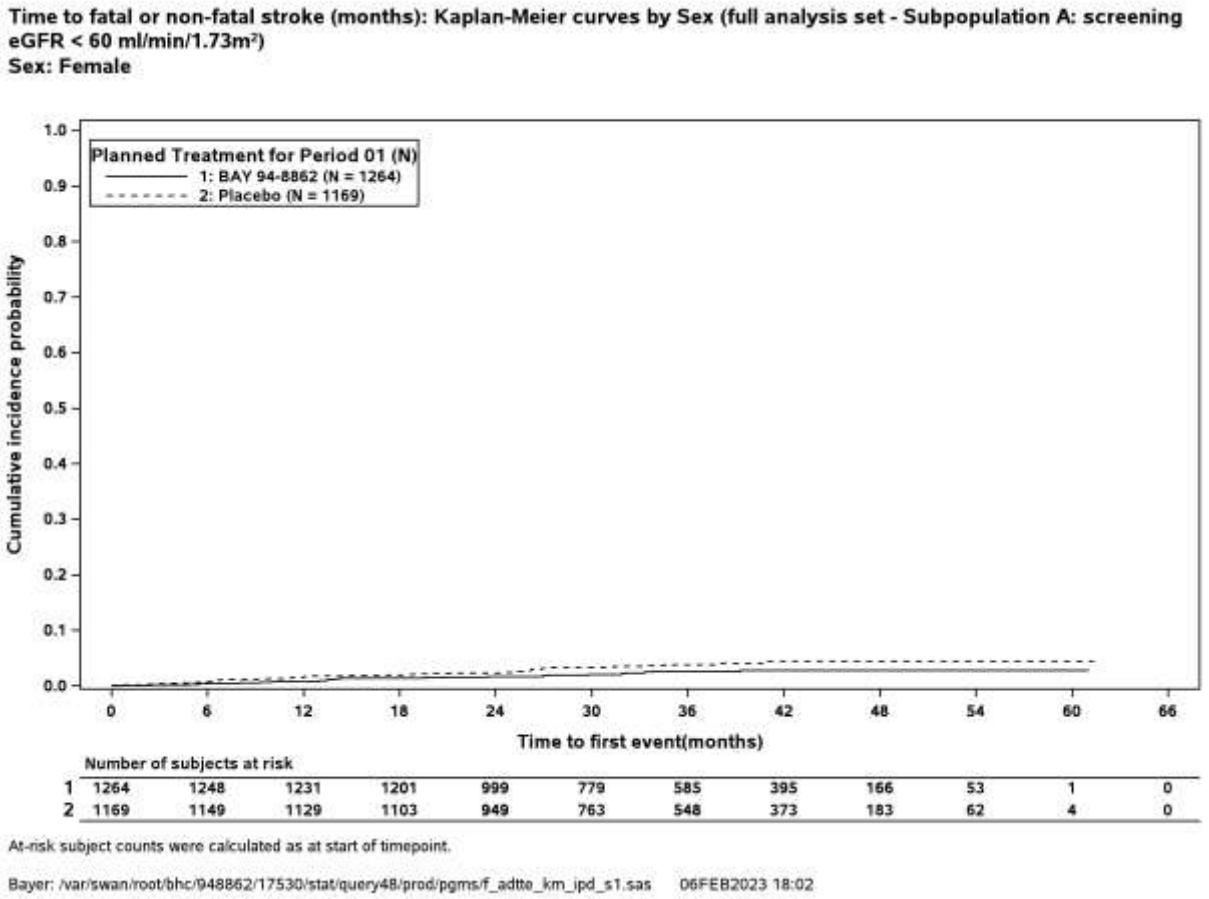


Figure 1.2.1 / 70: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

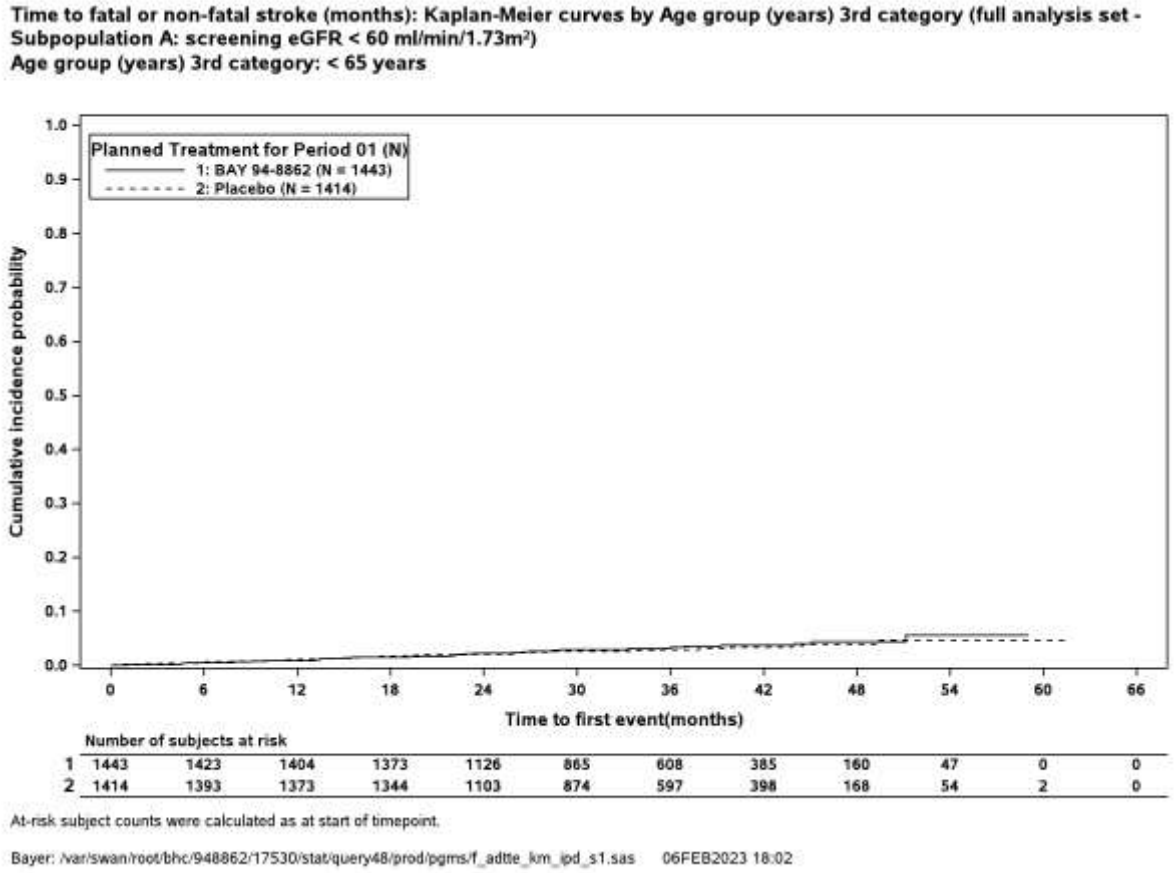


Figure 1.2.1 / 70: Time to fatal or non-fatal stroke (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

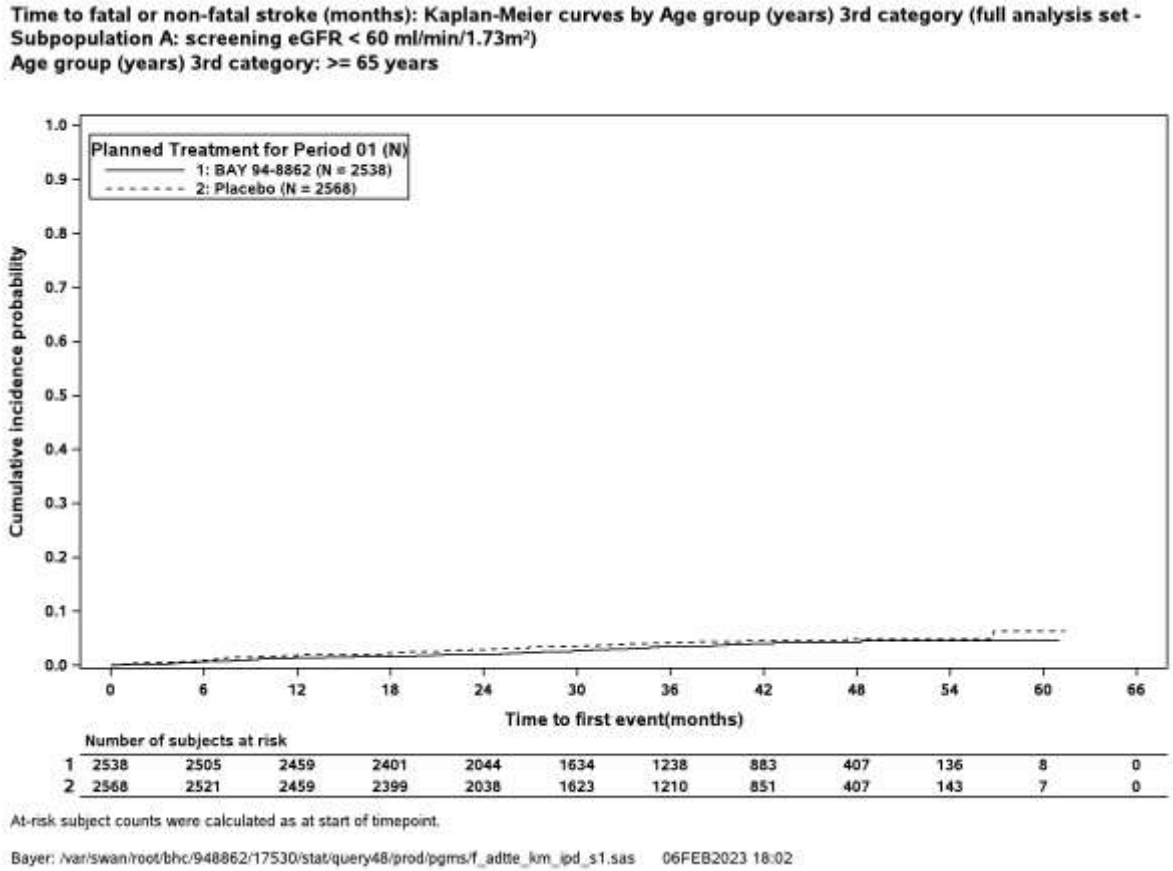


Figure 1.2.1 / 71: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

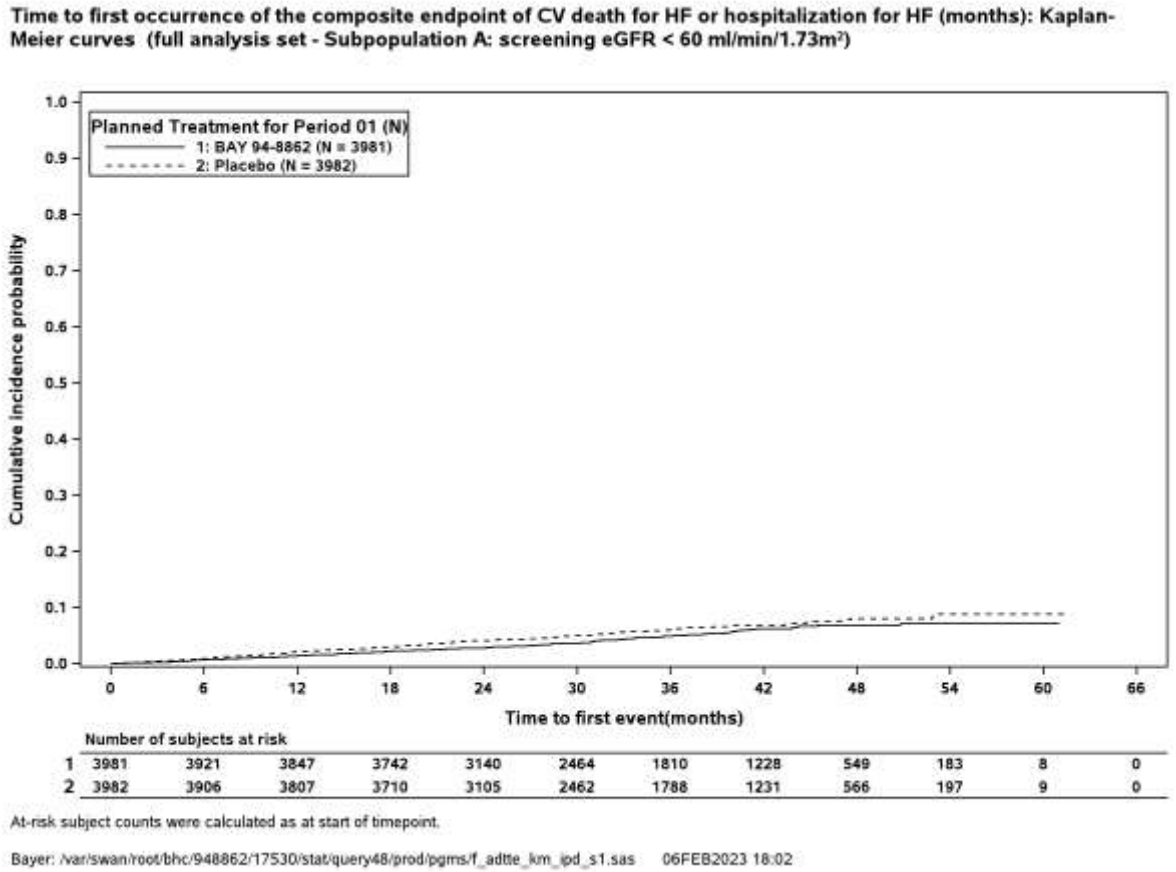


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

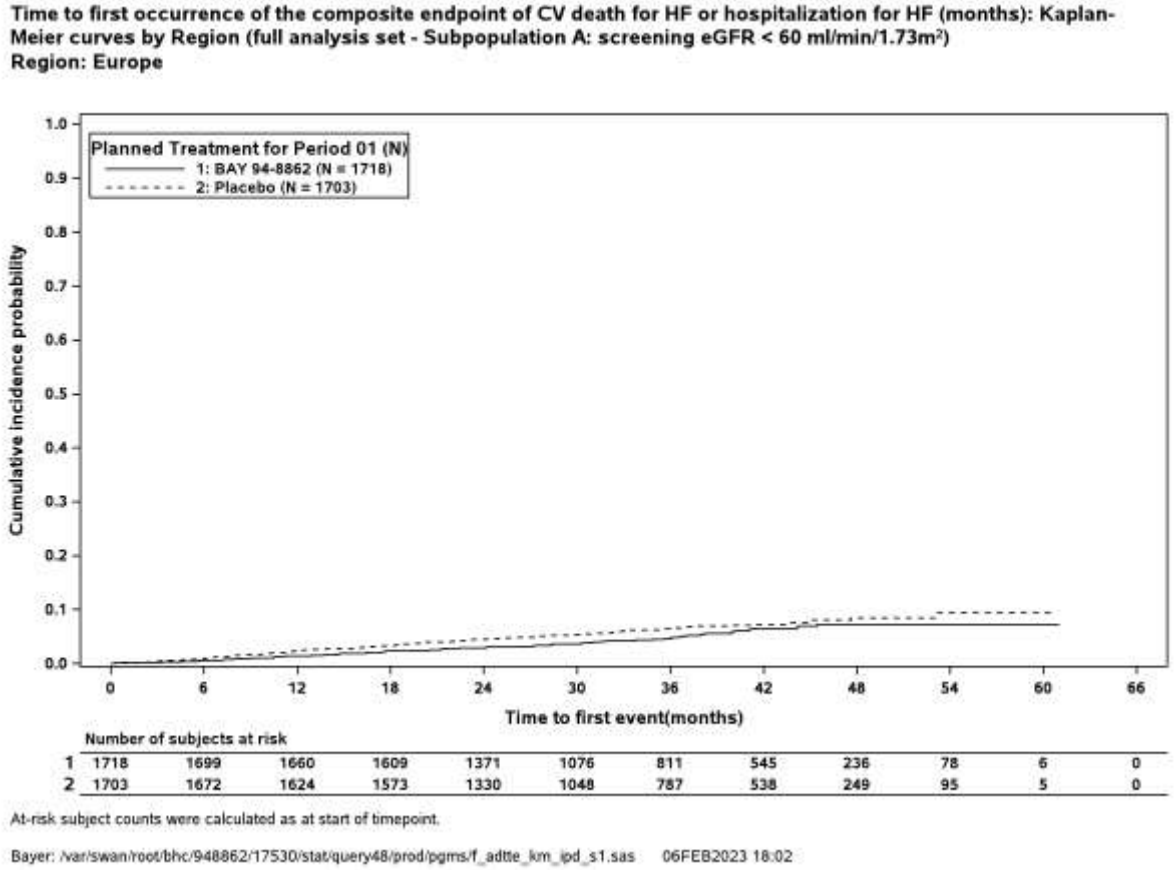


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

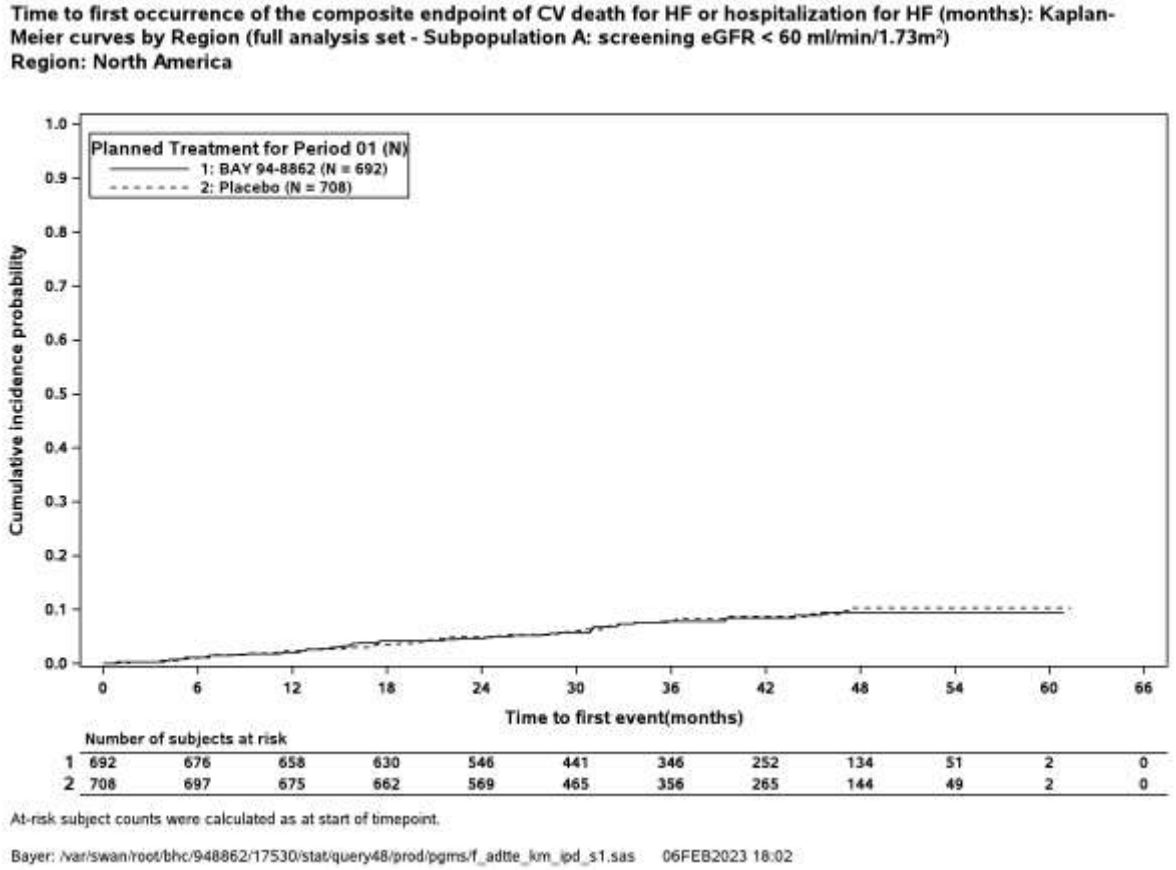


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

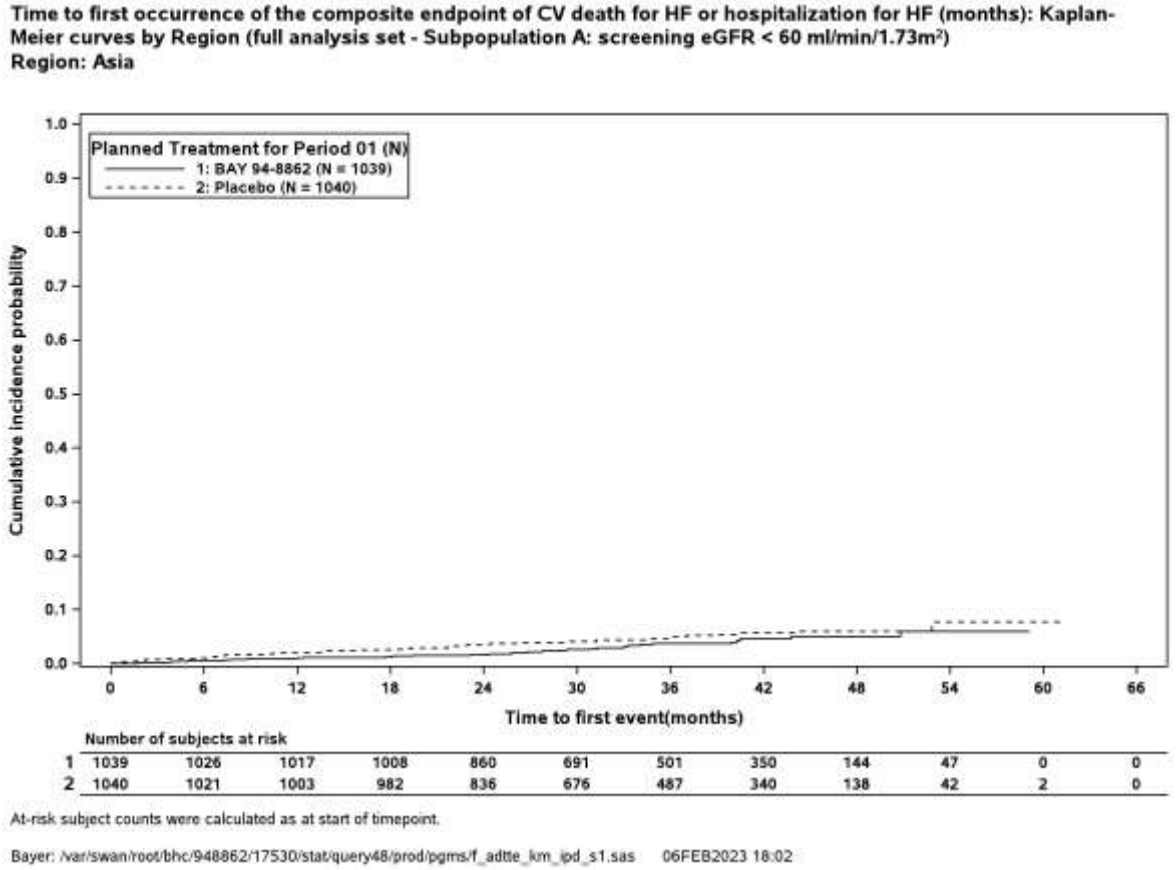


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

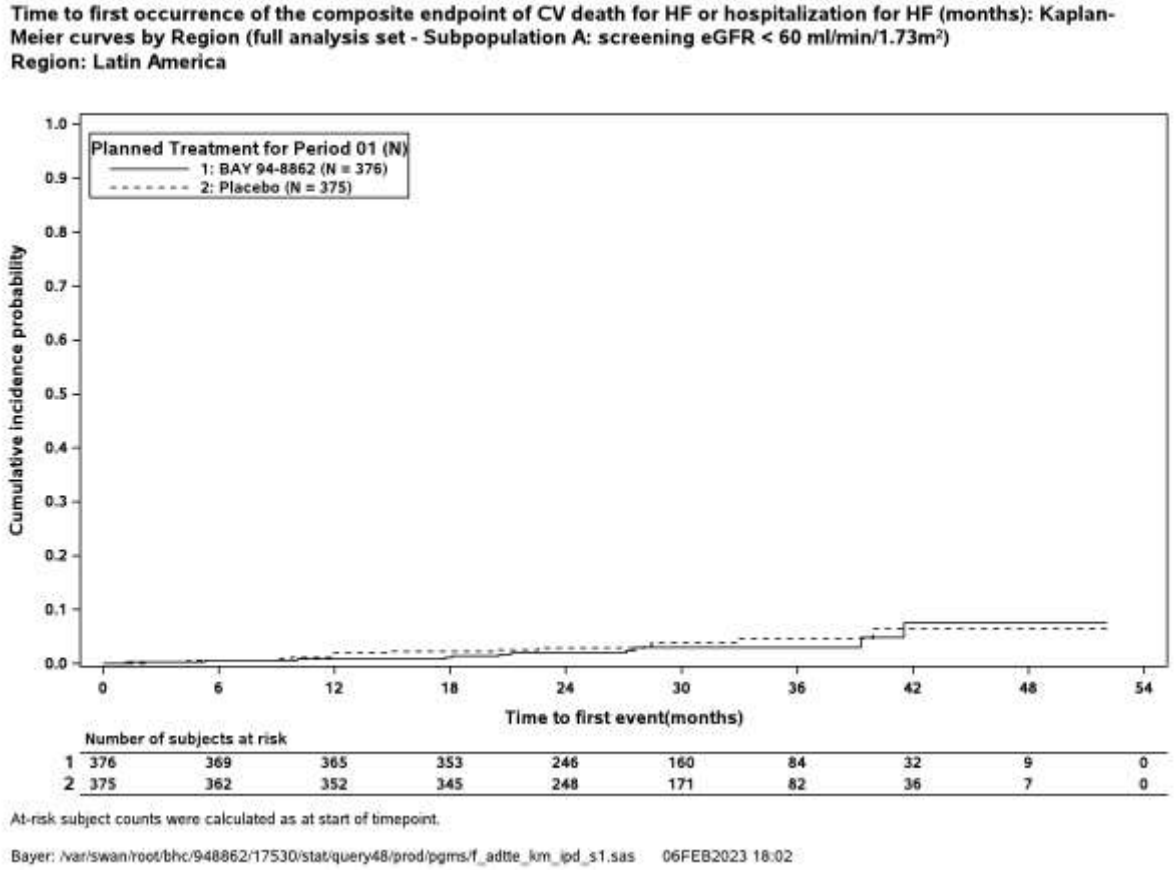


Figure 1.2.1 / 72: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

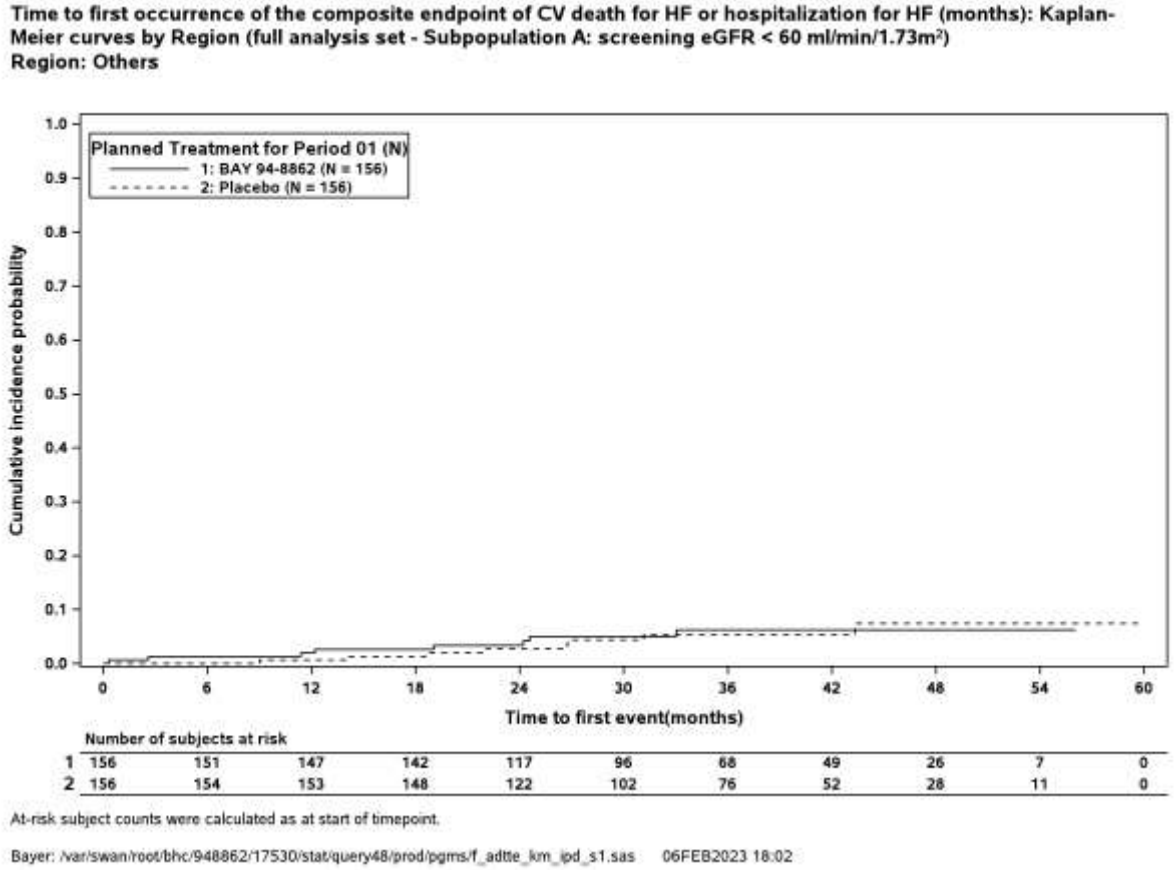


Figure 1.2.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

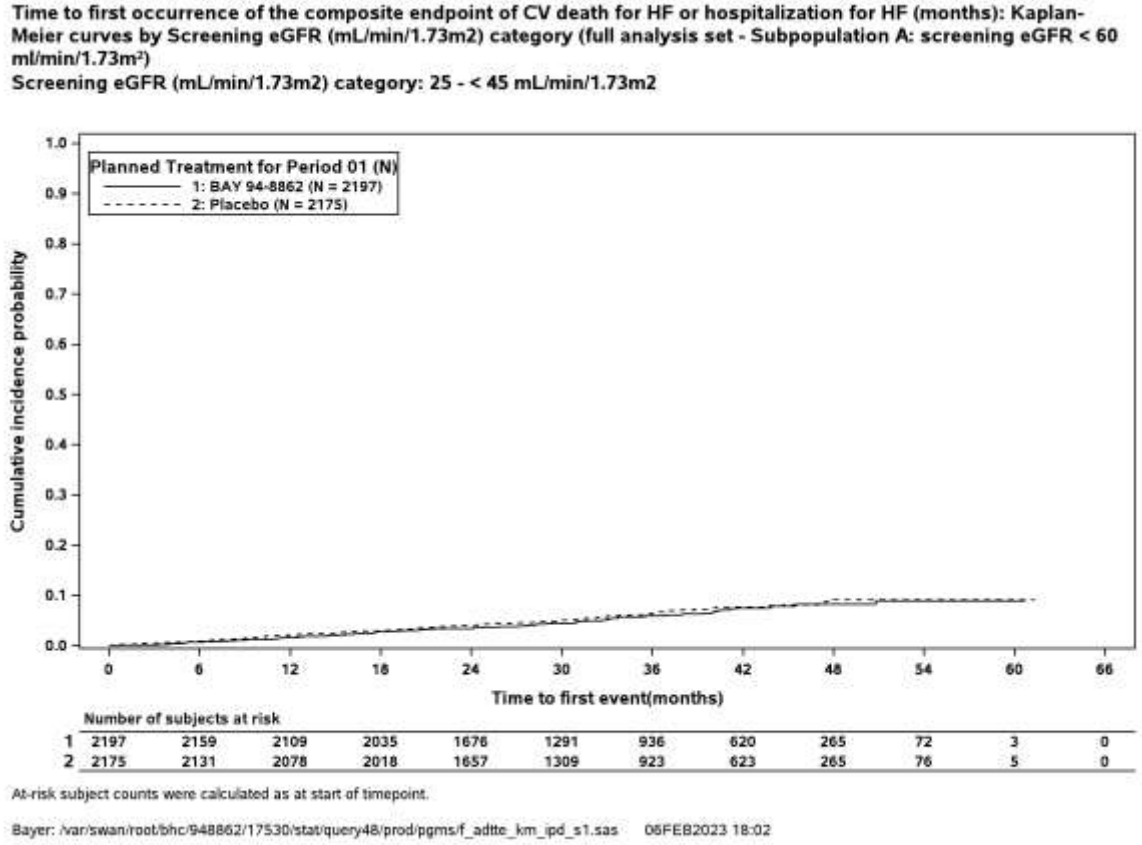
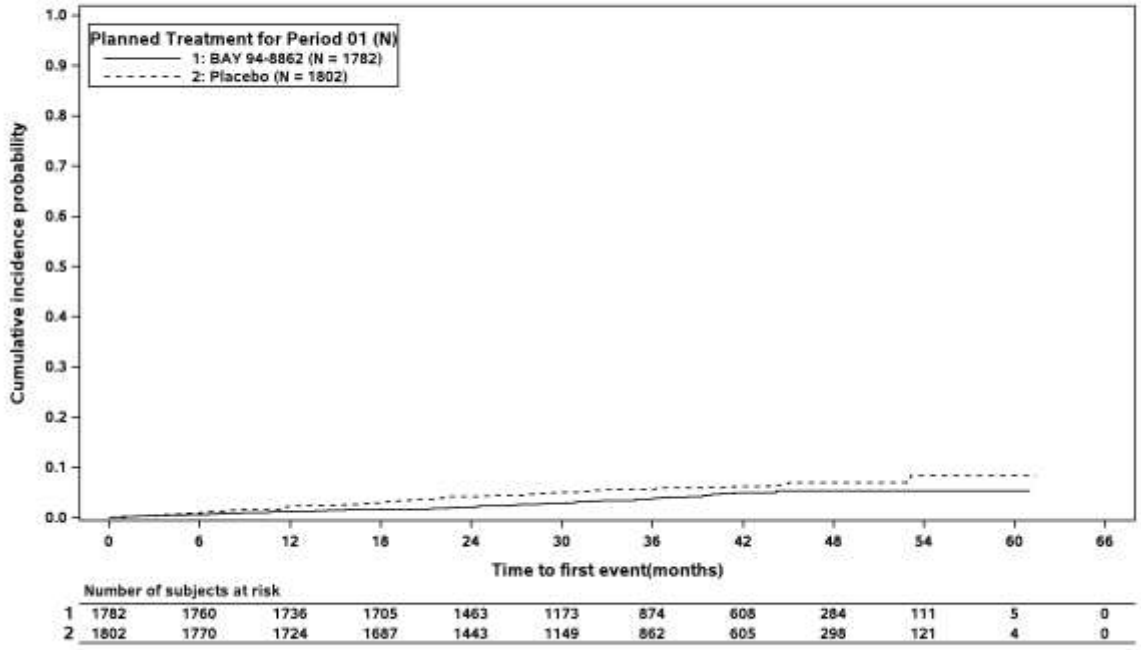


Figure 1.2.1 / 73: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)
Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2



Number of subjects at risk

1	1782	1760	1736	1705	1463	1173	874	608	284	111	5	0
2	1802	1770	1724	1687	1443	1149	862	605	298	121	4	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 74: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

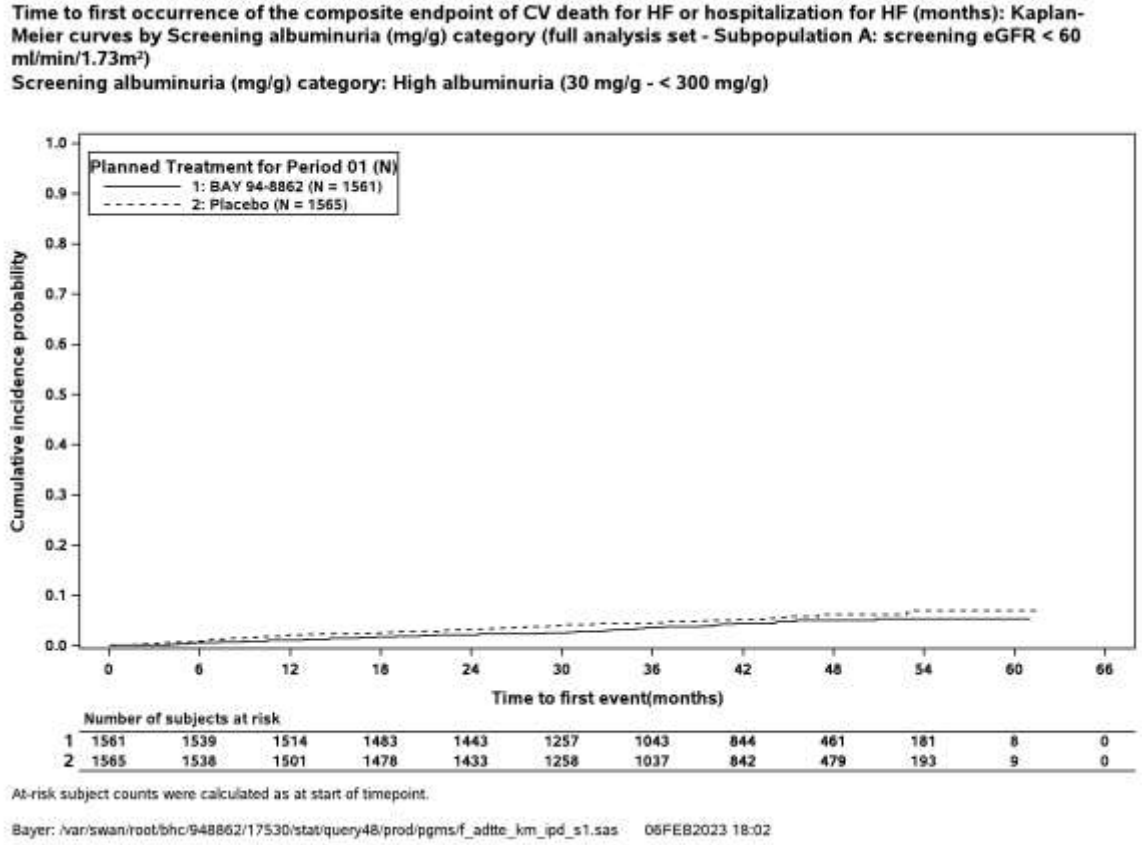
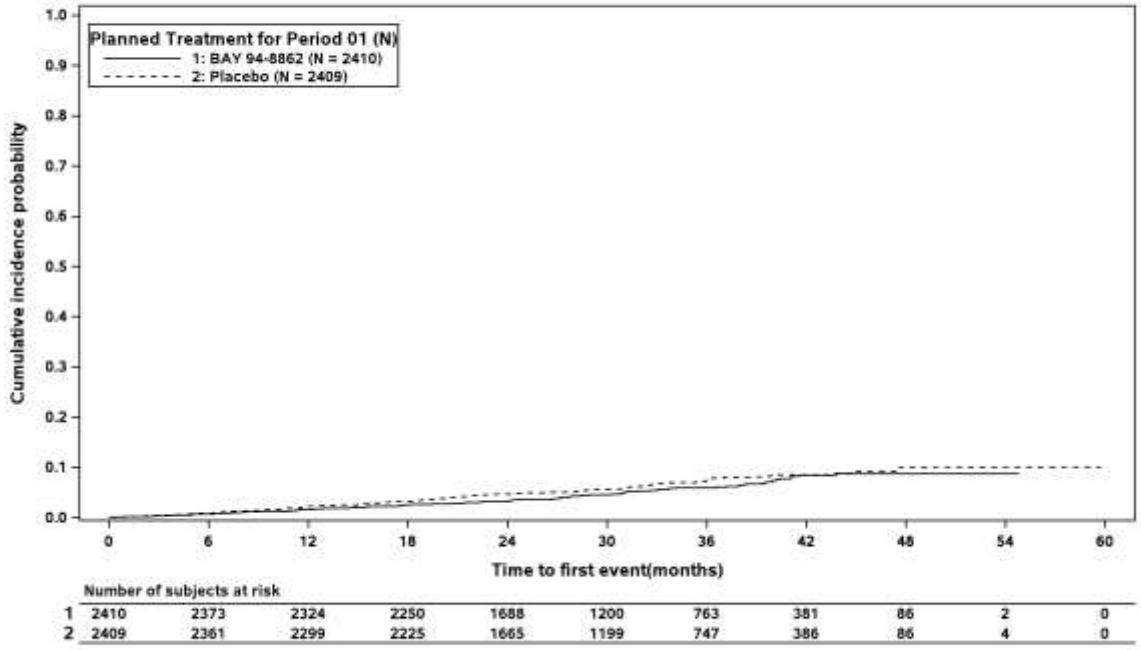


Figure 1.2.1 / 74: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)
Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)



Number of subjects at risk

1	2410	2373	2324	2250	1688	1200	763	381	86	2	0
2	2409	2361	2299	2225	1665	1199	747	386	86	4	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 75: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

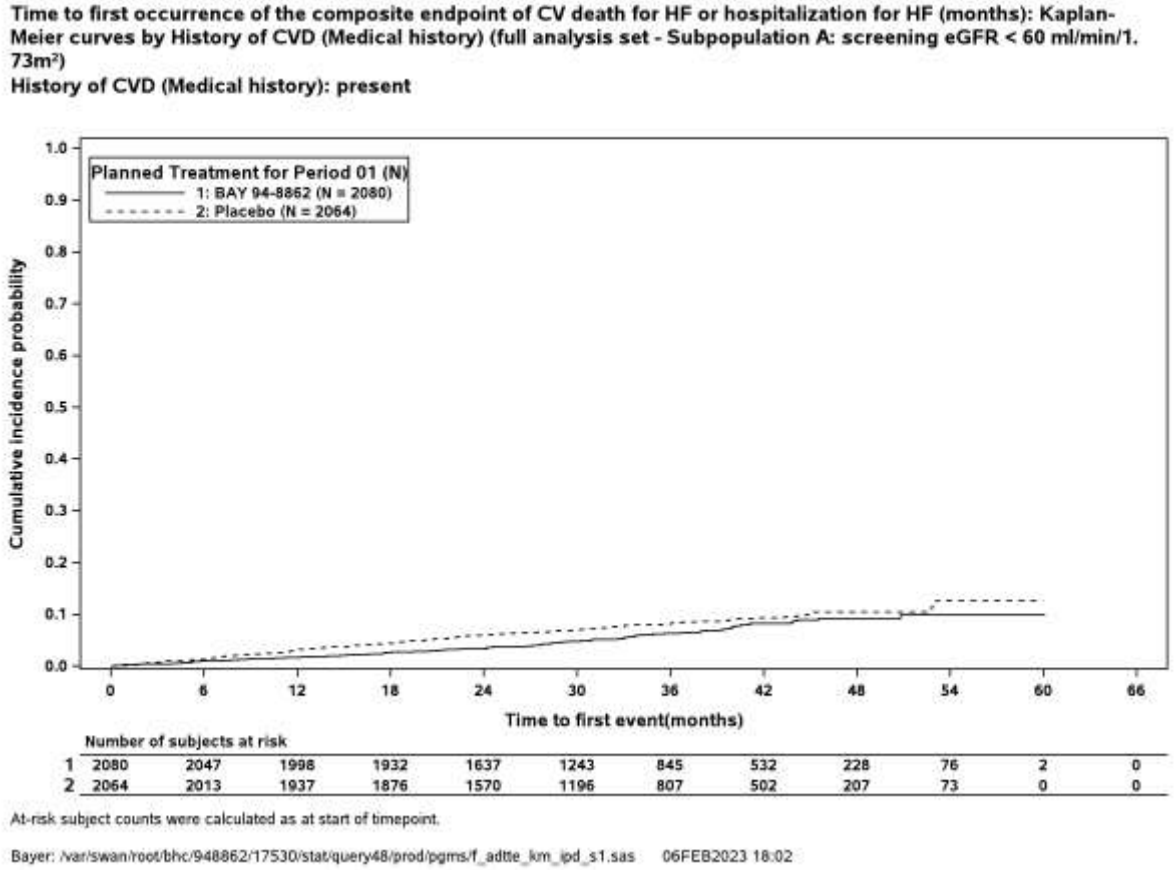


Figure 1.2.1 / 75: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

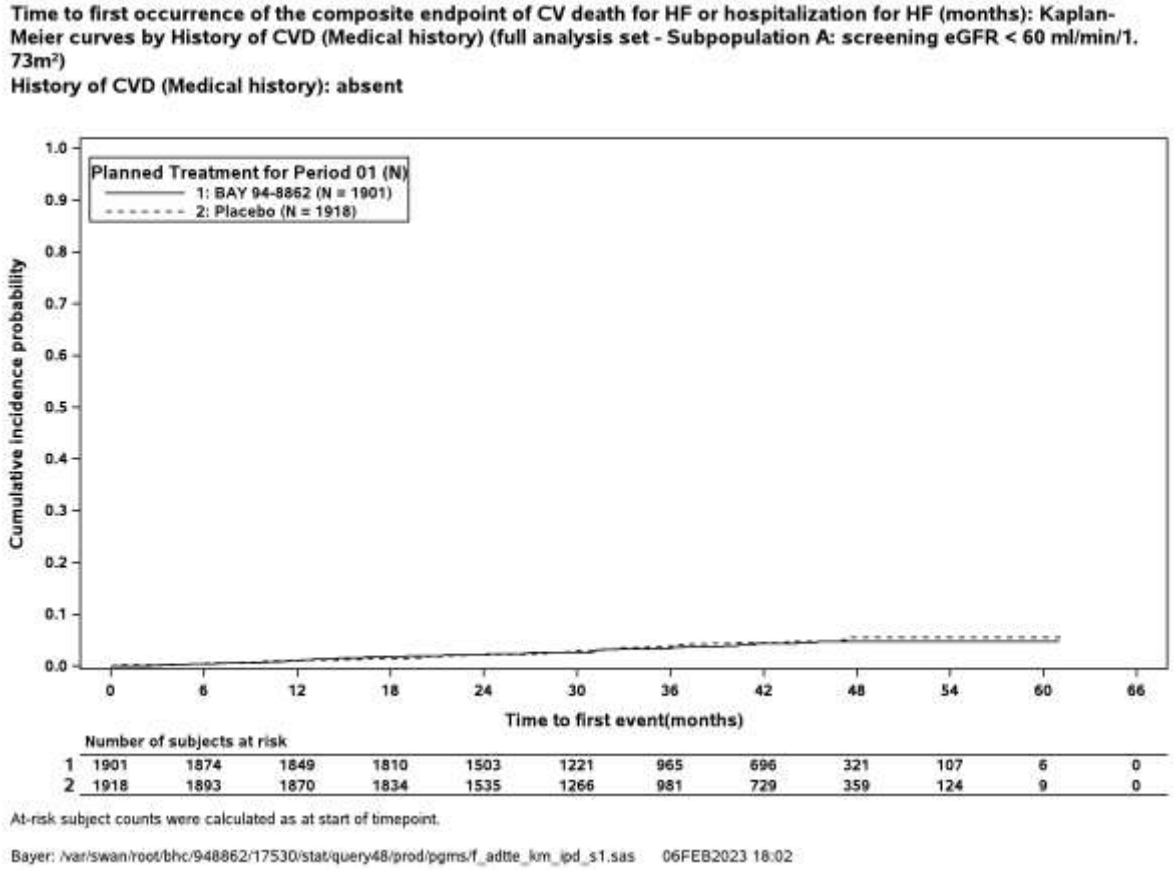


Figure 1.2.1 / 76: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

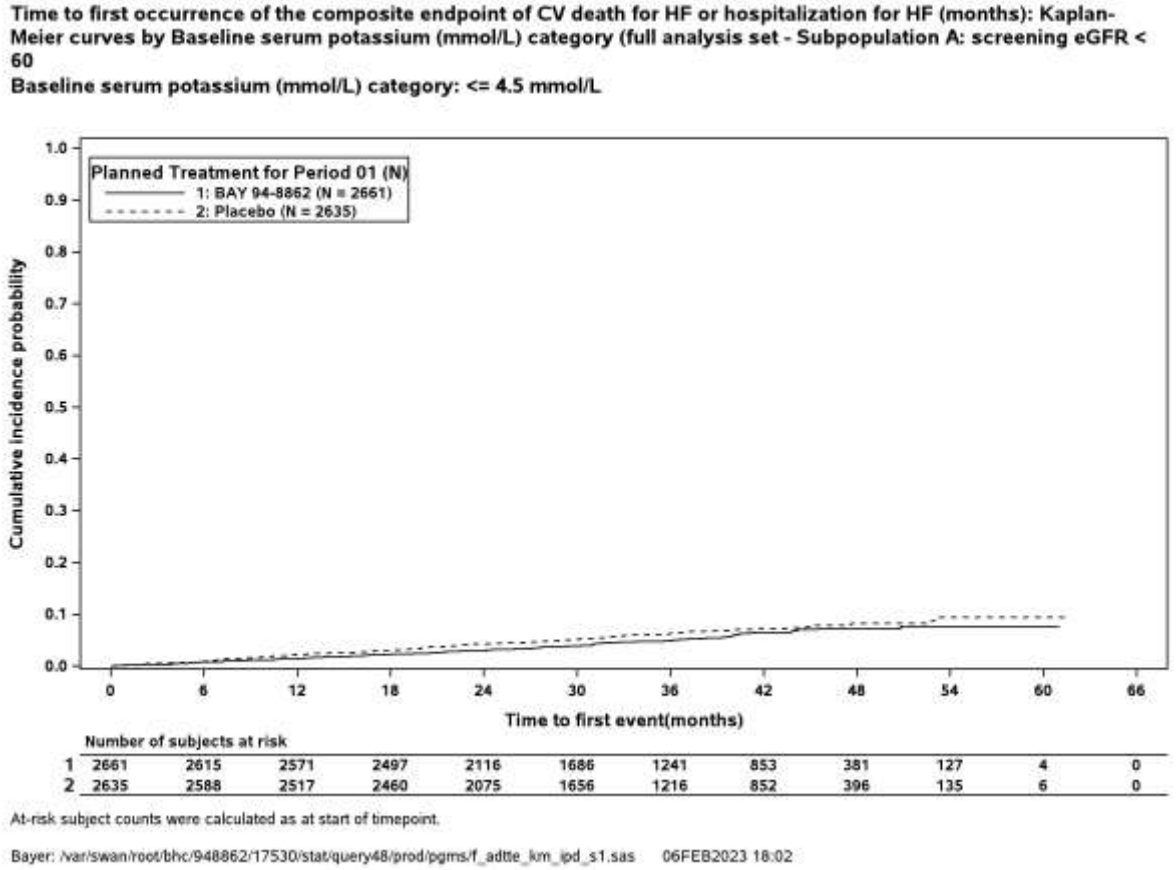
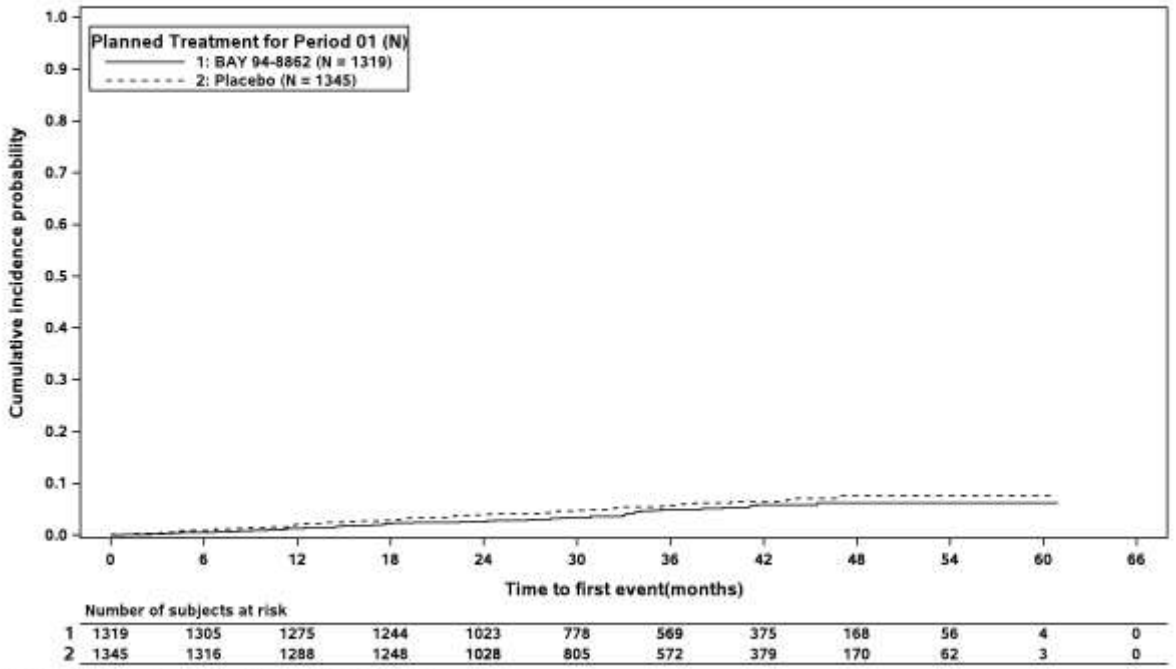


Figure 1.2.1 / 76: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60
Baseline serum potassium (mmol/L) category: > 4.5 mmol/L



Number of subjects at risk

1	1319	1305	1275	1244	1023	778	569	375	168	56	4	0
2	1345	1316	1288	1248	1028	805	572	379	170	62	3	0

At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

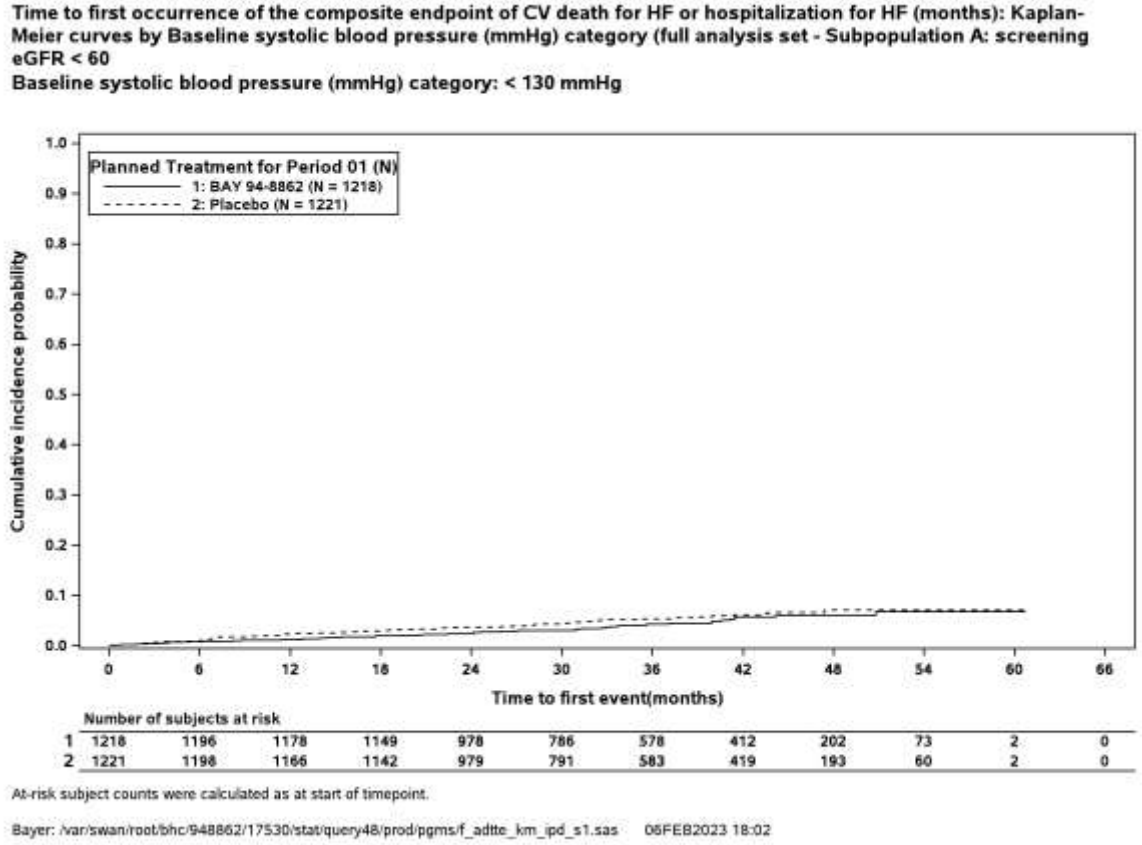
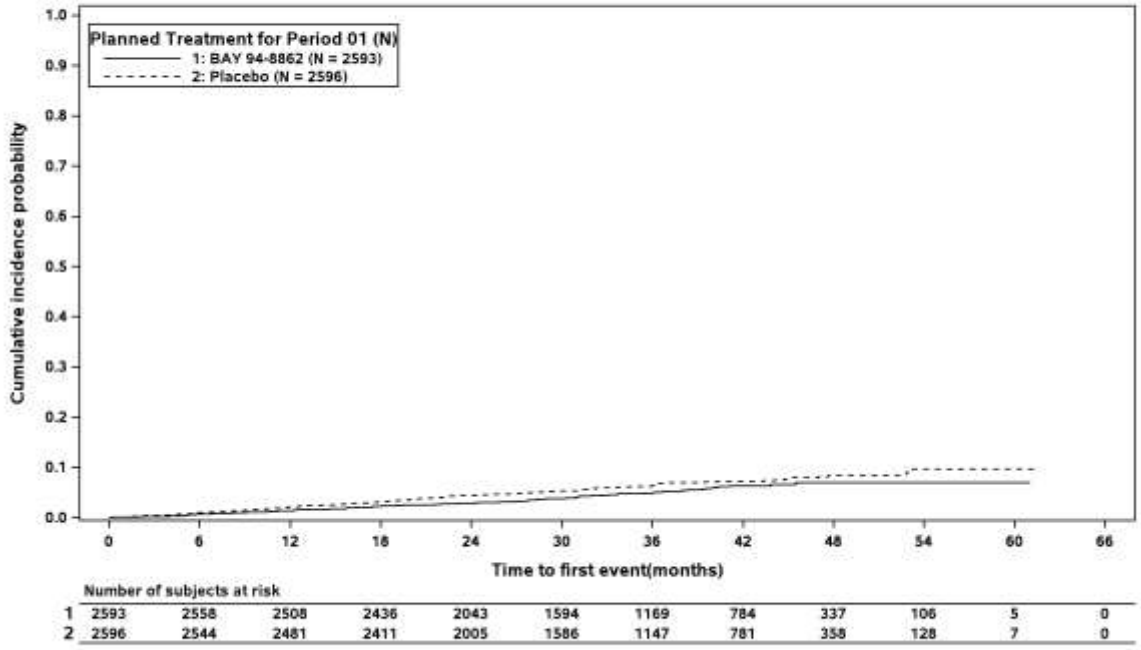


Figure 1.2.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60
Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

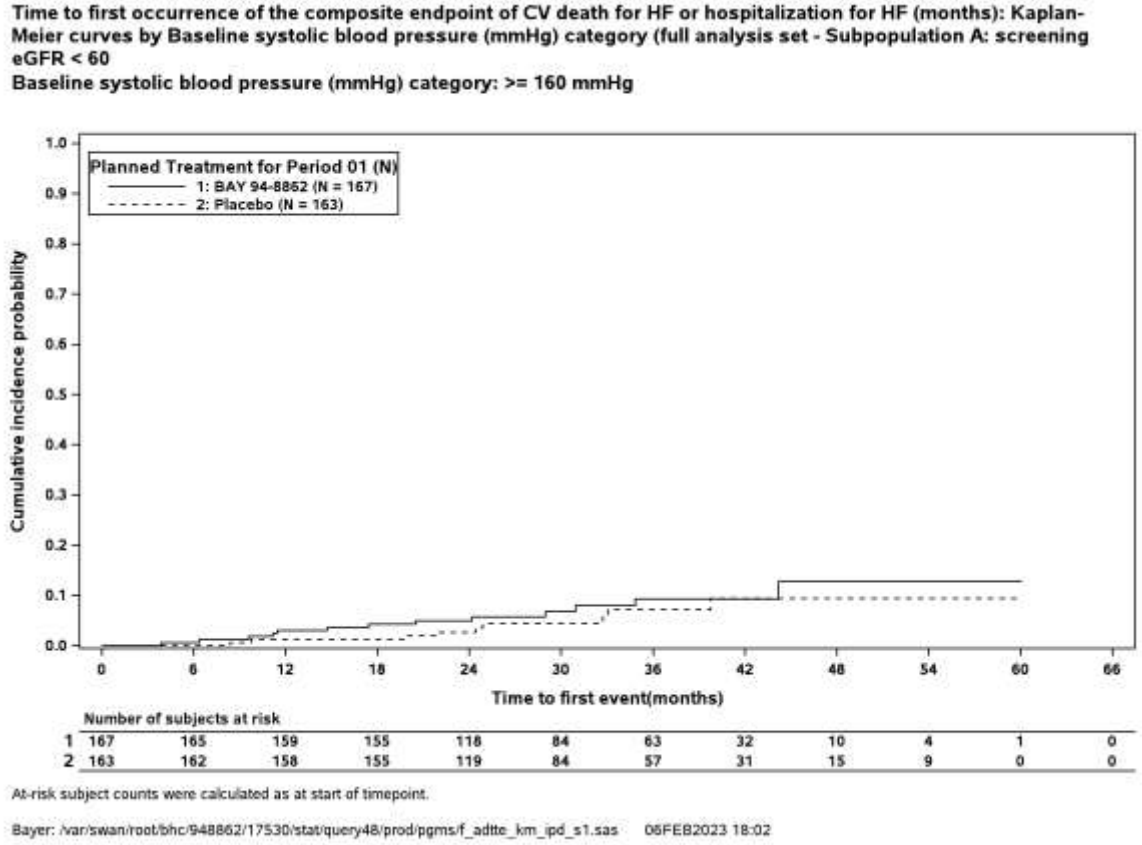


At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 77: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg



At-risk subject counts were calculated as at start of timepoint.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/f_adtte_km_ipd_s1.sas 06FEB2023 18:02

Figure 1.2.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

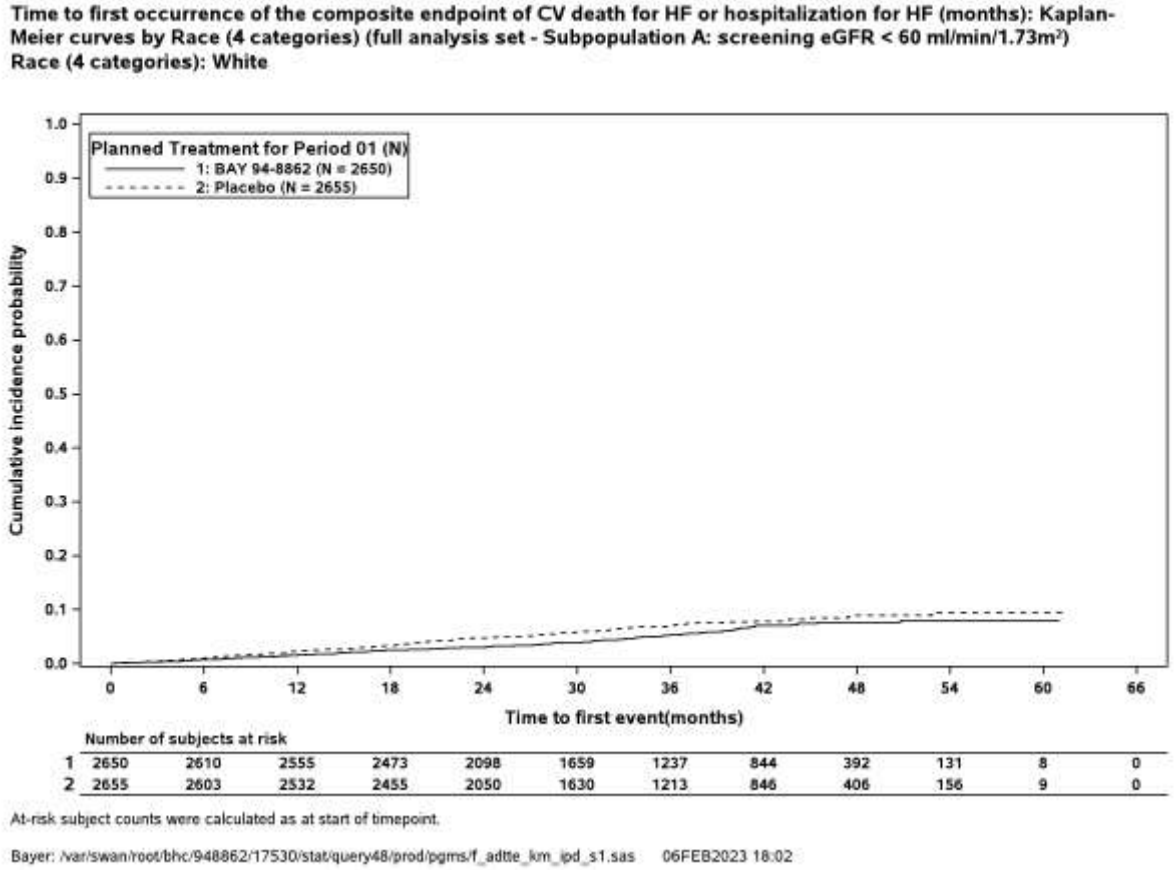


Figure 1.2.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

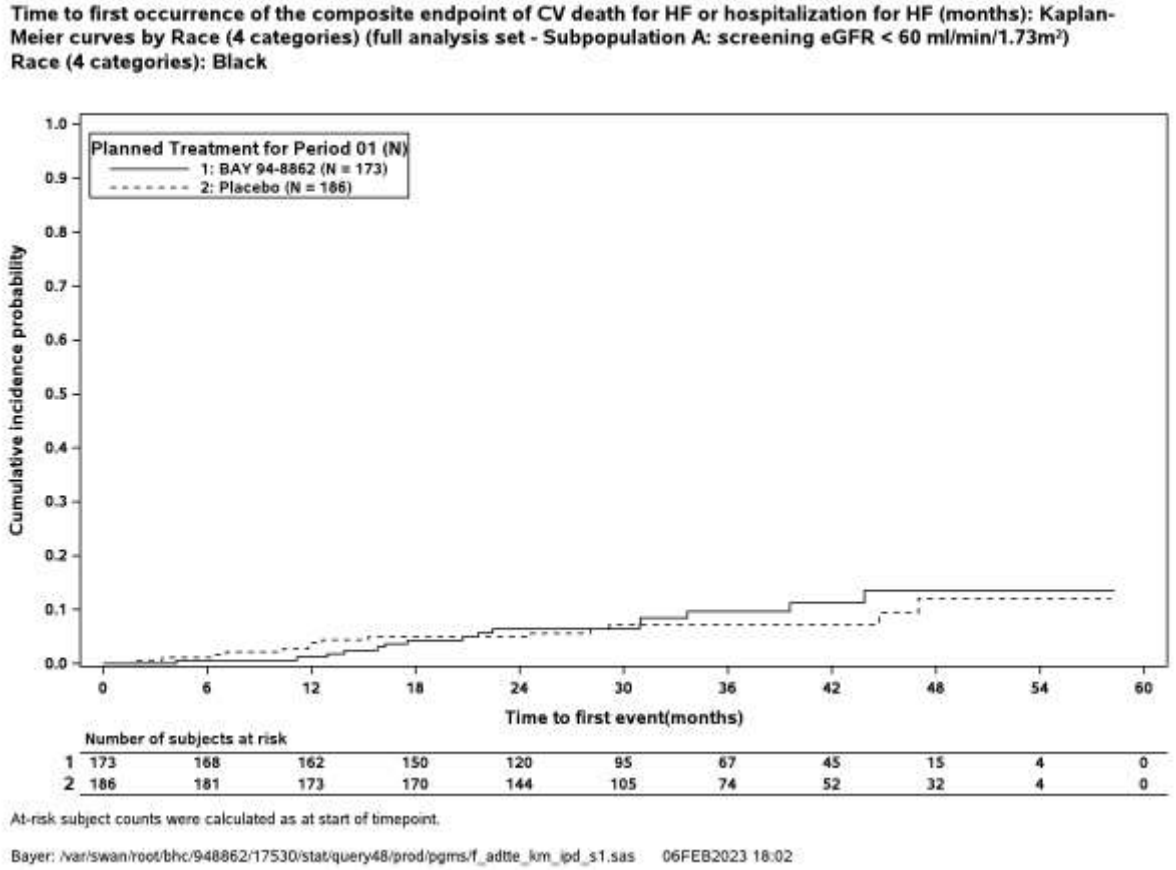


Figure 1.2.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

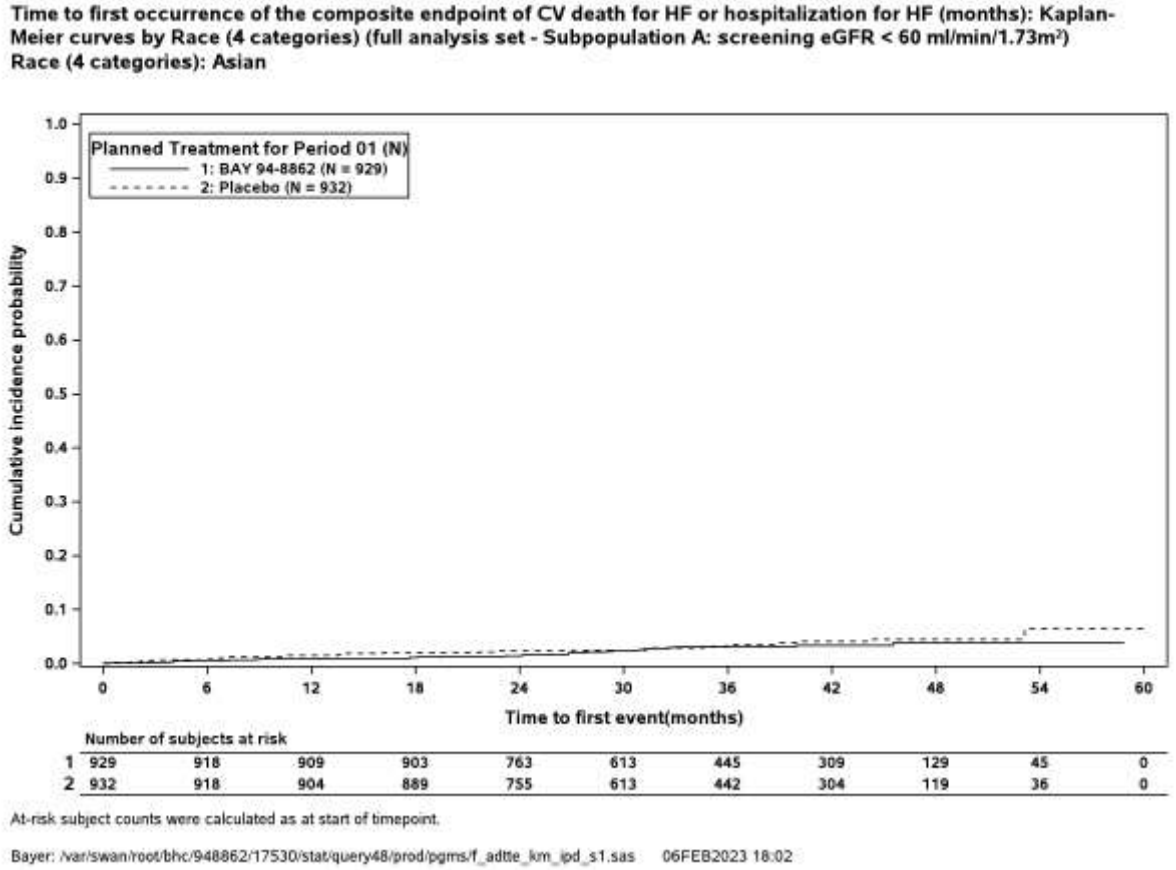


Figure 1.2.1 / 78: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

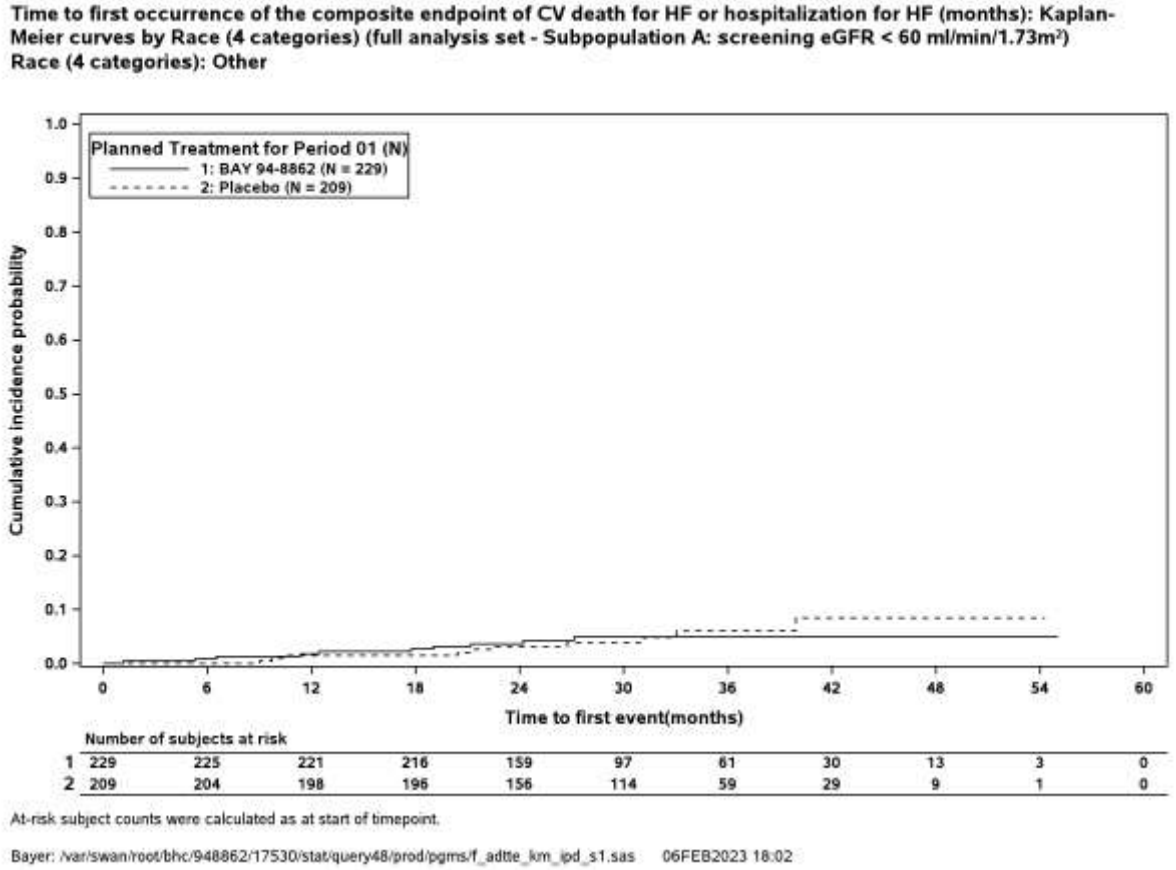


Figure 1.2.1 / 79: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

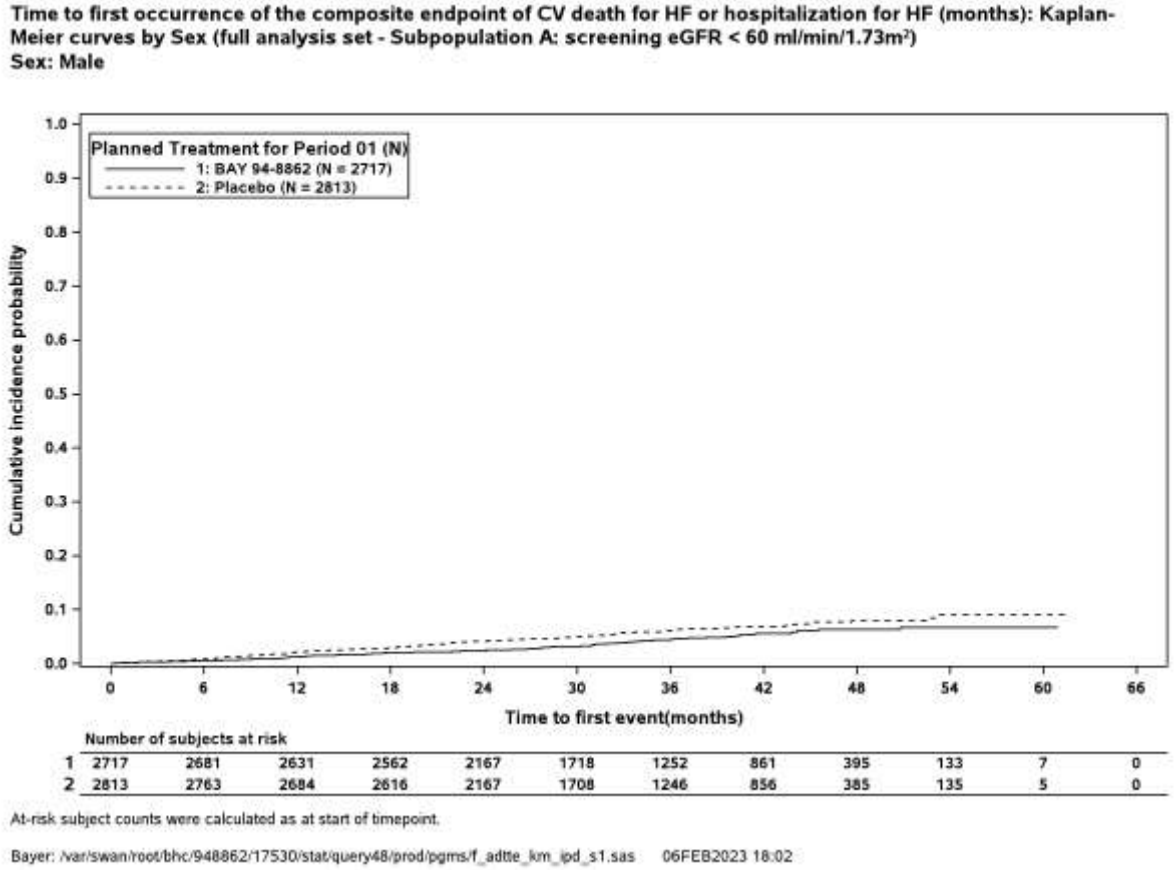


Figure 1.2.1 / 79: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

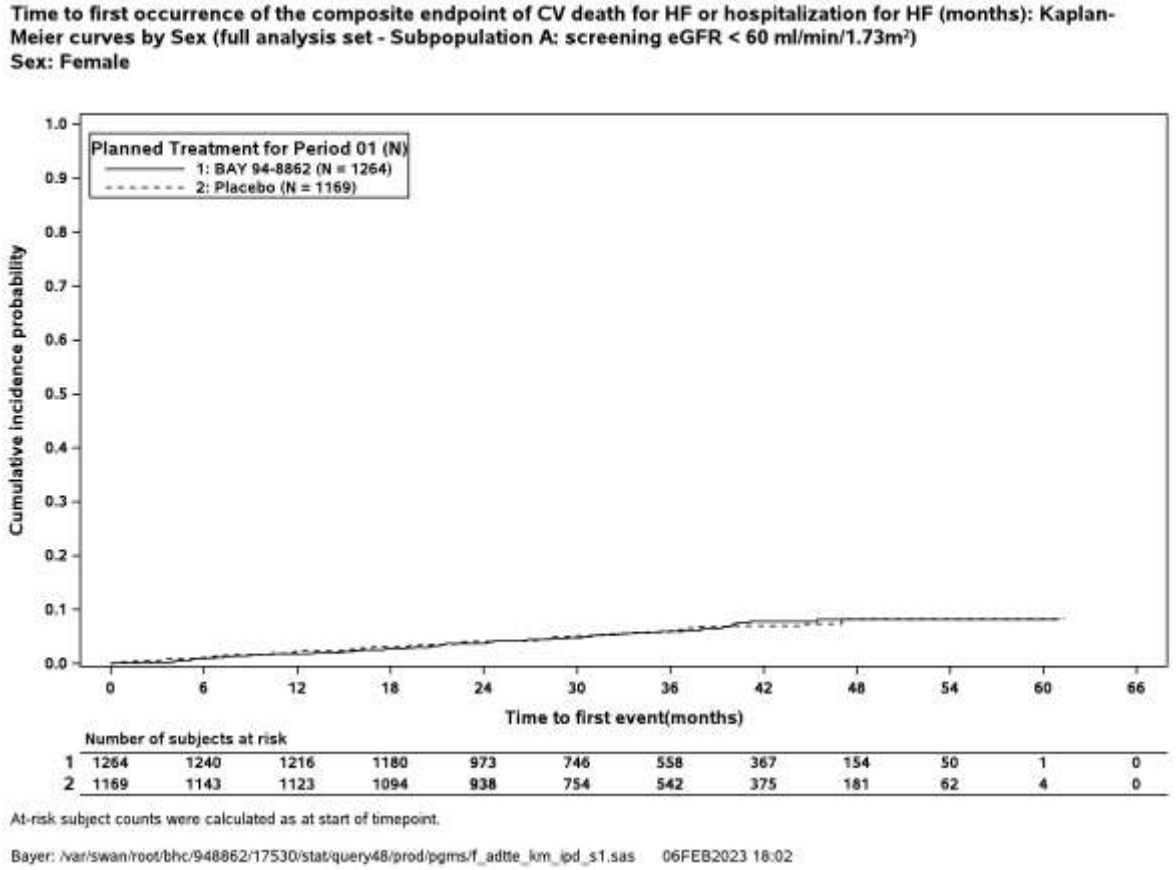


Figure 1.2.1 / 80: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

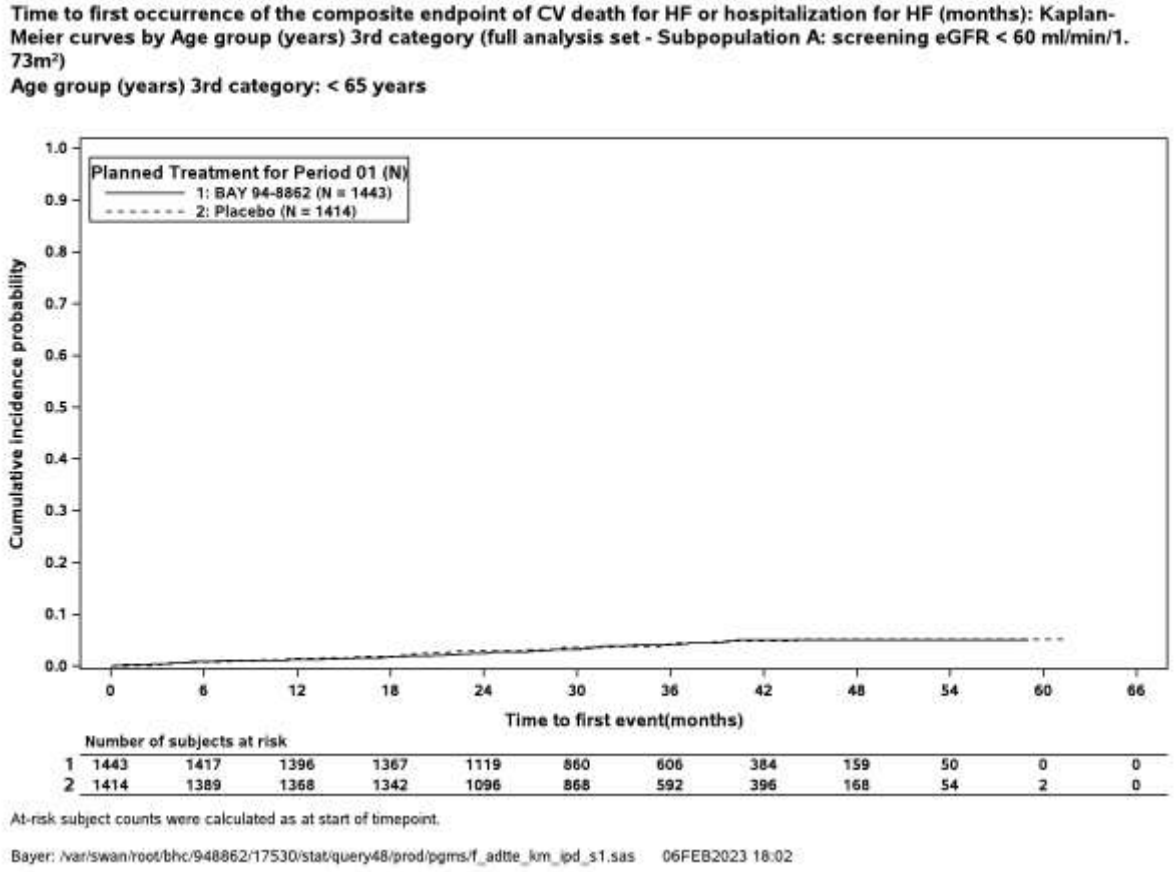


Figure 1.2.1 / 80: Time to first occurrence of the composite endpoint of CV death for HF or hospitalization for HF (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Age group (years) 3rd category: >= 65 years

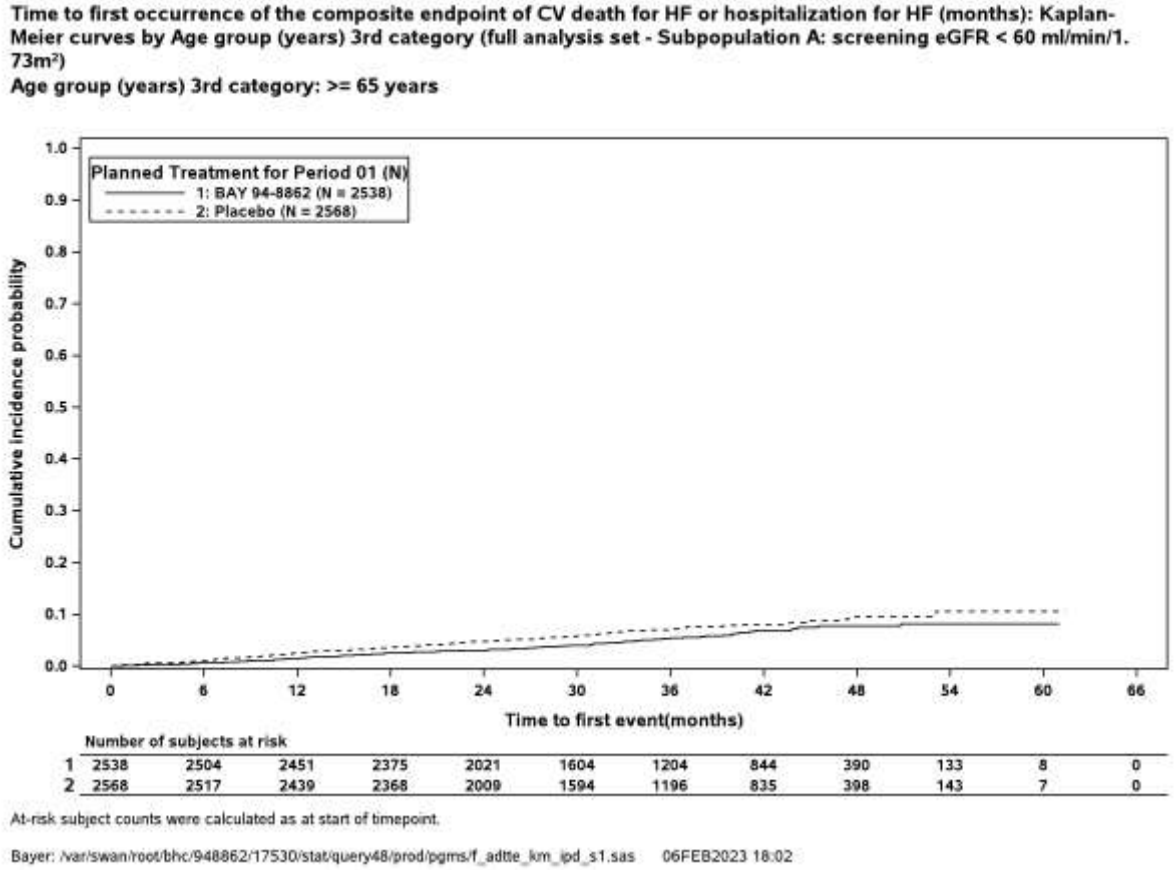


Figure 1.2.1 / 81: Time to all-cause hospitalization (months): Kaplan-Meier curves (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

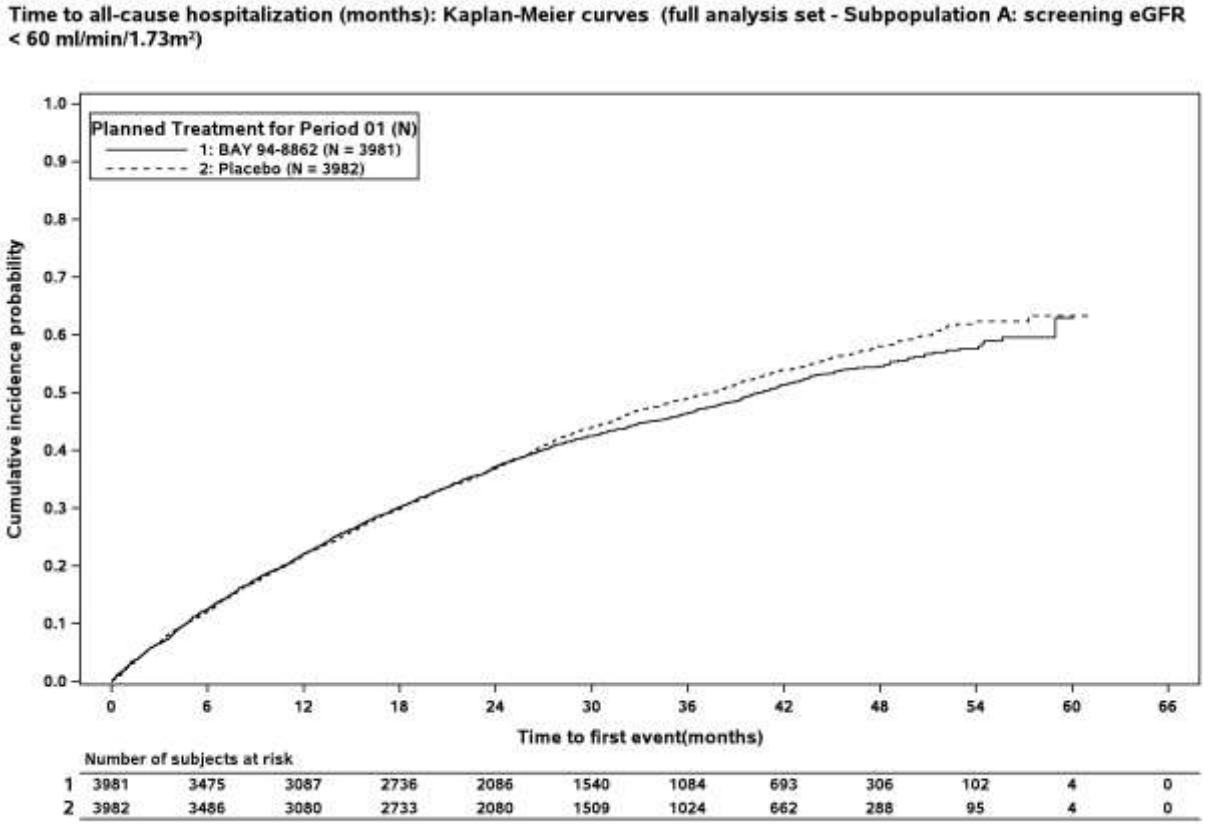


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Region: Europe

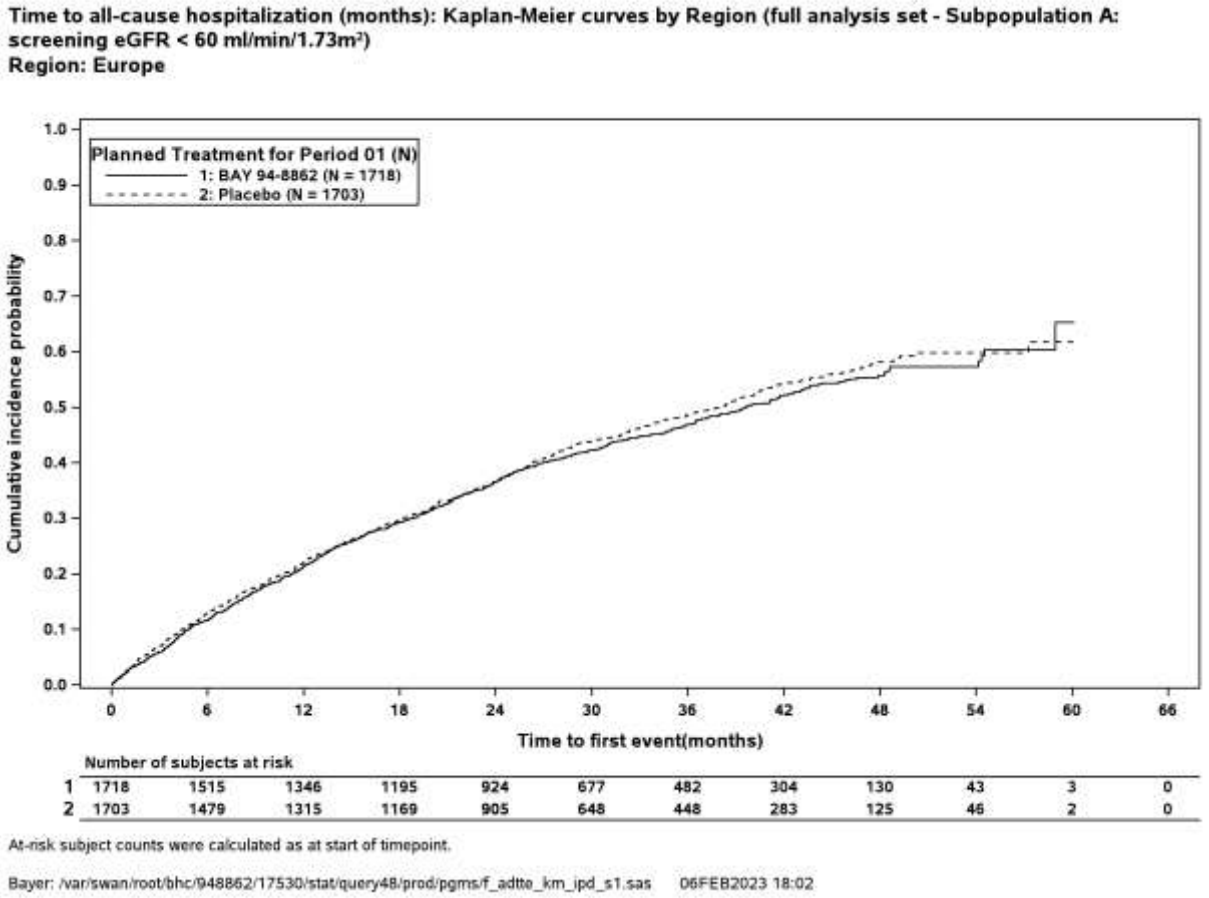


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: North America

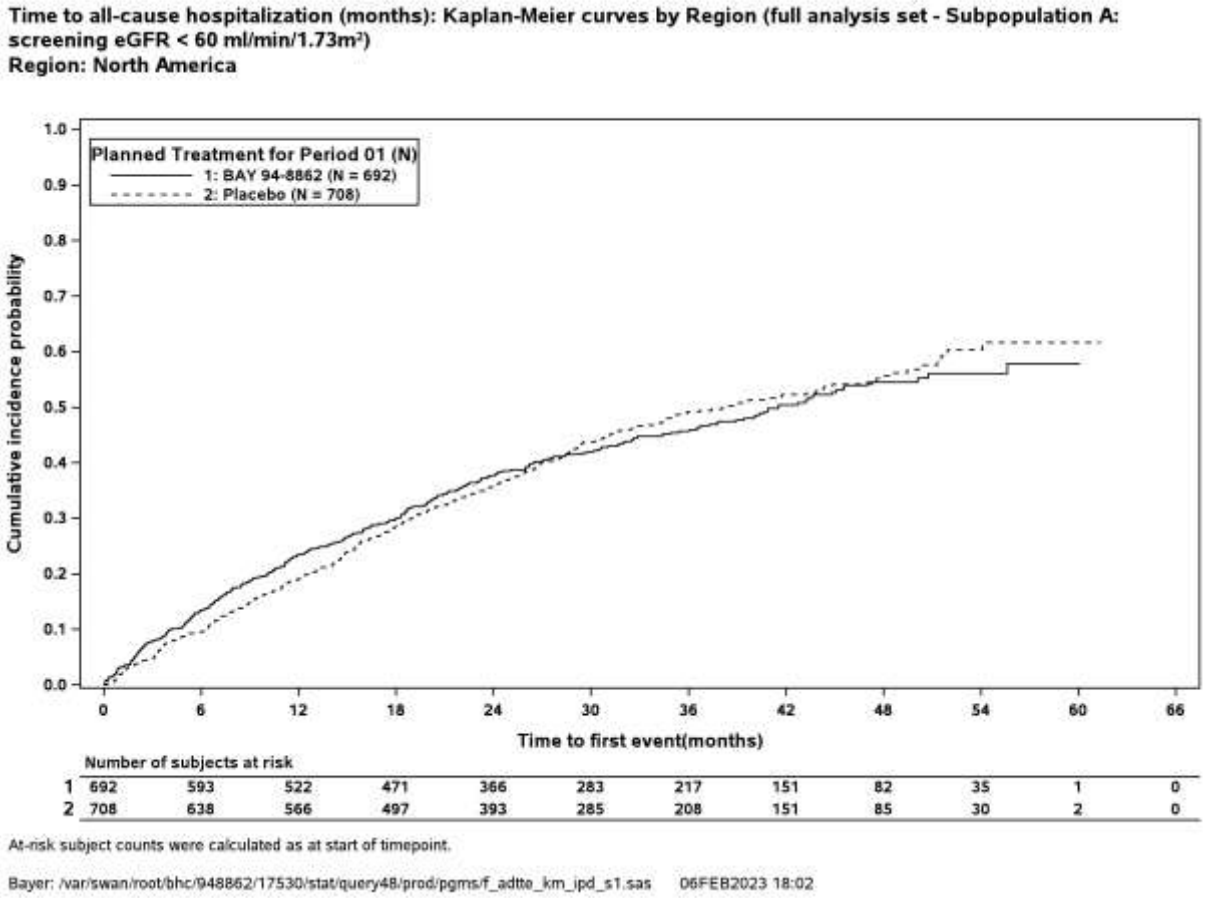


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Asia

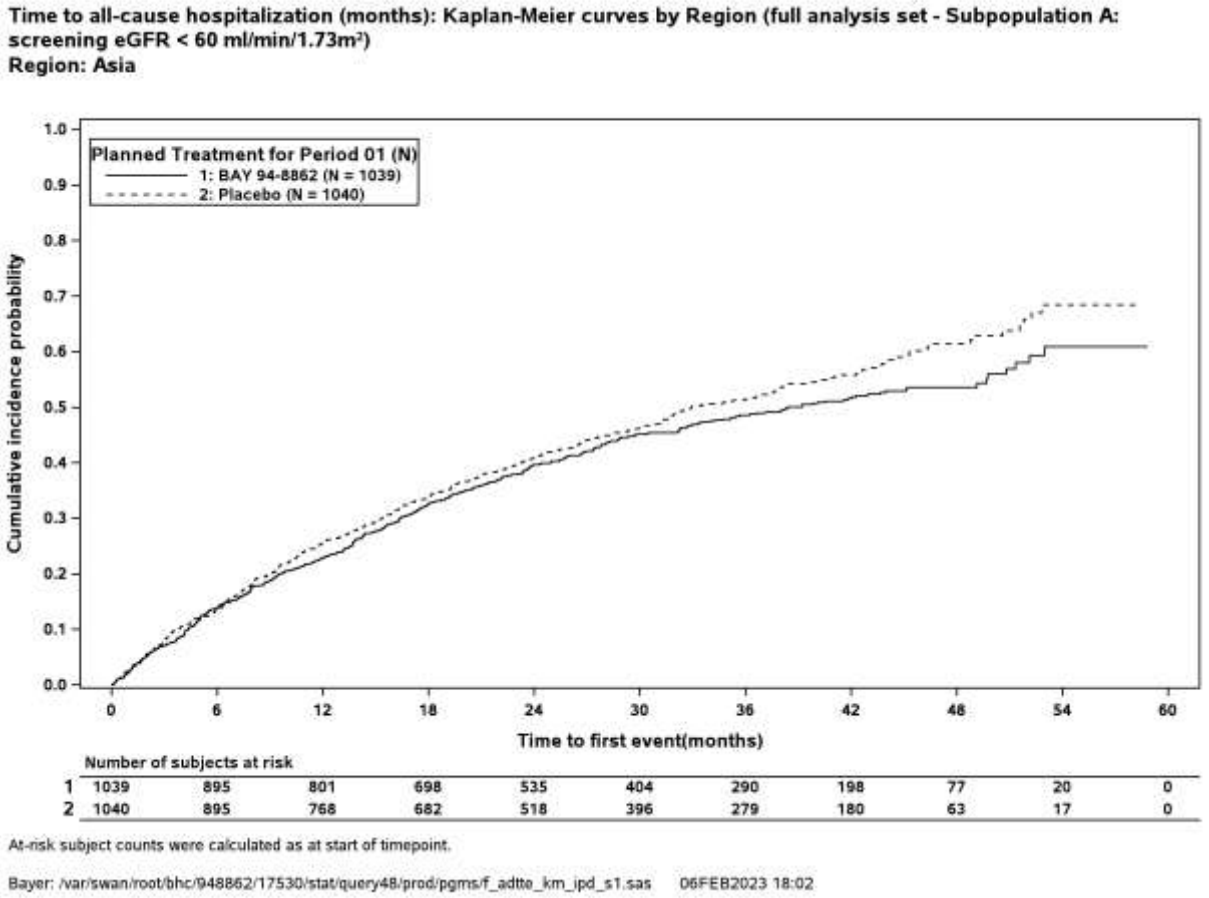


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Latin America

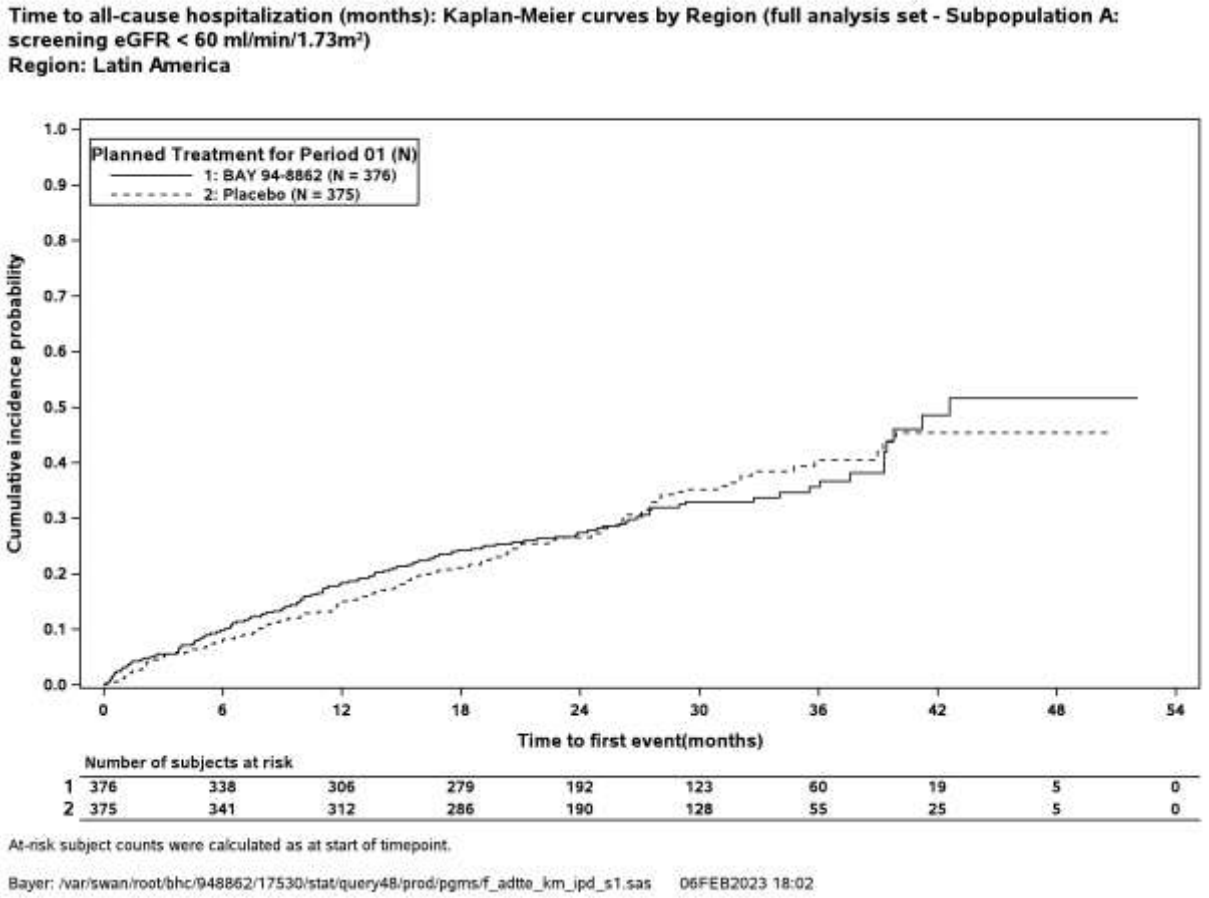


Figure 1.2.1 / 82: Time to all-cause hospitalization (months): Kaplan-Meier curves by Region (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Region: Others

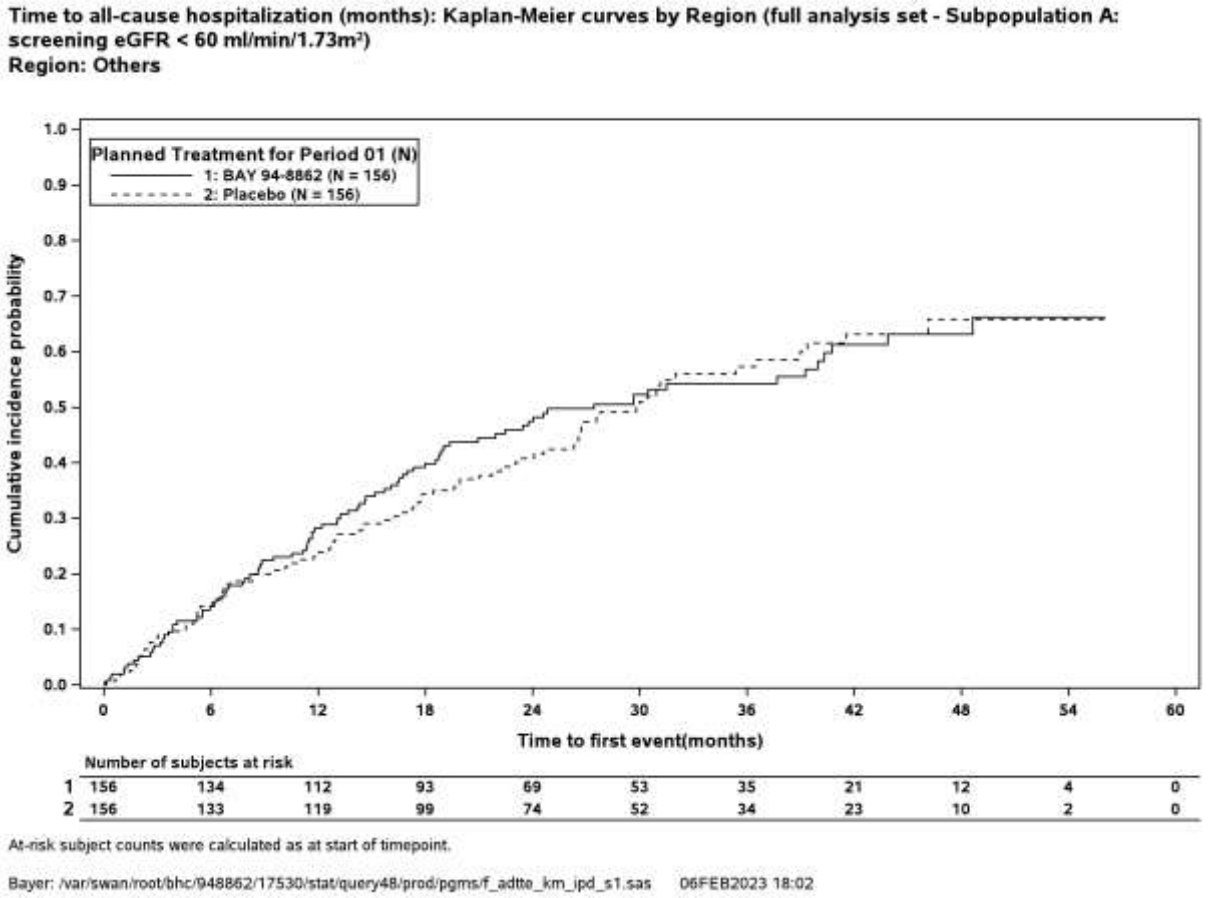


Figure 1.2.1 / 83: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening eGFR (mL/min/1.73m2) category: 25 - < 45 mL/min/1.73m2

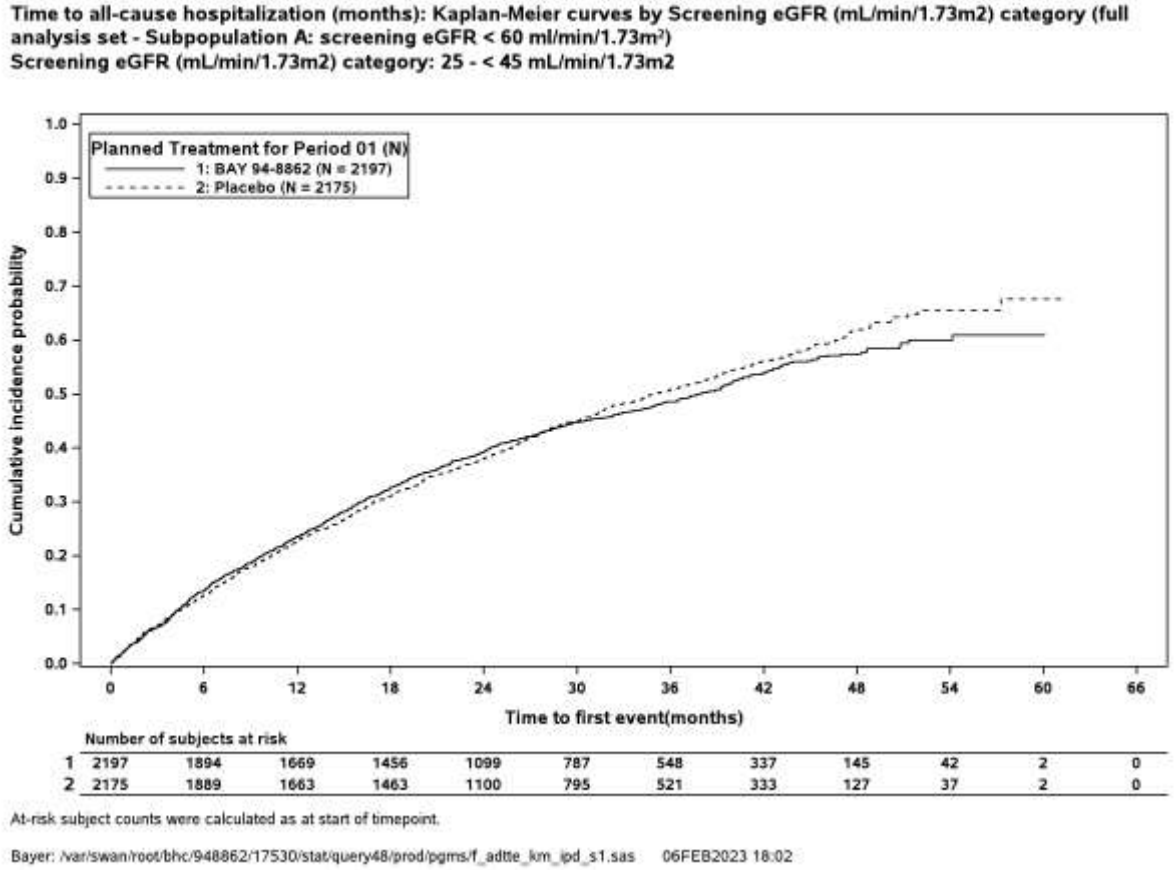


Figure 1.2.1 / 83: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening eGFR (mL/min/1.73m2) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening eGFR (mL/min/1.73m2) category: 45 - < 60 mL/min/1.73m2

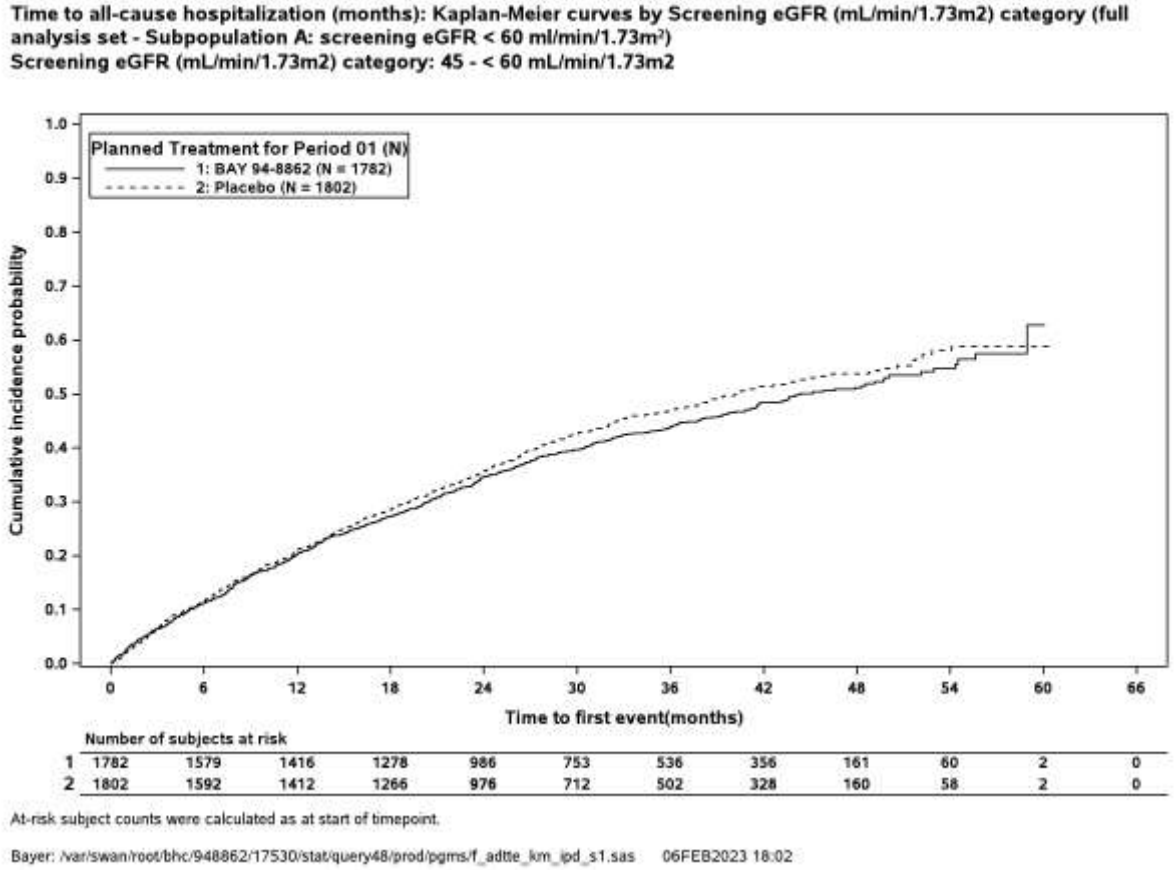


Figure 1.2.1 / 84: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Screening albuminuria (mg/g) category: High albuminuria (30 mg/g - < 300 mg/g)

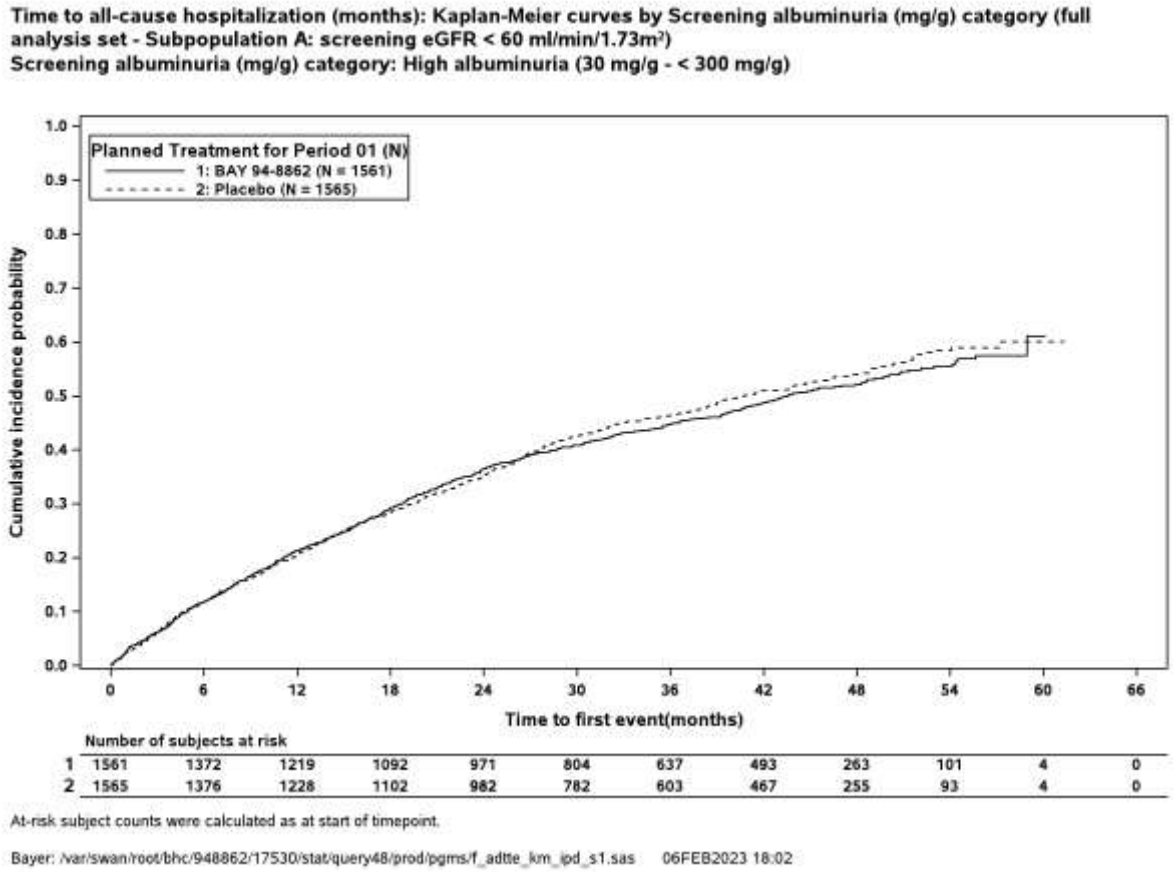


Figure 1.2.1 / 84: Time to all-cause hospitalization (months): Kaplan-Meier curves by Screening albuminuria (mg/g) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Screening albuminuria (mg/g) category: Very high albuminuria (>= 300 mg/g)

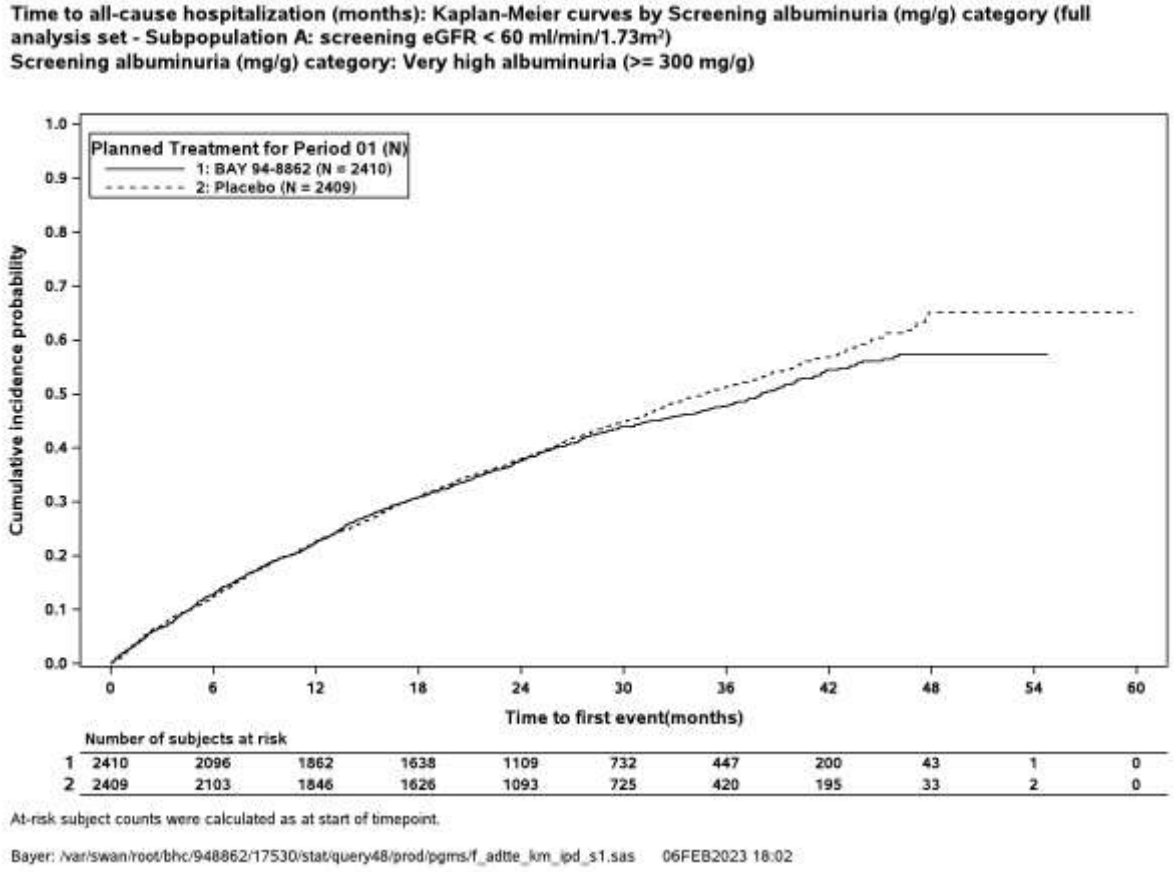


Figure 1.2.1 / 85: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

History of CVD (Medical history): present

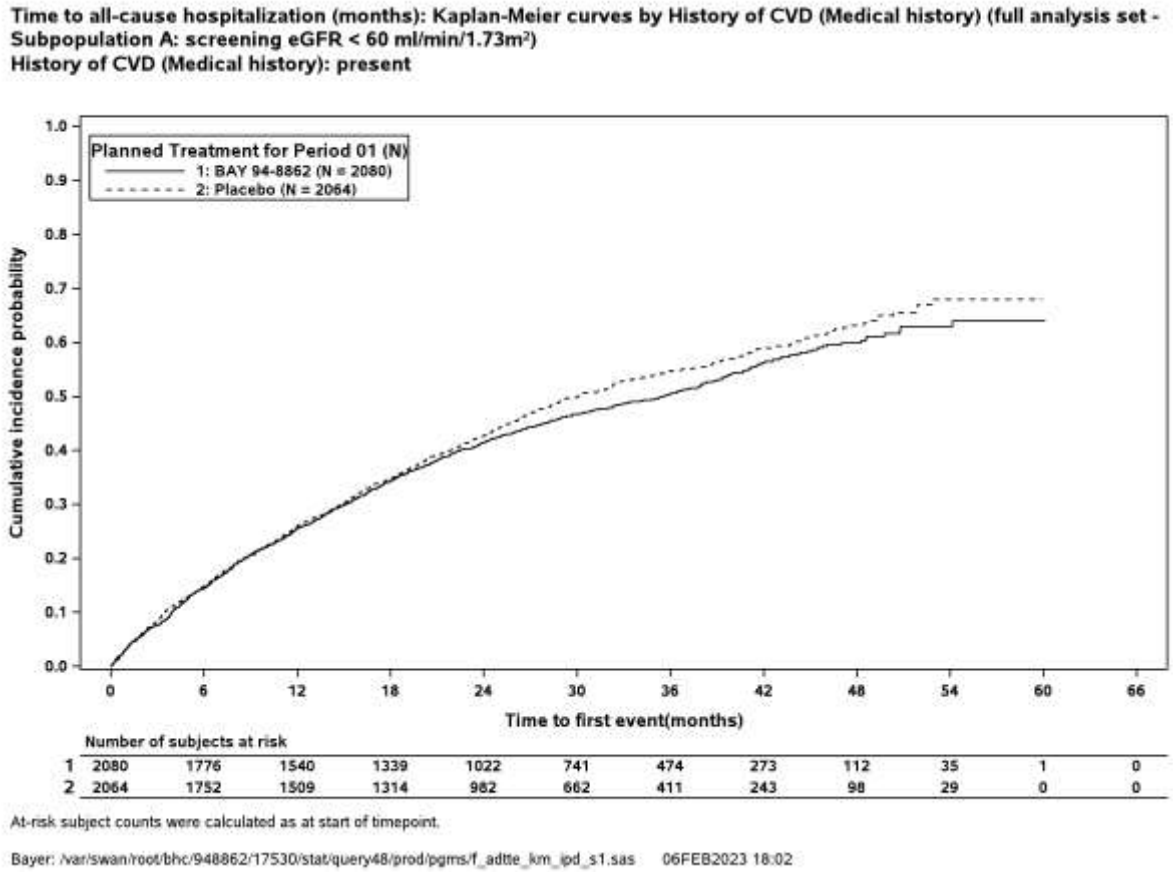


Figure 1.2.1 / 85: Time to all-cause hospitalization (months): Kaplan-Meier curves by History of CVD (Medical history) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

History of CVD (Medical history): absent

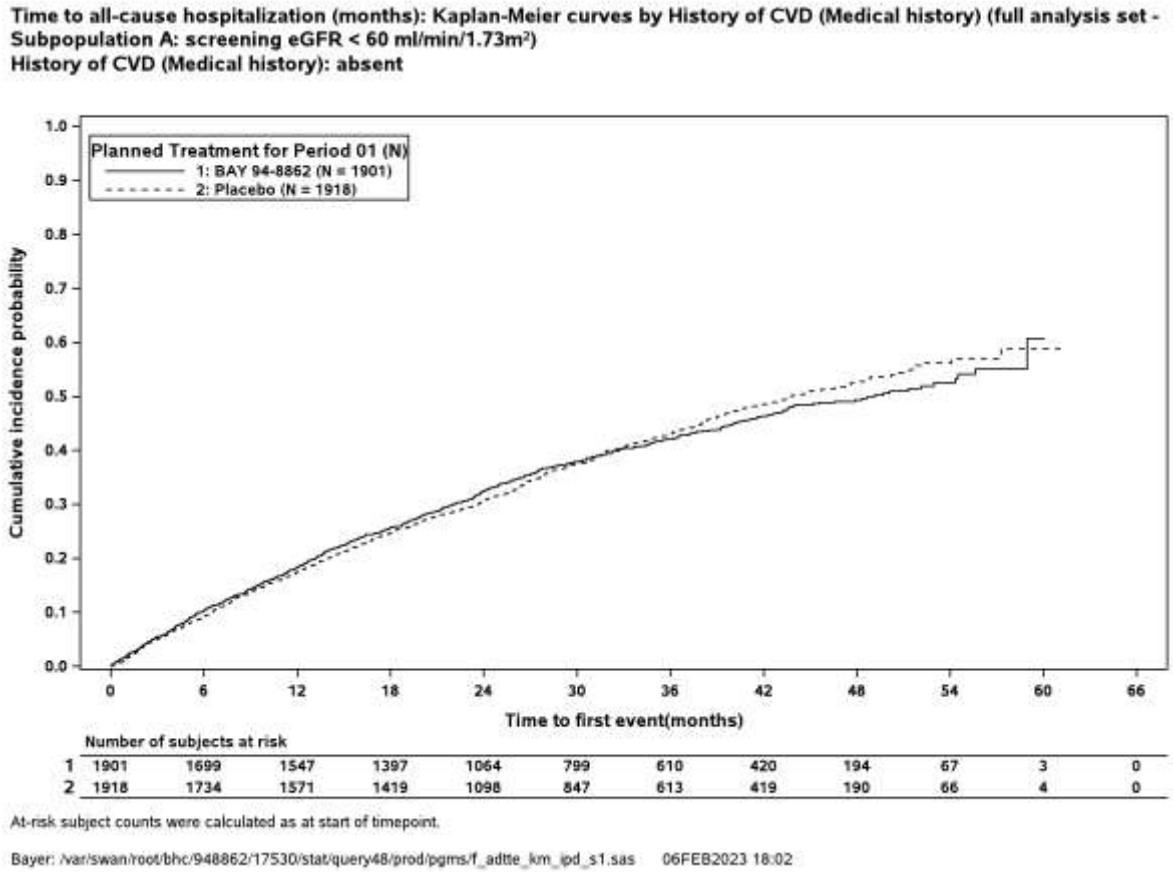


Figure 1.2.1 / 86: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline serum potassium (mmol/L) category: <= 4.5 mmol/L

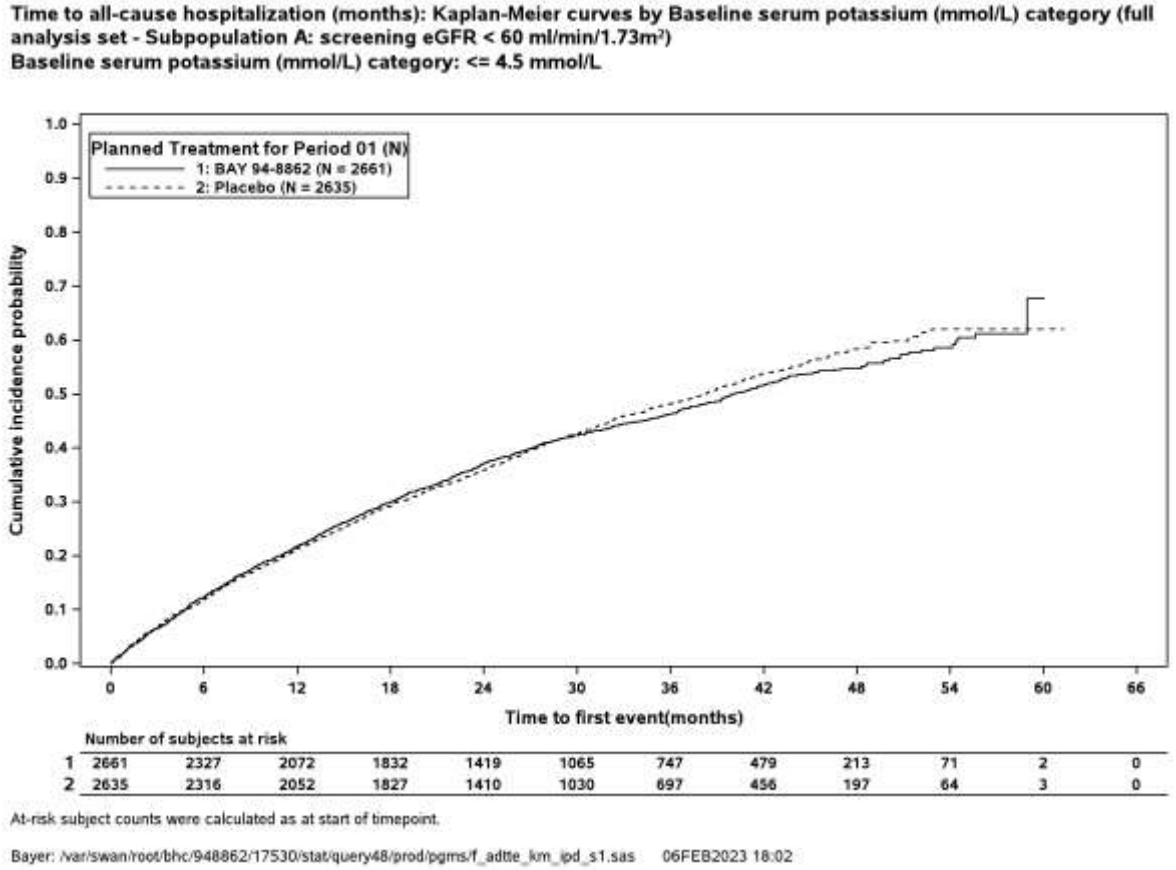


Figure 1.2.1 / 86: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline serum potassium (mmol/L) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline serum potassium (mmol/L) category: > 4.5 mmol/L

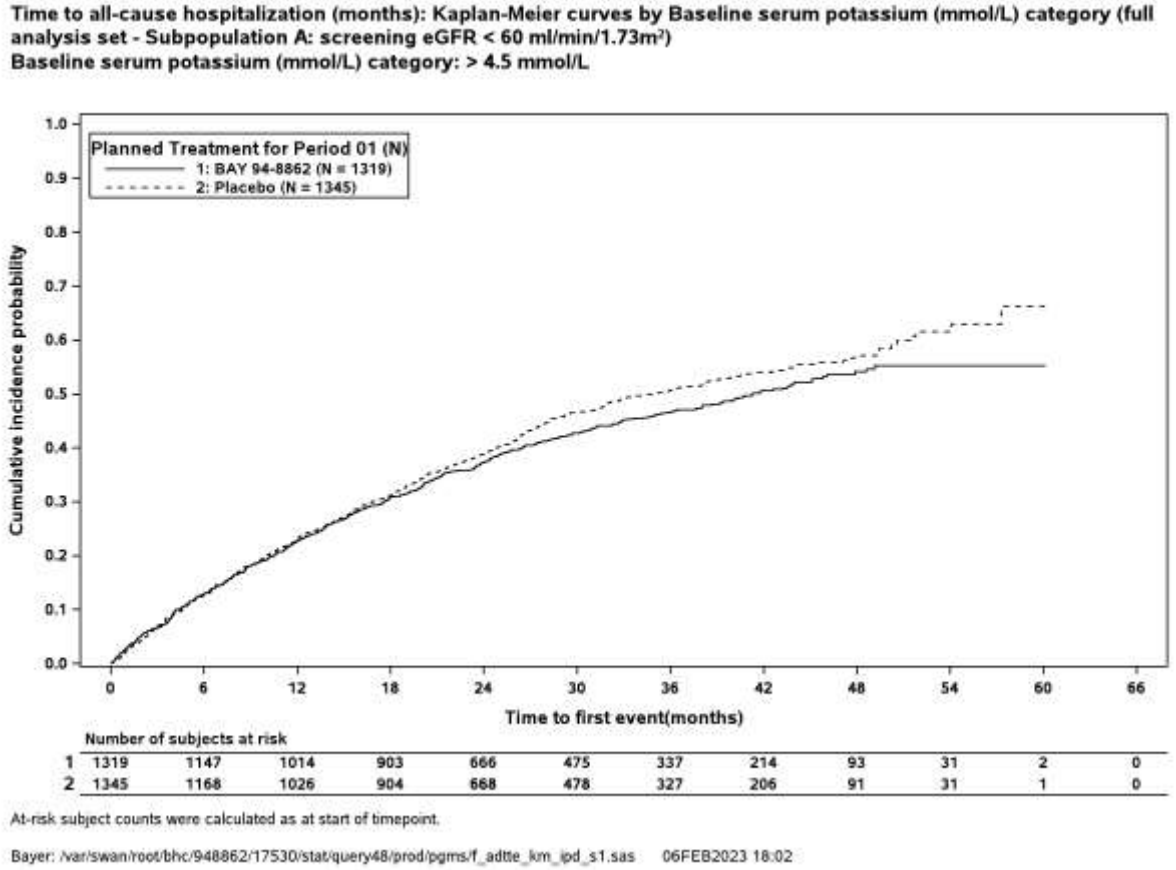


Figure 1.2.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Baseline systolic blood pressure (mmHg) category: < 130 mmHg

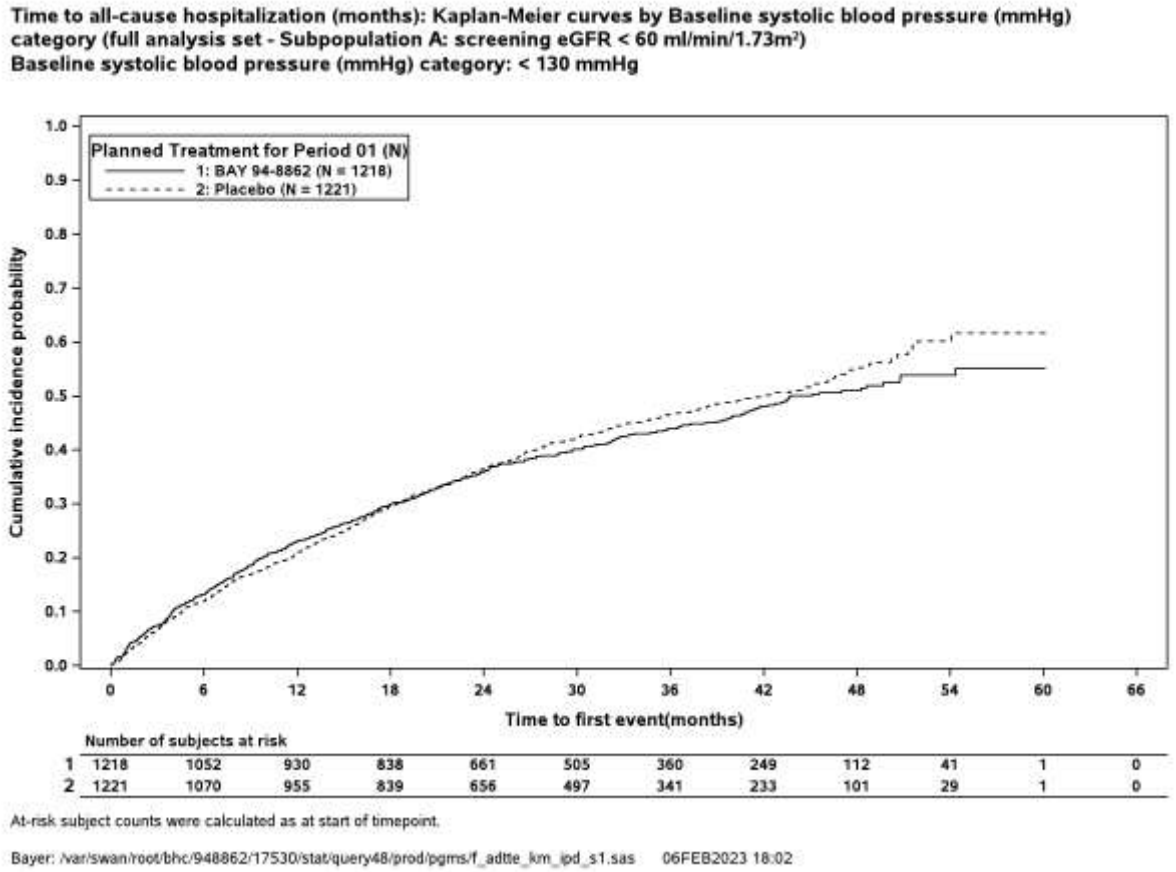


Figure 1.2.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: 130 - < 160 mmHg

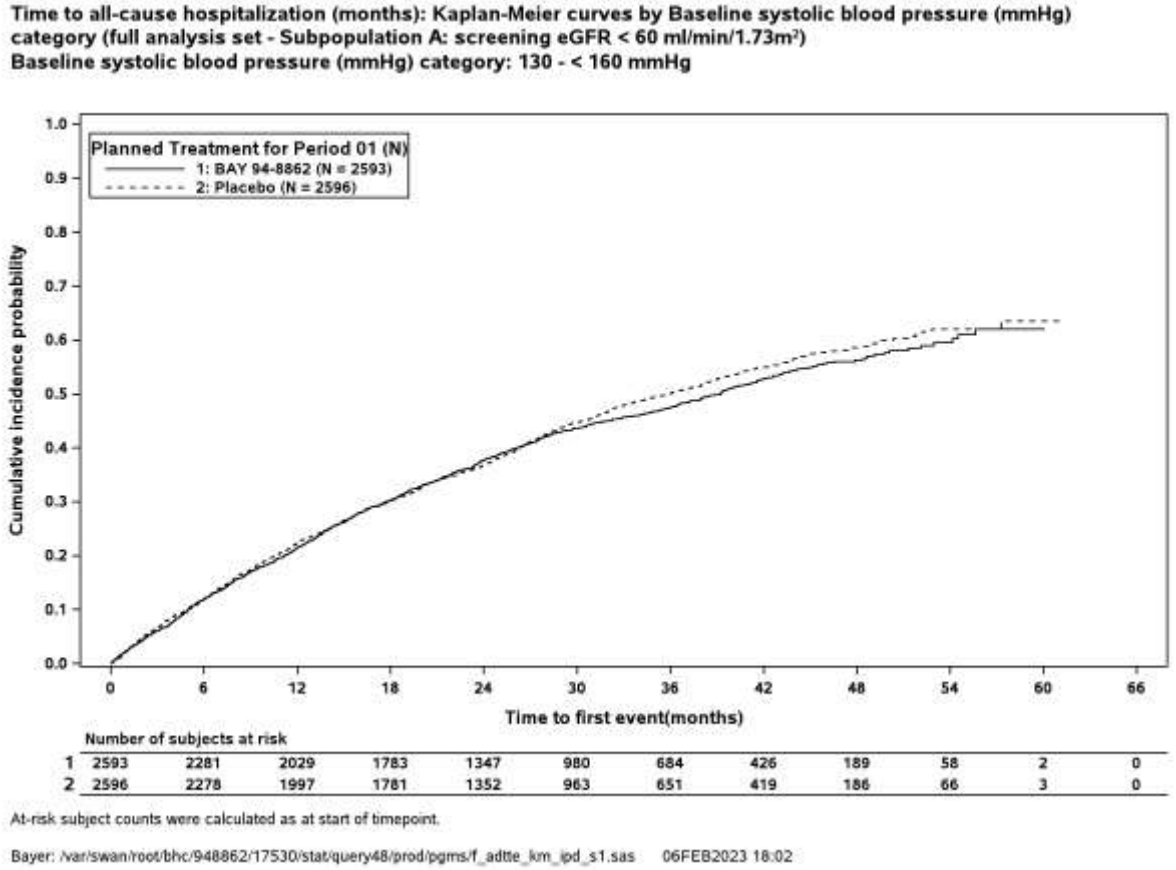


Figure 1.2.1 / 87: Time to all-cause hospitalization (months): Kaplan-Meier curves by Baseline systolic blood pressure (mmHg) category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Baseline systolic blood pressure (mmHg) category: >= 160 mmHg

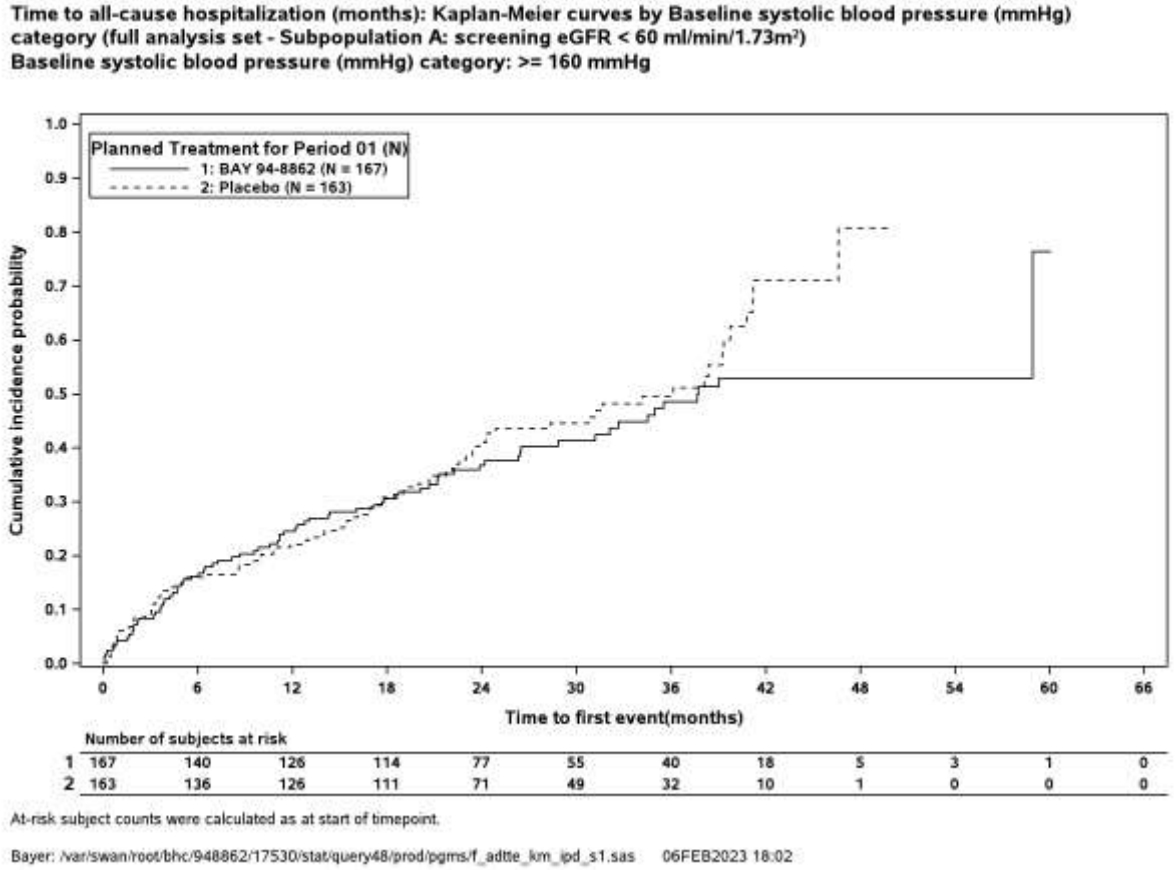


Figure 1.2.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Race (4 categories): White

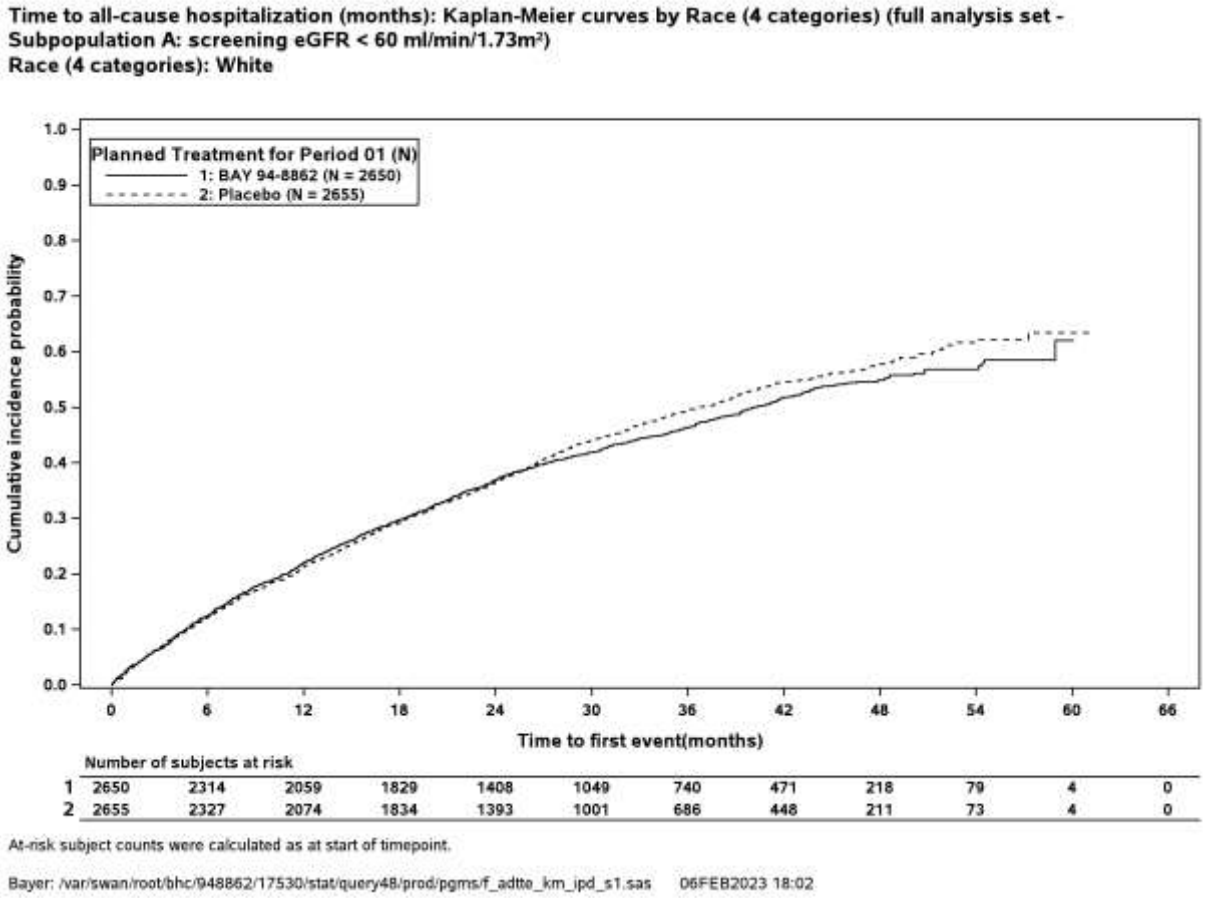


Figure 1.2.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Black

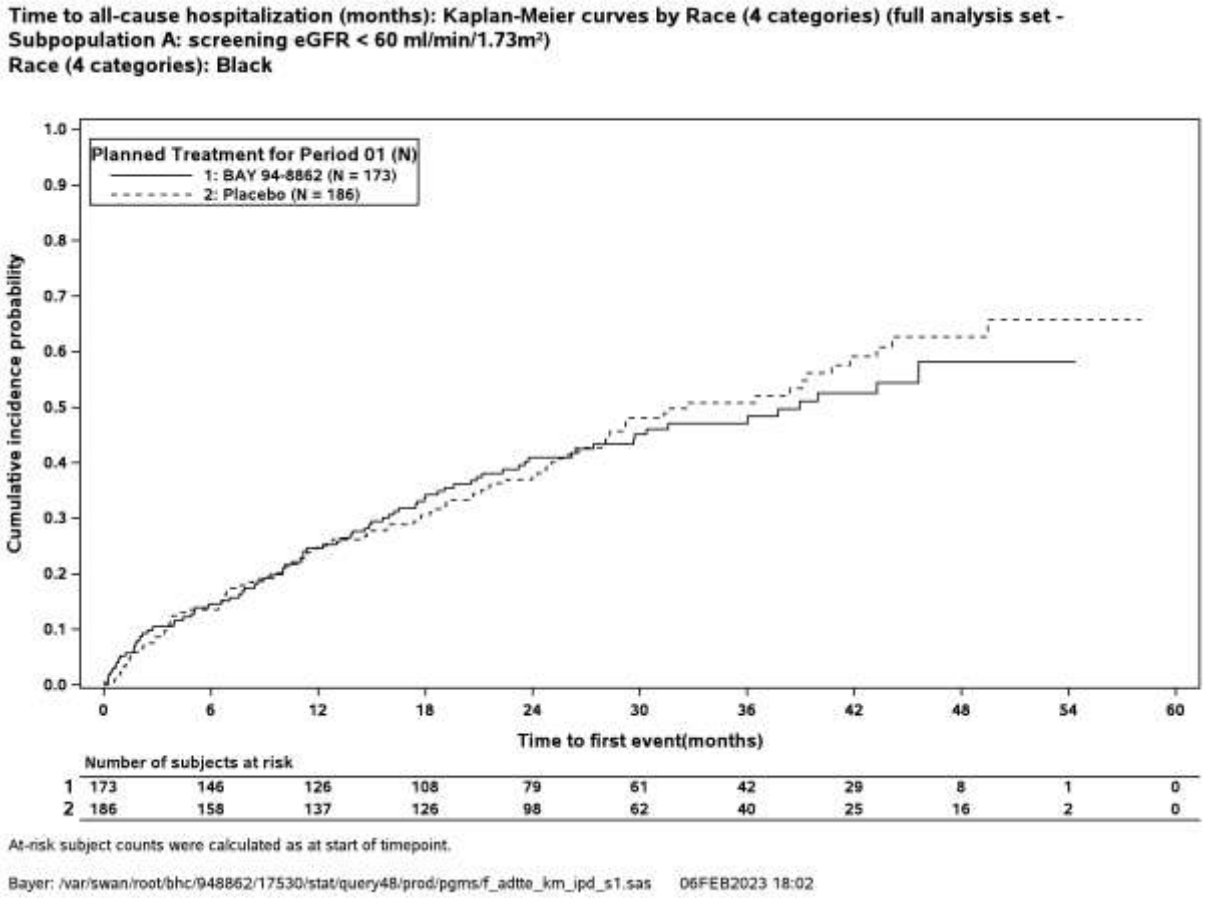


Figure 1.2.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Asian

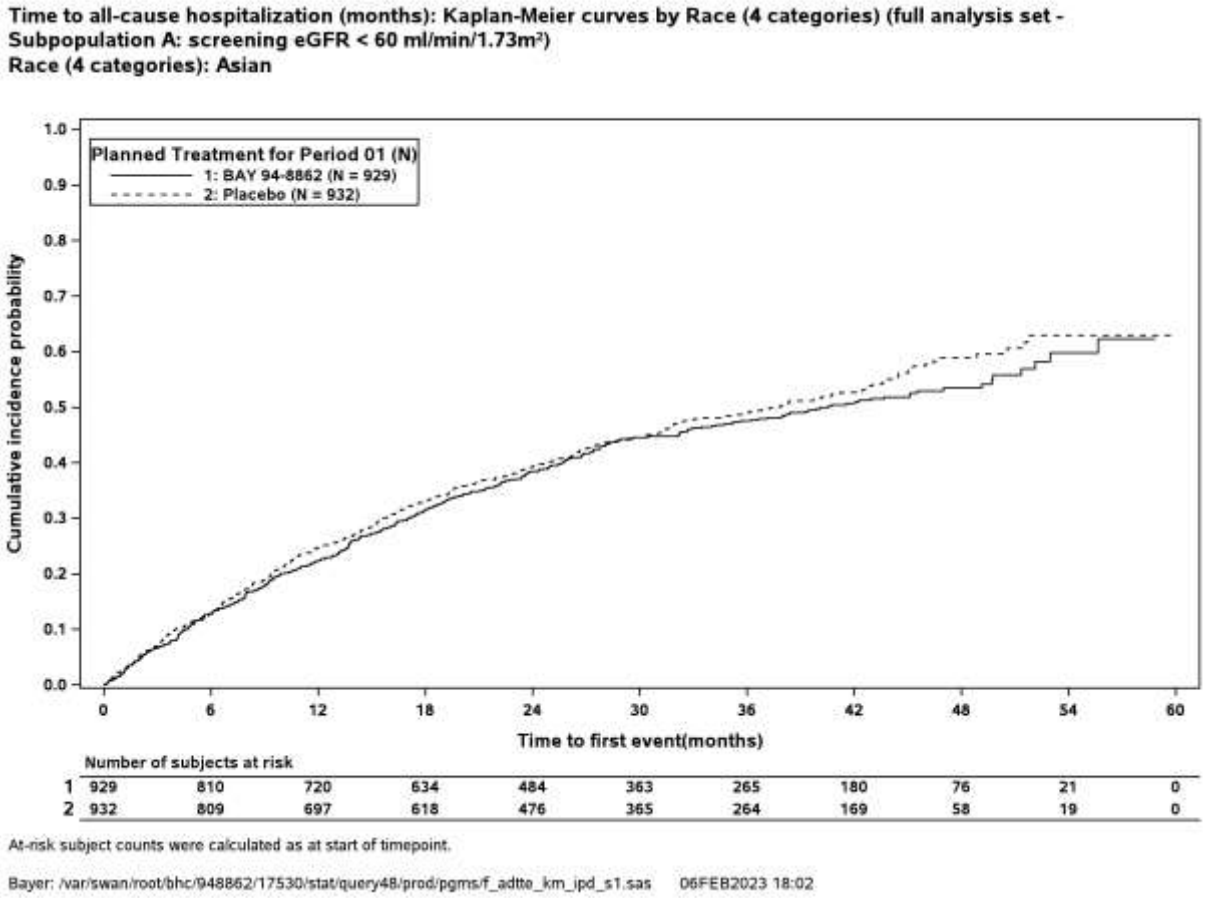


Figure 1.2.1 / 88: Time to all-cause hospitalization (months): Kaplan-Meier curves by Race (4 categories) (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Race (4 categories): Other

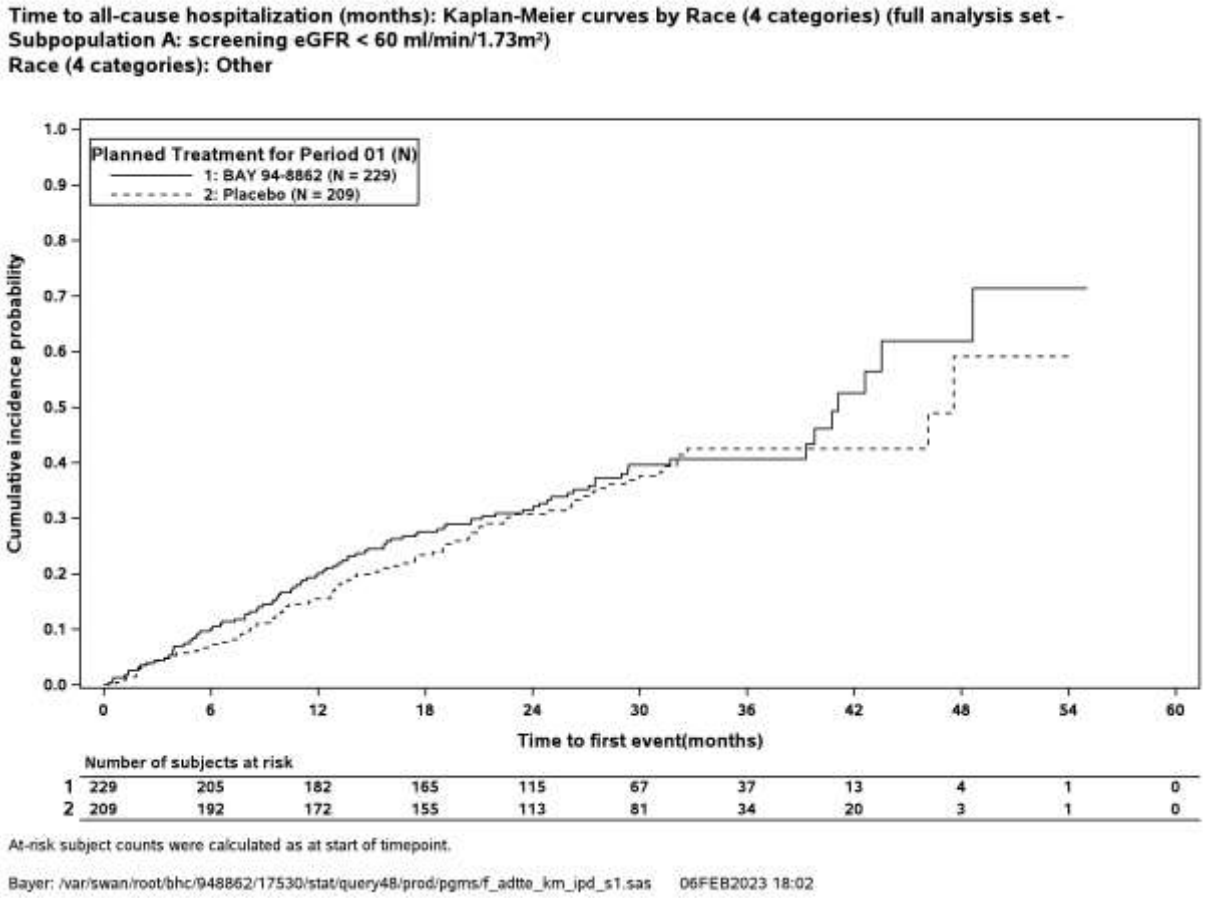


Figure 1.2.1 / 89: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Sex: Male

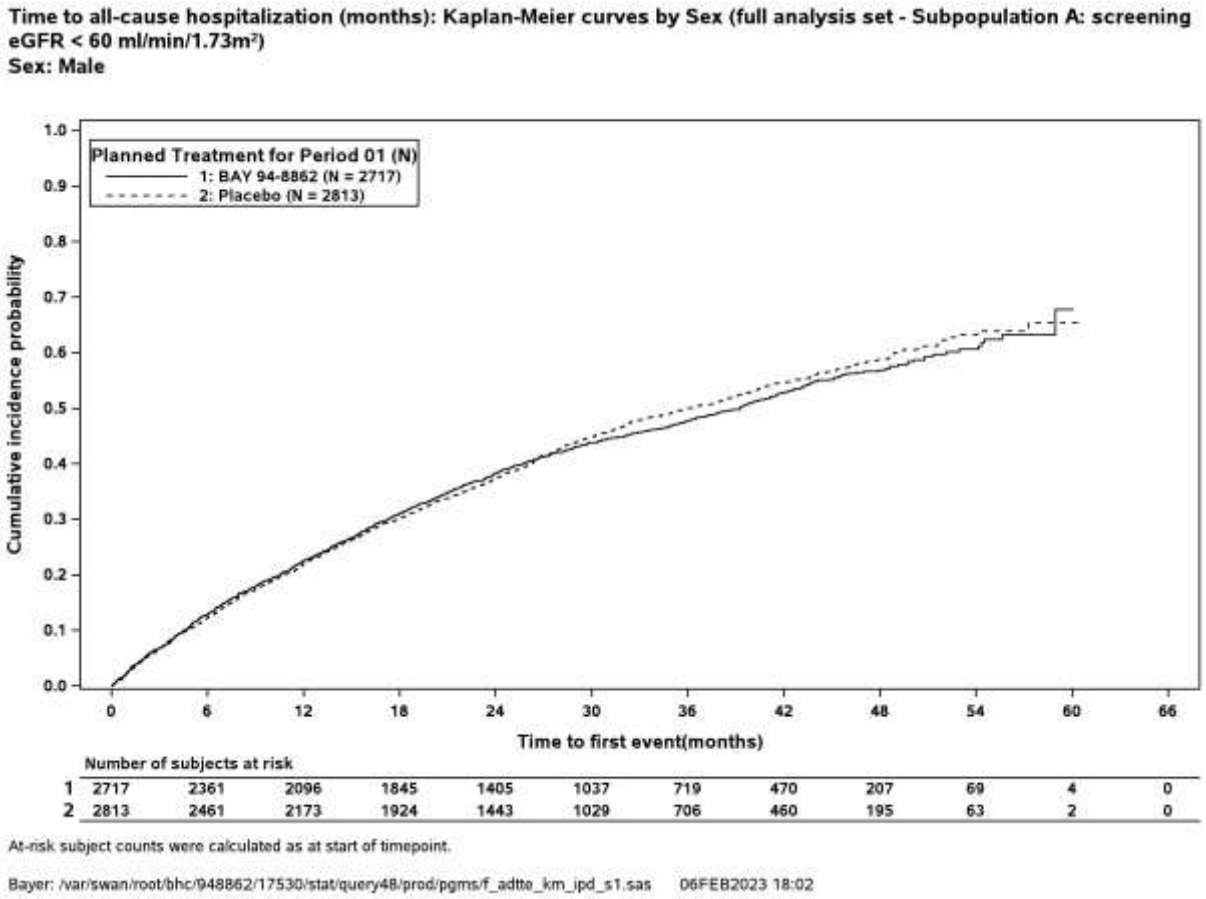


Figure 1.2.1 / 89: Time to all-cause hospitalization (months): Kaplan-Meier curves by Sex (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

Sex: Female

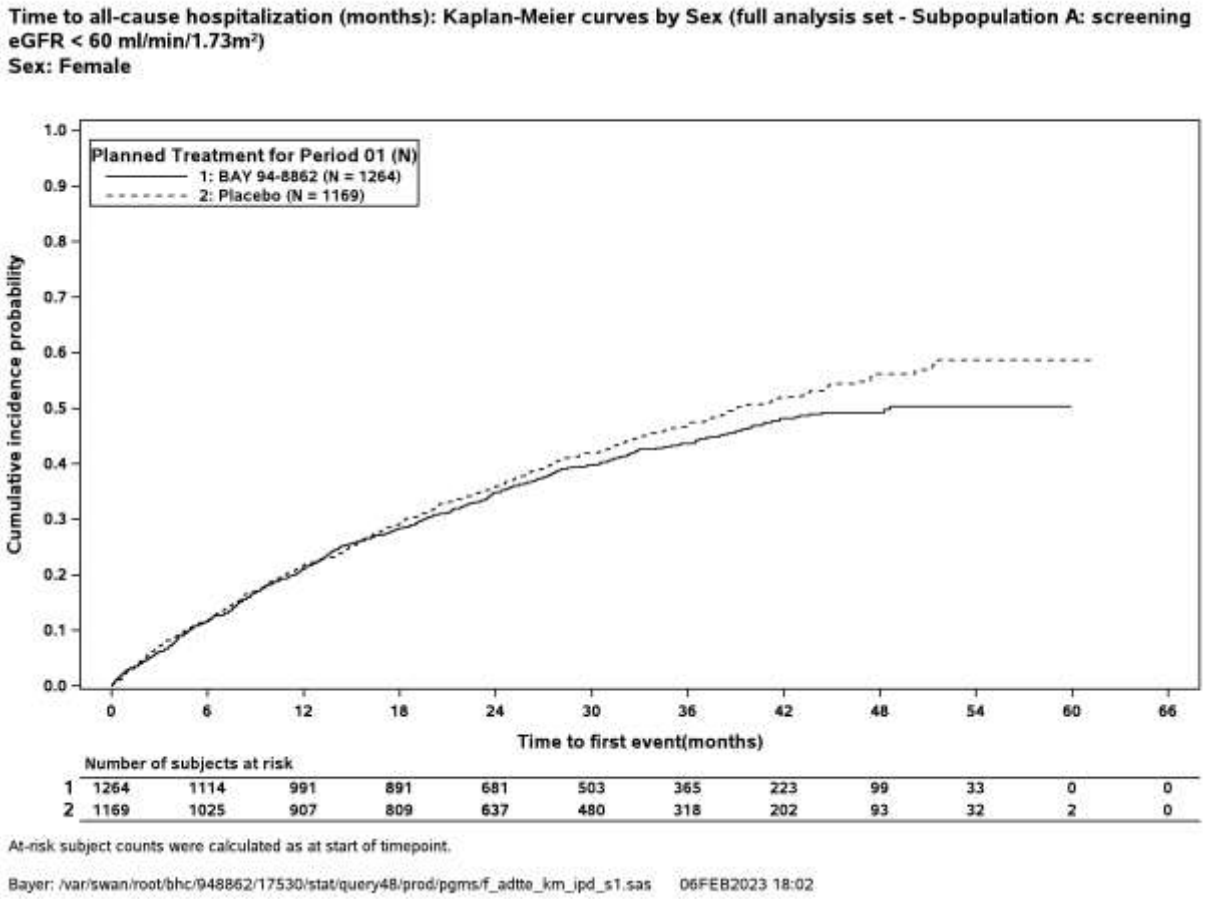


Figure 1.2.1 / 90: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Age group (years) 3rd category: < 65 years

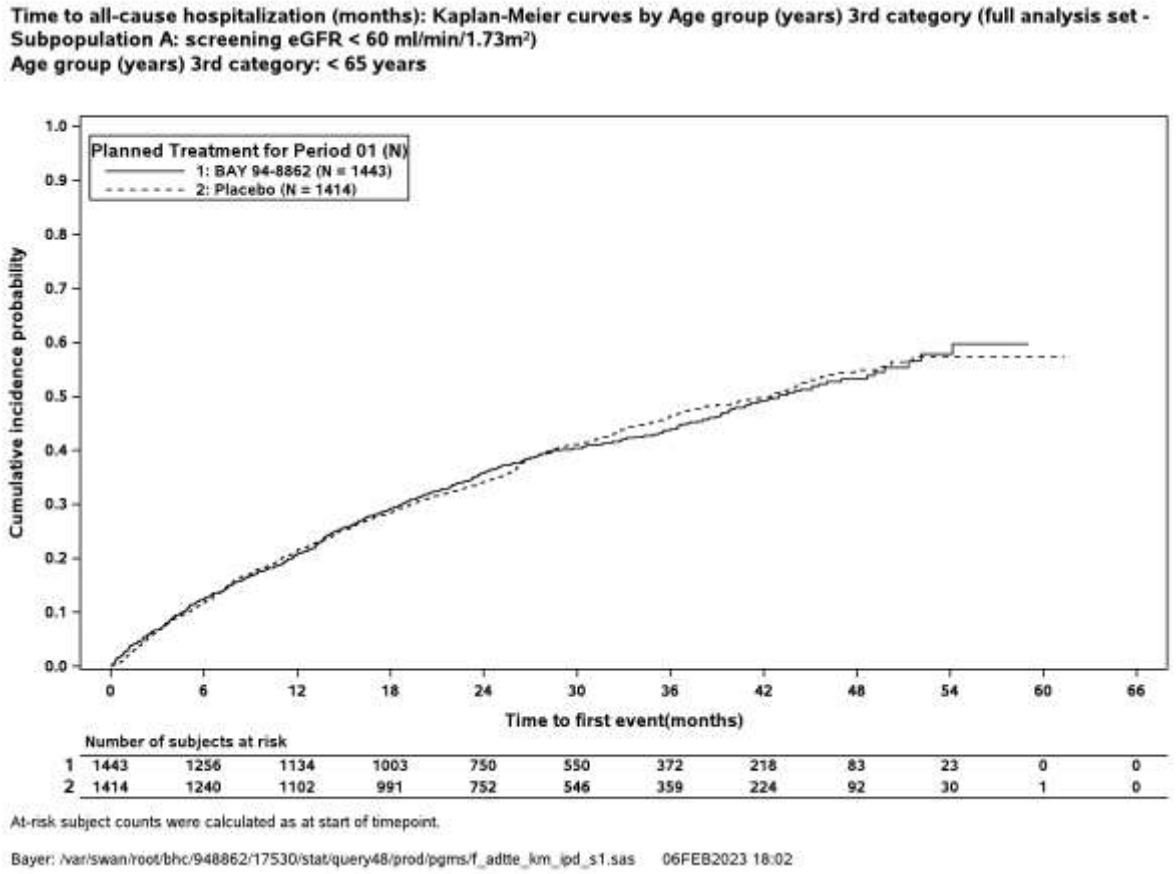
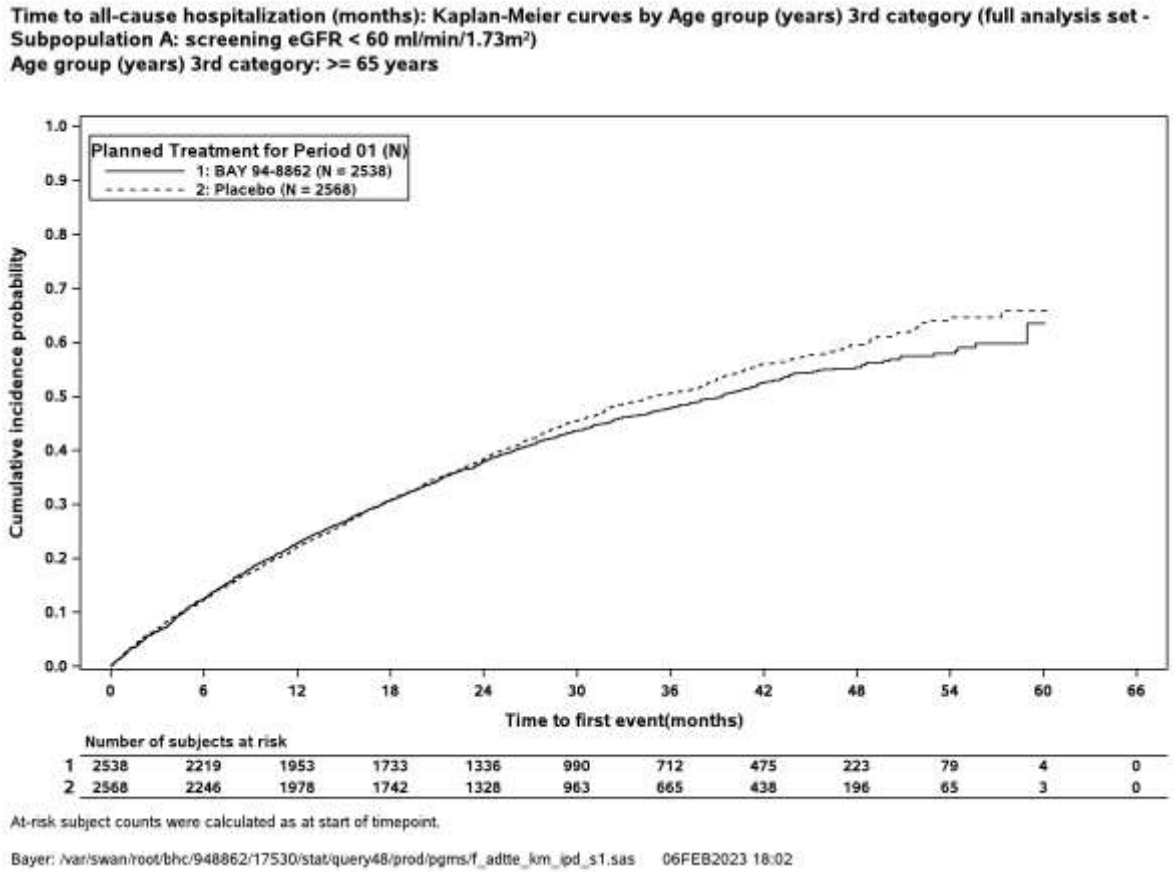


Figure 1.2.1 / 90: Time to all-cause hospitalization (months): Kaplan-Meier curves by Age group (years) 3rd category (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²) (cont.)

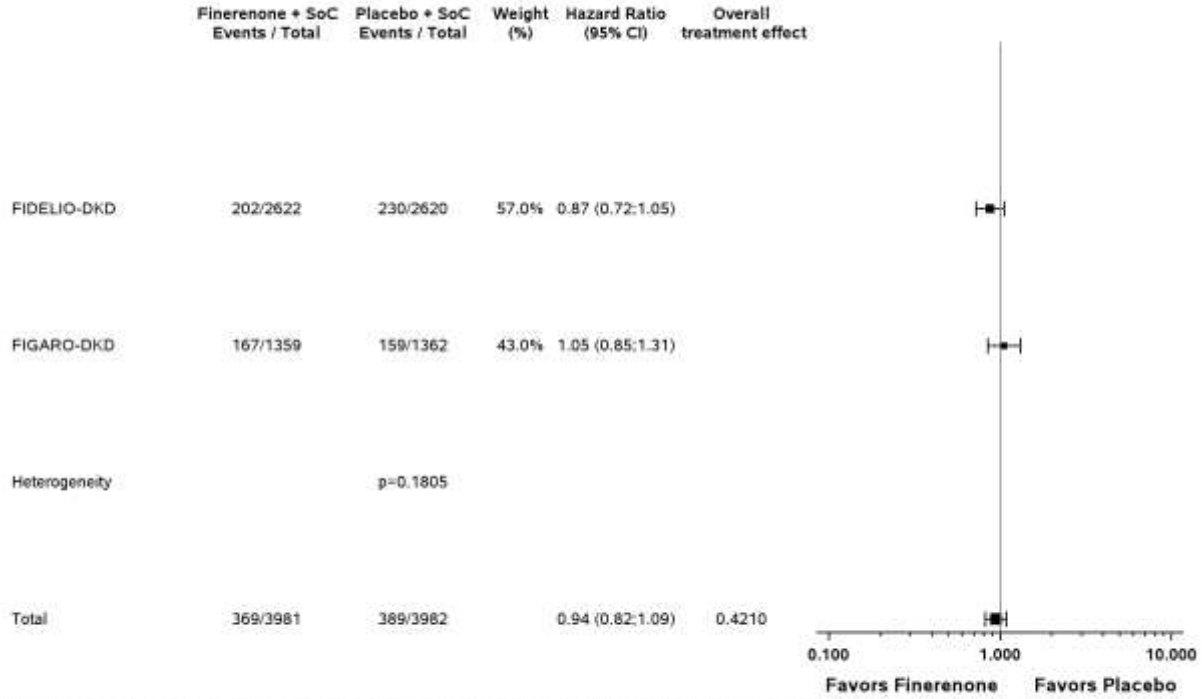
Age group (years) 3rd category: >= 65 years



1.2.2 Forest plots for time-to-event Analyses

Figure 1.2.2 / 1: Forest plot of all-cause mortality: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 2: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=40% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

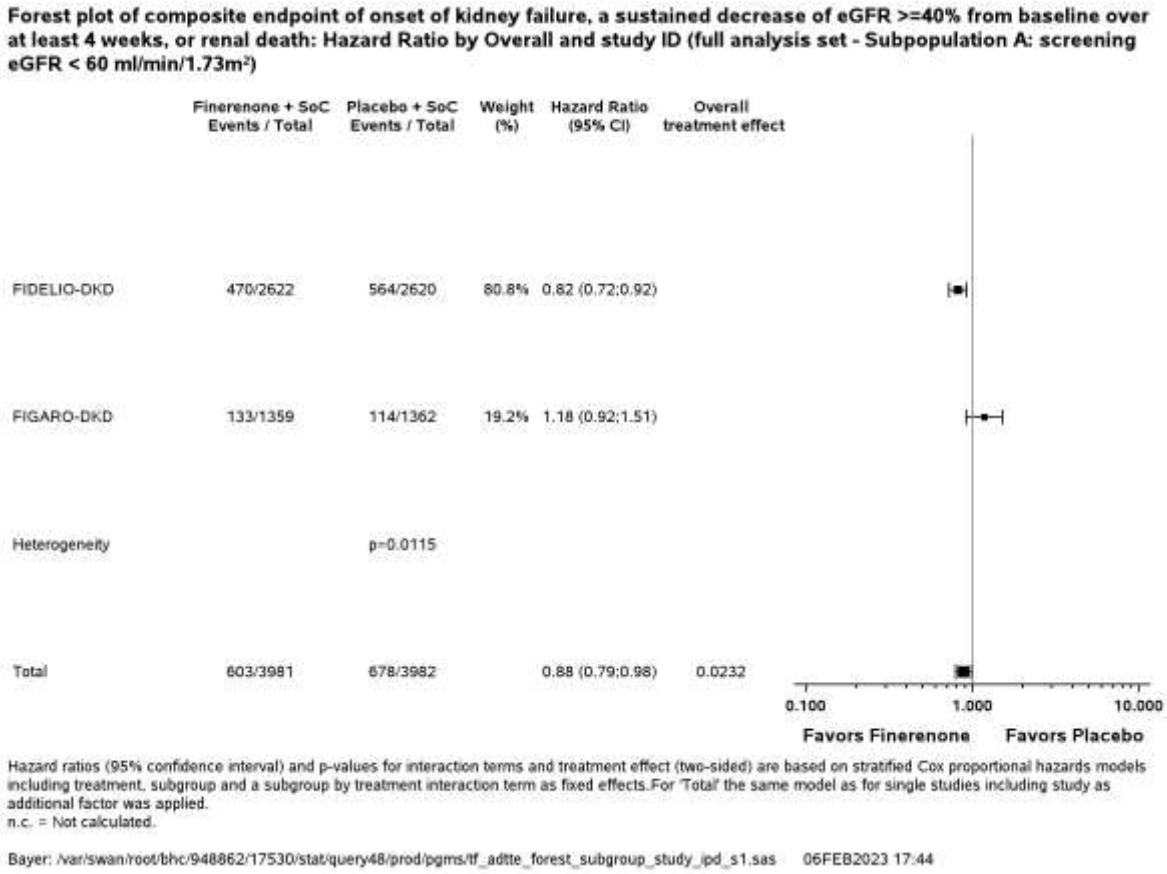
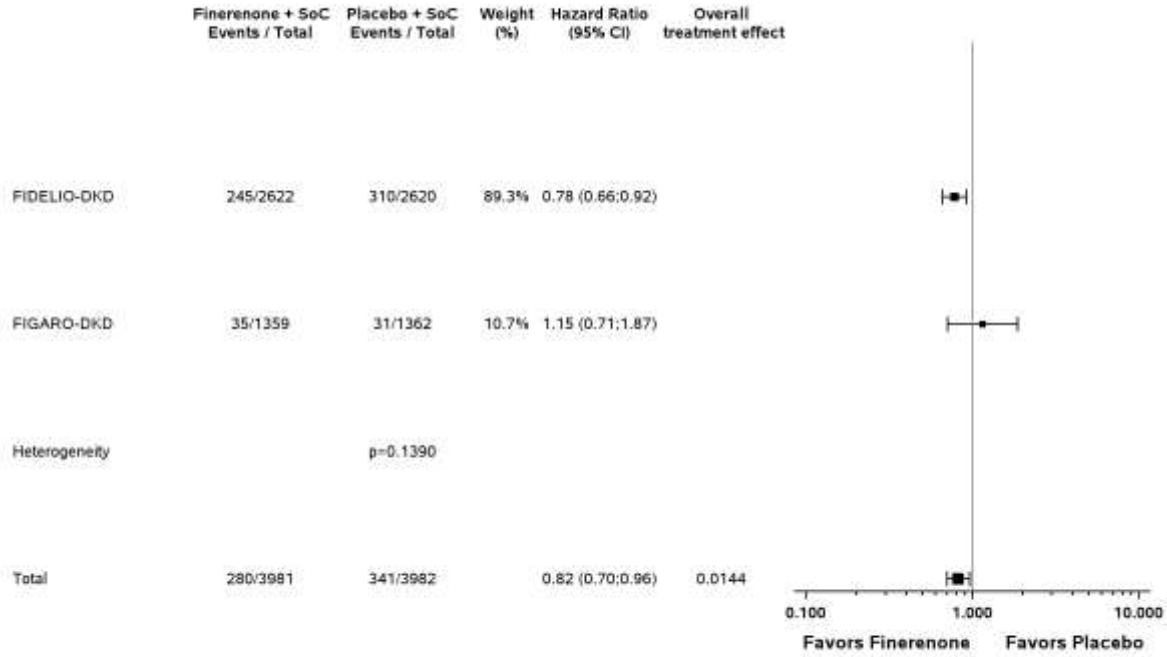


Figure 1.2.2 / 3: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

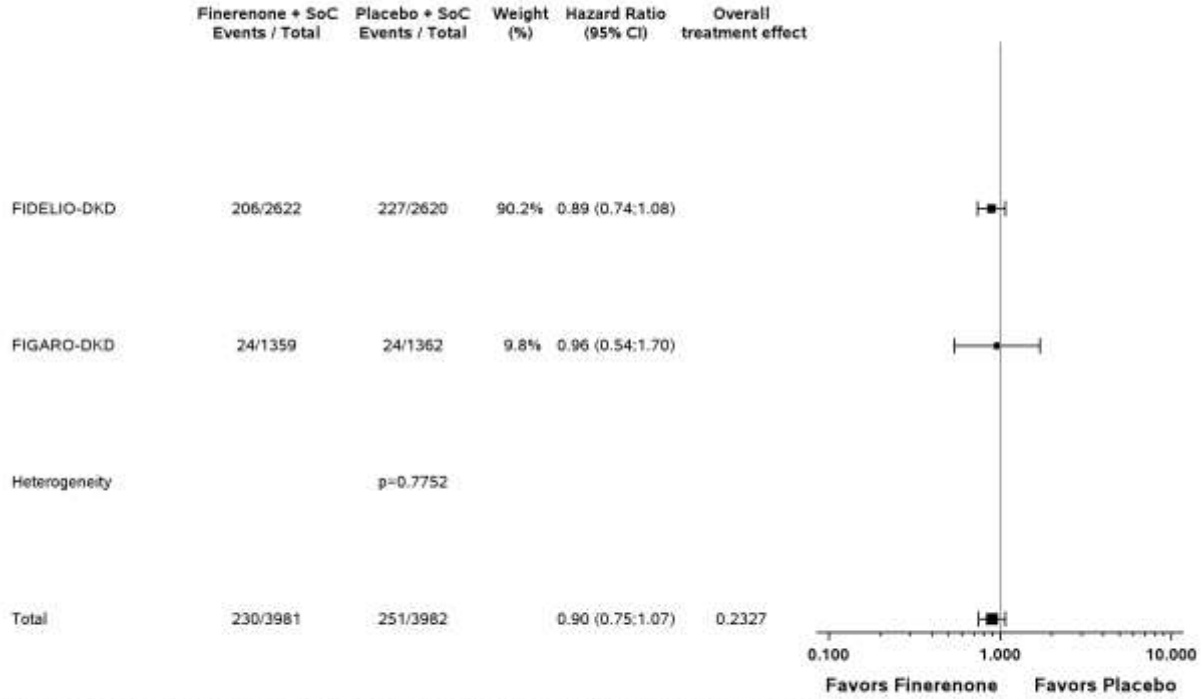


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 4: Forest plot of onset of kidney failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

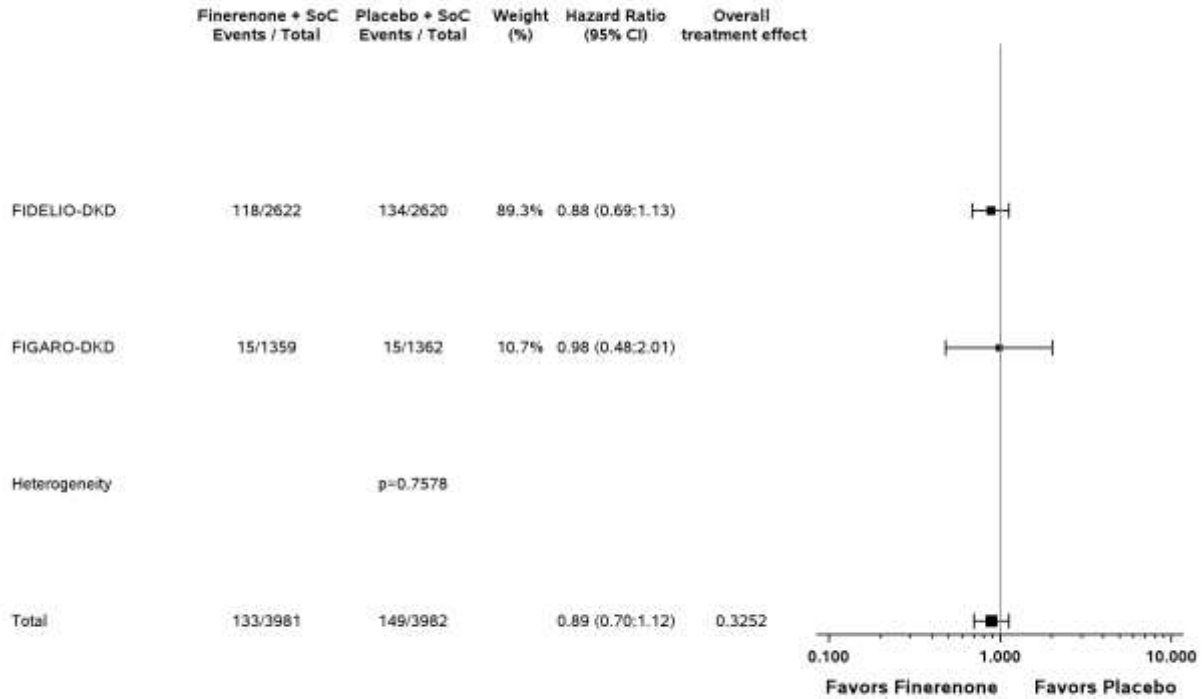


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 5: Forest plot of end-stage renal disease: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

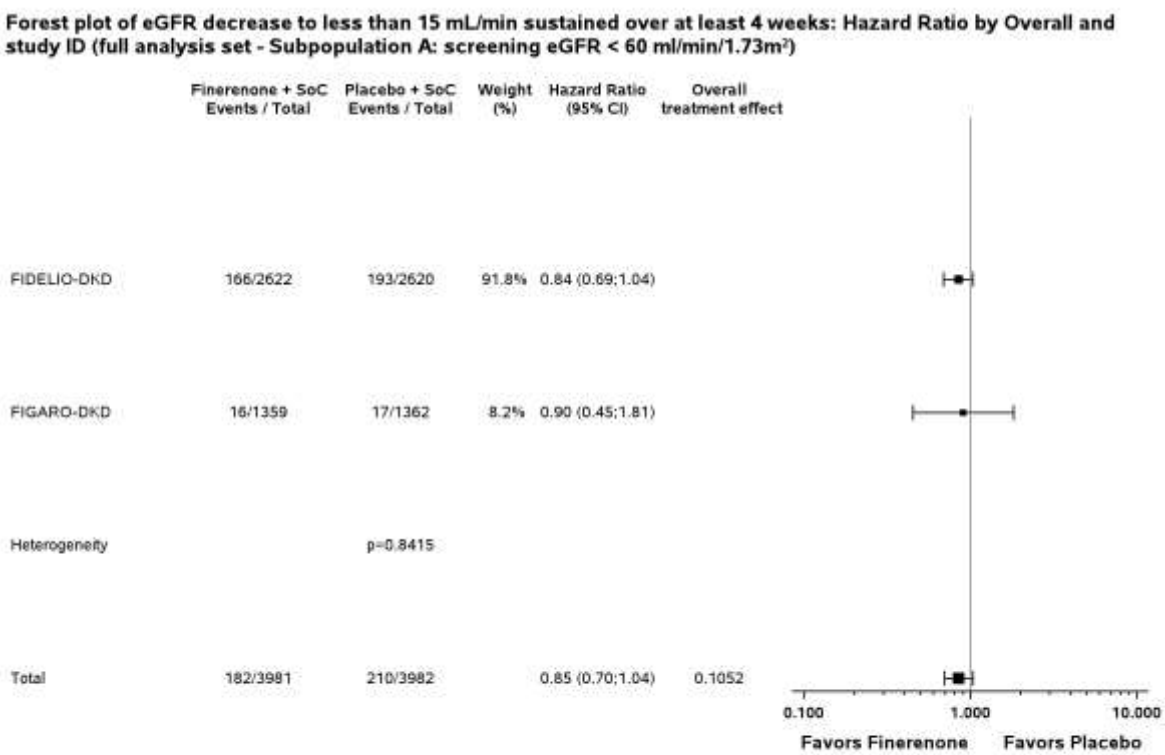
Forest plot of end-stage renal disease: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

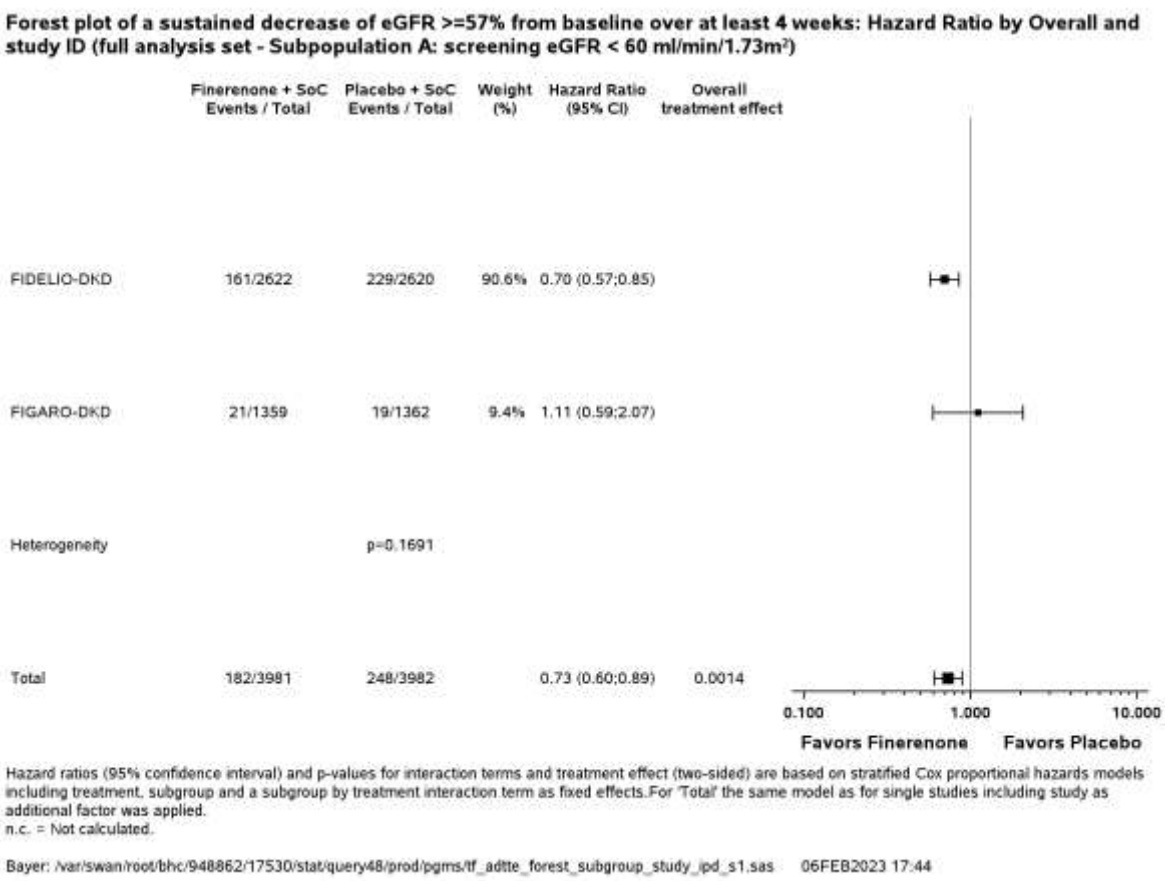
Figure 1.2.2 / 6: Forest plot of eGFR decrease to less than 15 mL/min sustained over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 7: Forest plot of a sustained decrease of eGFR >=57% from baseline over at least 4 weeks: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 8: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

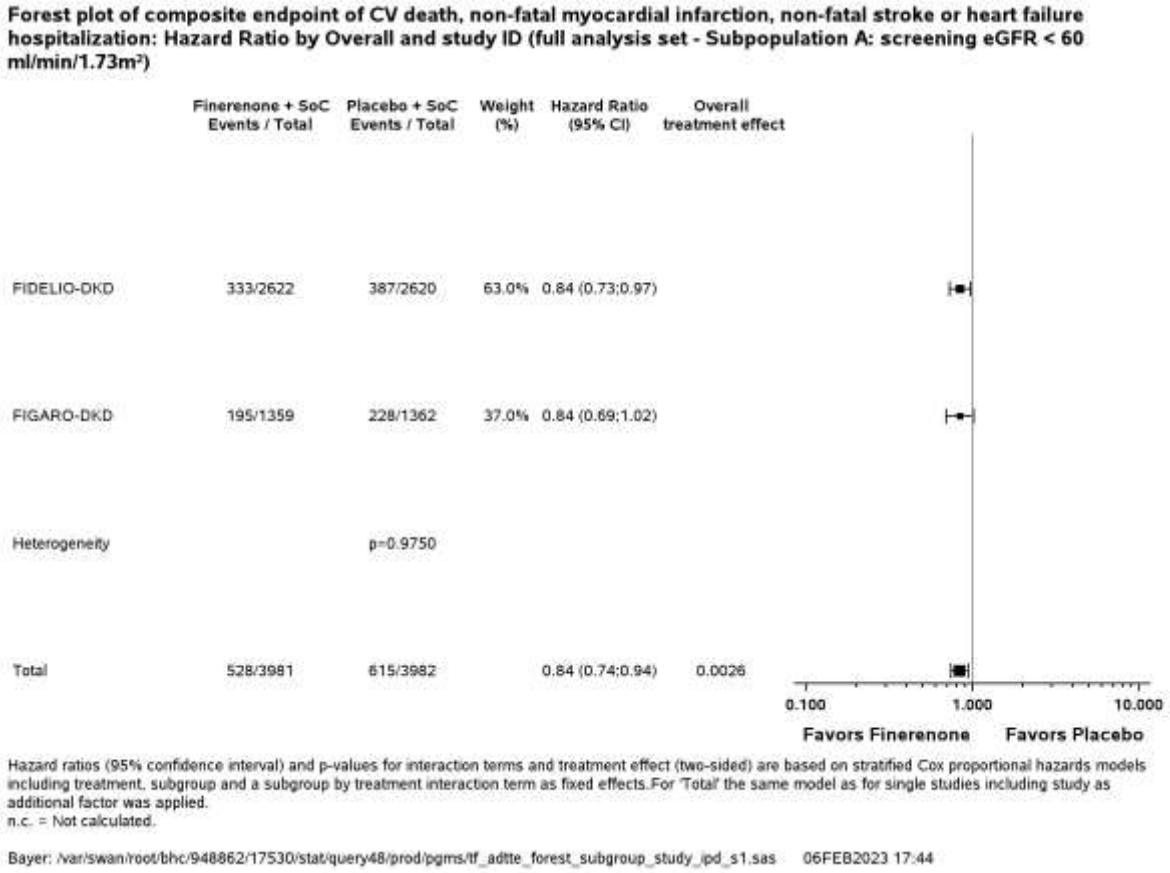
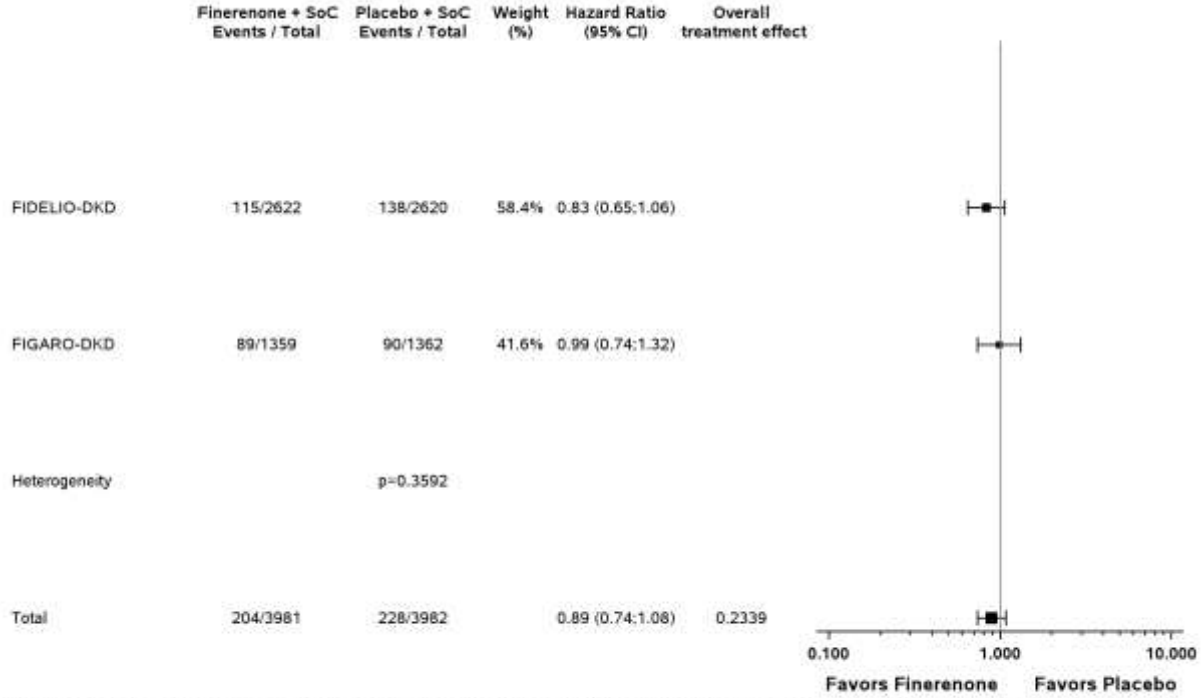


Figure 1.2.2 / 9: Forest plot of cardiovasular (CV) death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of cardiovasular (CV) death: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

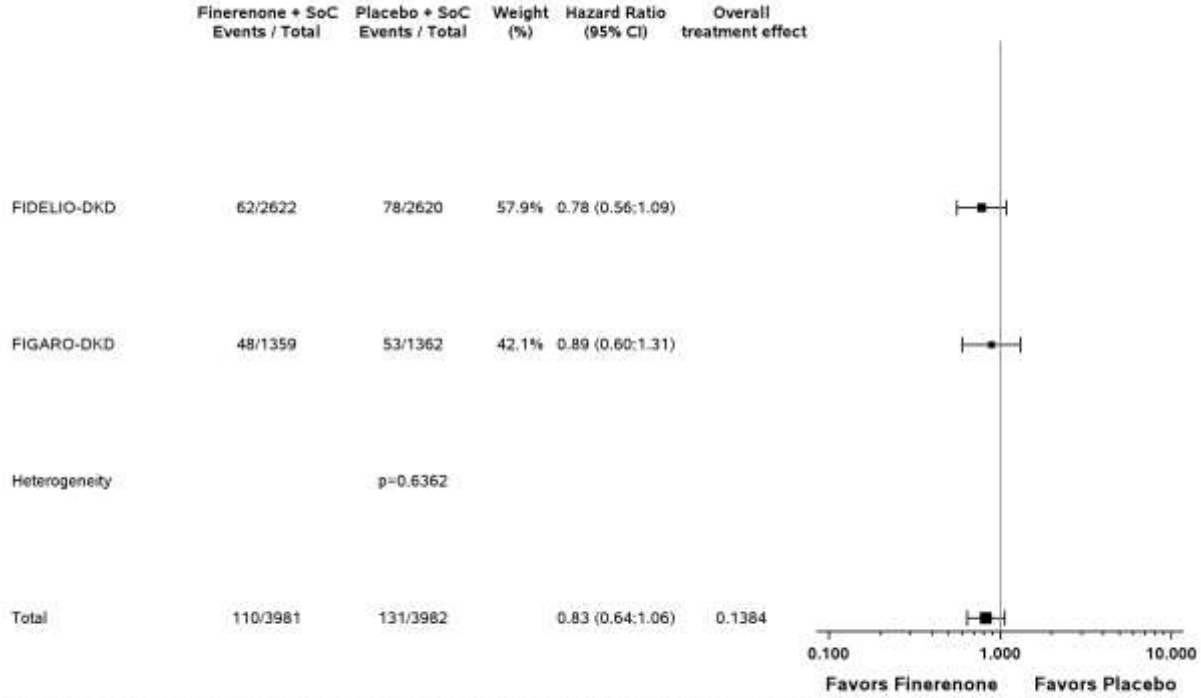


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 10: Forest plot of non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

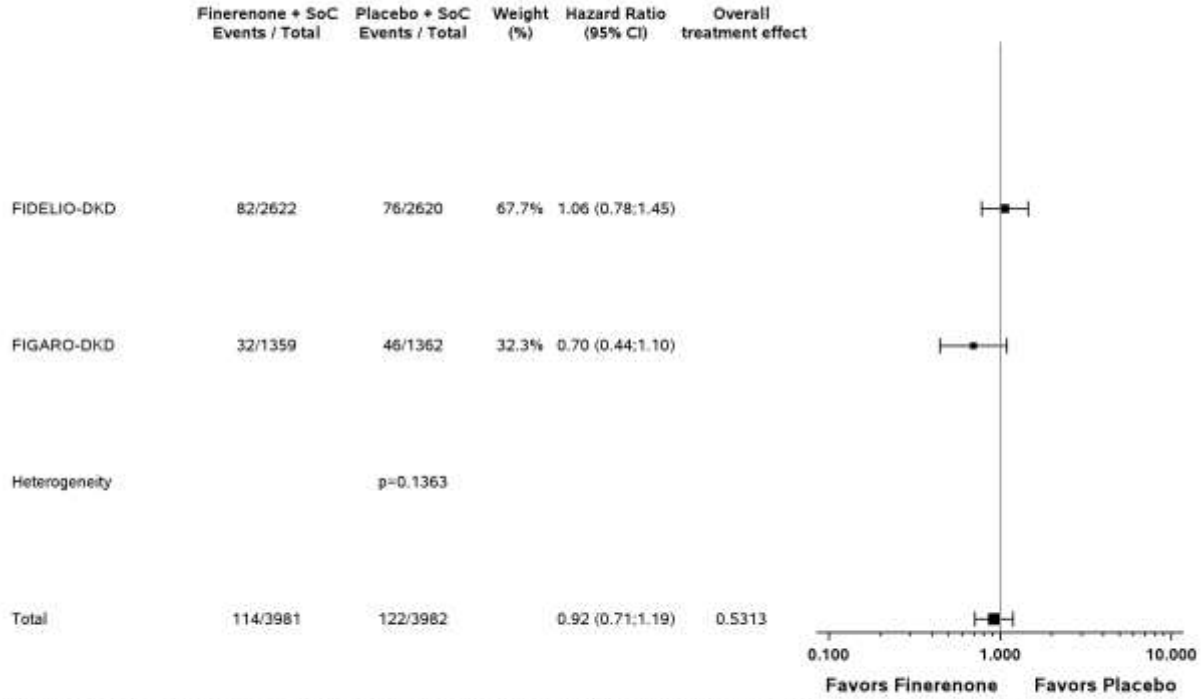


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 11: Forest plot of non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

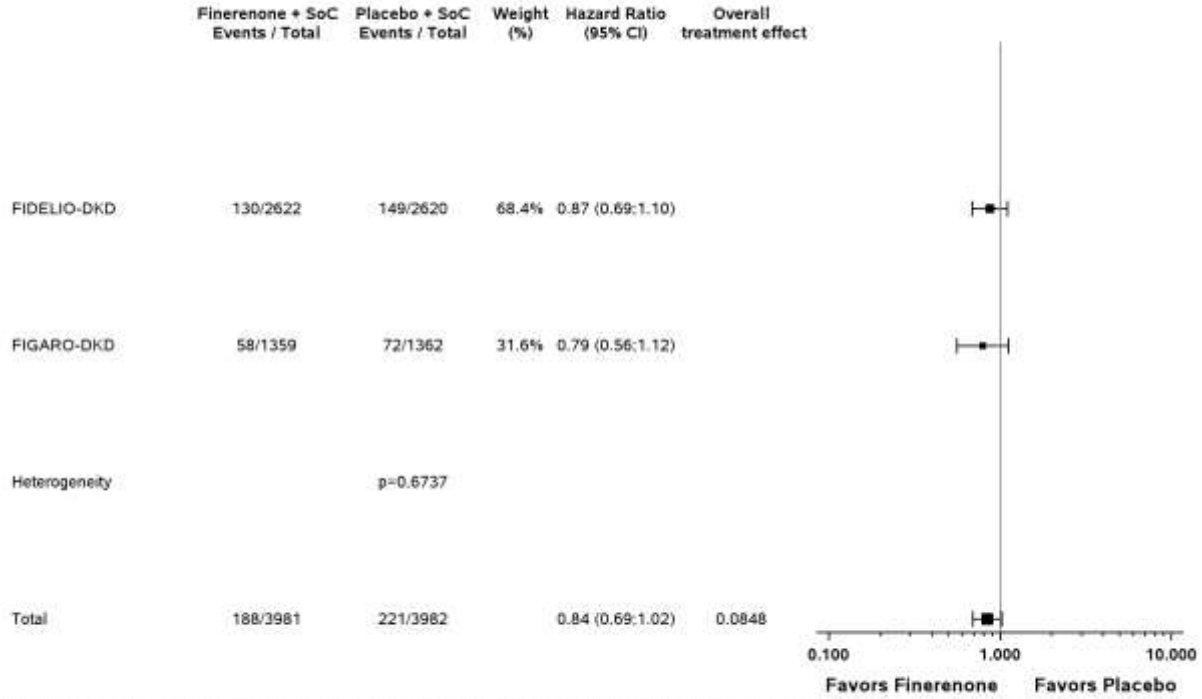


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 12: Forest plot of hospitalization due to heart failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of hospitalization due to heart failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

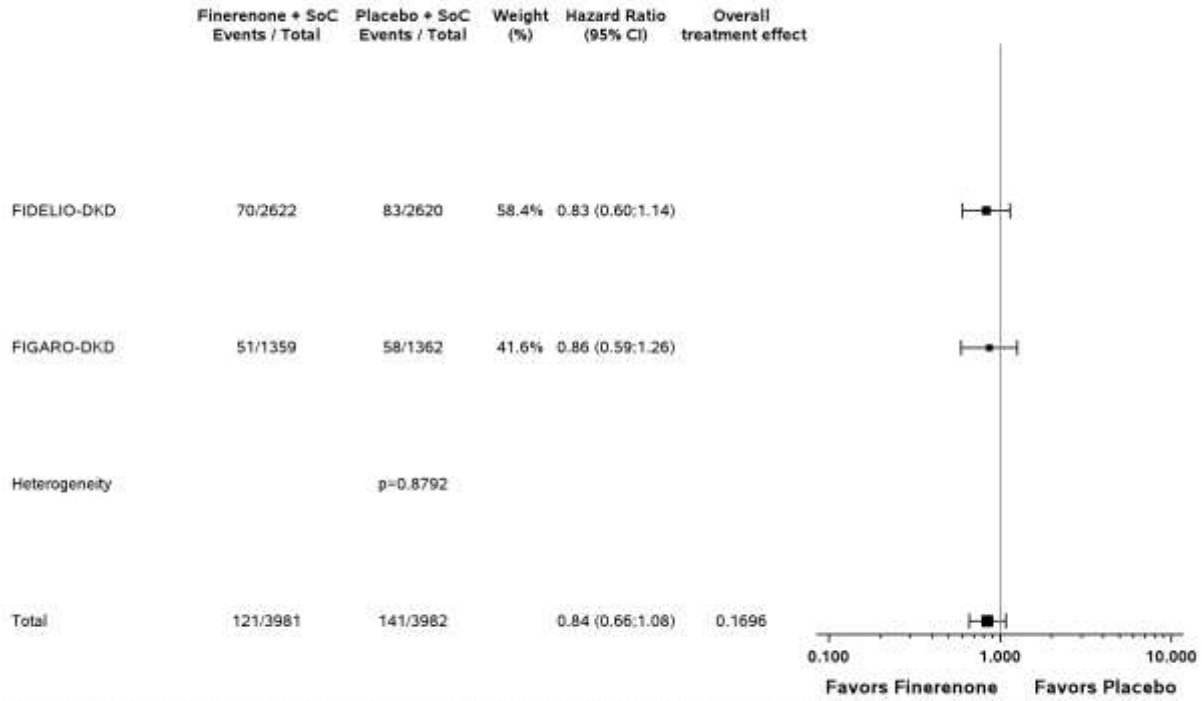


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 13: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

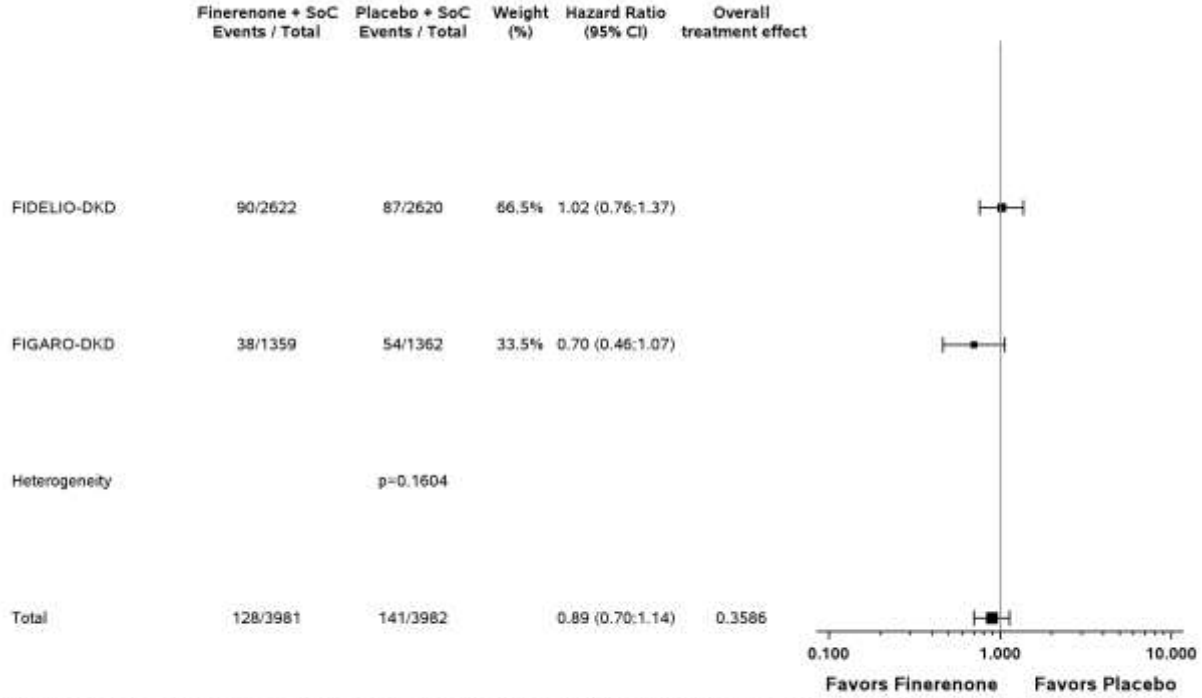


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 14: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

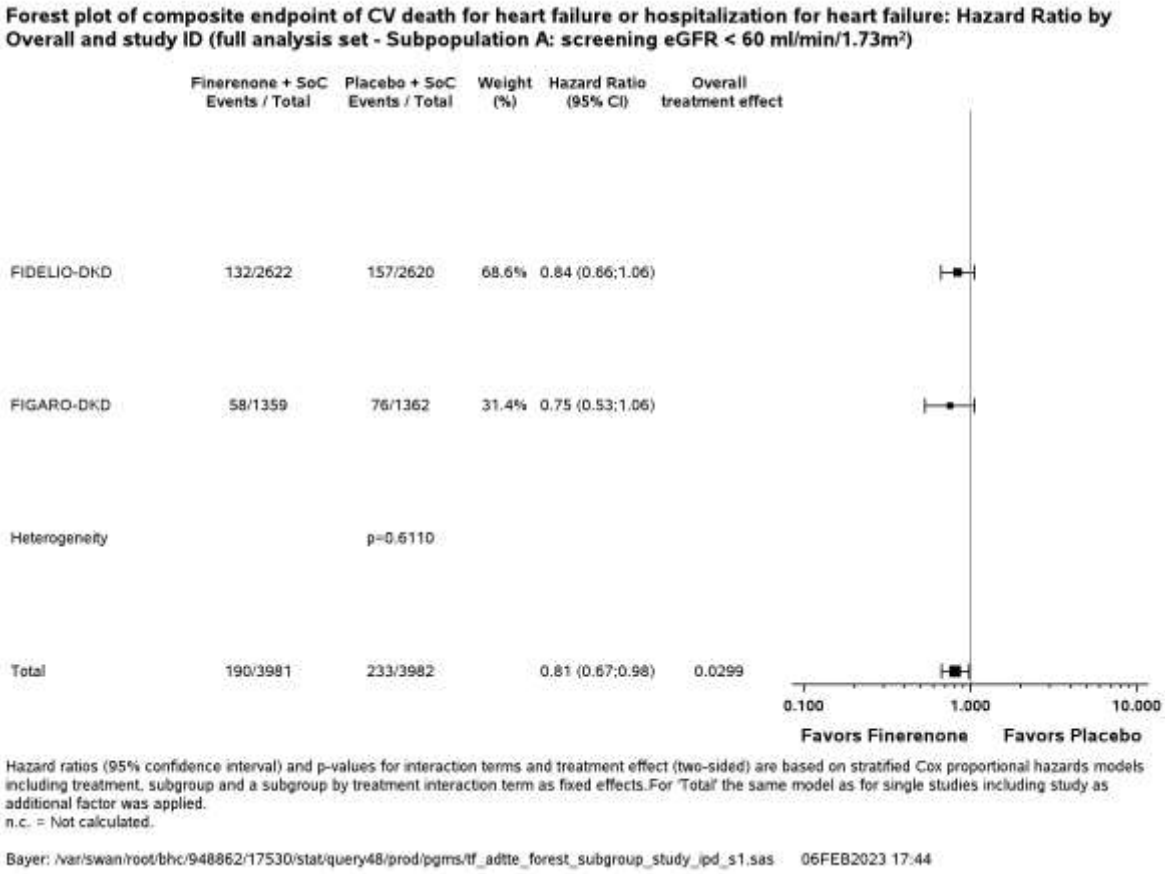
Forest plot of fatal or non-fatal stroke: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 15: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



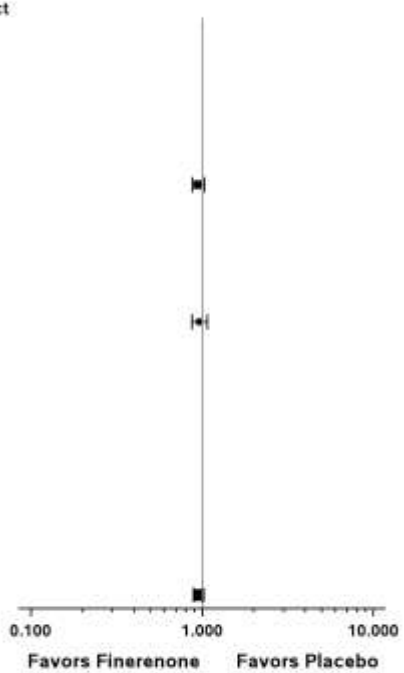
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 16: Forest plot of all-cause hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

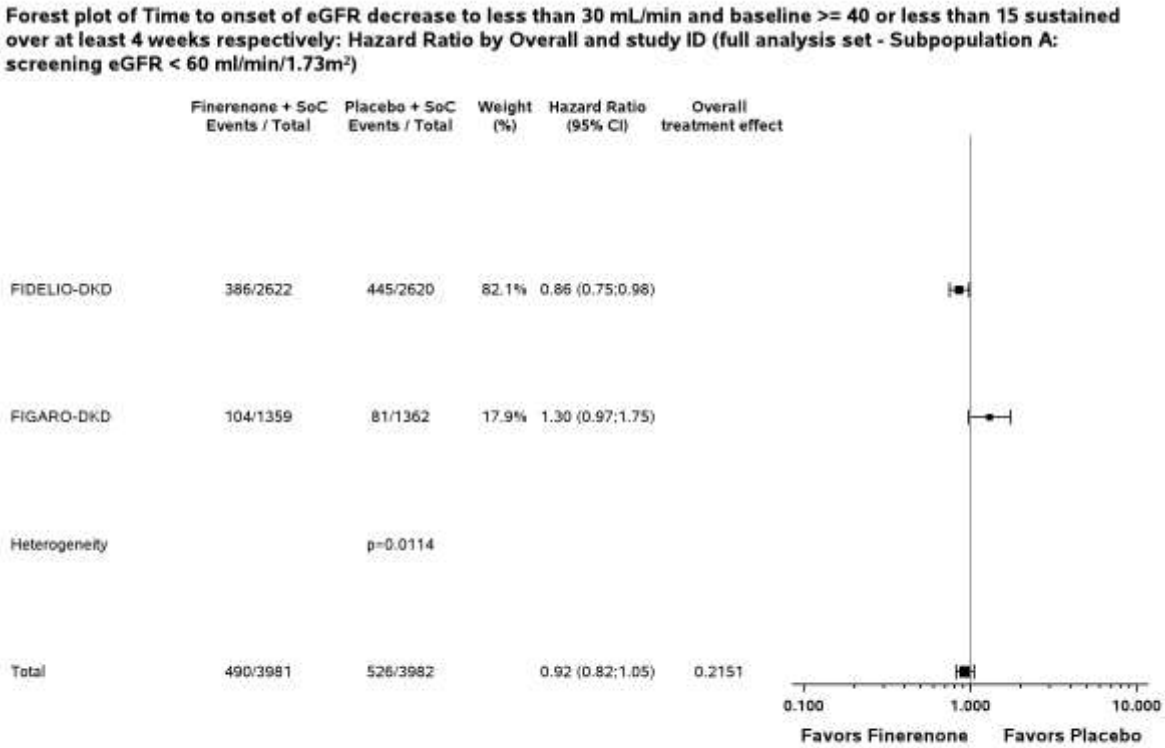
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
FIDELIO-DKD	1176/2622	1227/2620	64.0%	0.95 (0.87;1.03)	
FIGARO-DKD	670/1359	687/1362	36.0%	0.97 (0.87;1.07)	
Heterogeneity		p=0.6970			
Total	1846/3981	1914/3982		0.95 (0.89;1.01)	0.1162



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 17: Forest plot of Time to onset of eGFR decrease to less than 30 mL/min and baseline >= 40 or less than 15 sustained over at least 4 weeks respectively: Hazard Ratio by Overall and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



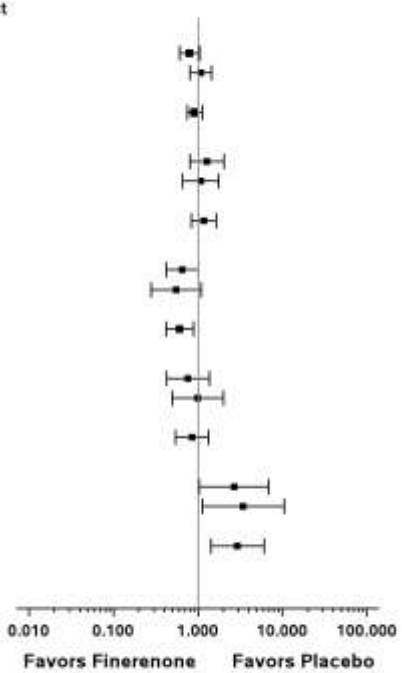
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_ipd_s1.sas 06FEB2023 17:44

Figure 1.2.2 / 18: Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	93/1078	115/1064	53.8%	0.80 (0.60;1.04)	
FIGARO-DKD	92/640	85/639	46.2%	1.08 (0.80;1.45)	
Heterogeneity		p=0.1392			
Total	185/1718	200/1703		0.92 (0.75;1.12)	0.4045
North America					
FIDELIO-DKD	40/425	32/437	53.0%	1.28 (0.81;2.04)	
FIGARO-DKD	32/267	31/271	47.0%	1.08 (0.66;1.76)	
Heterogeneity		p=0.6229			
Total	72/692	63/708		1.18 (0.84;1.65)	0.3490
Asia					
FIDELIO-DKD	34/751	51/748	71.2%	0.65 (0.42;1.01)	
FIGARO-DKD	13/288	23/292	28.8%	0.55 (0.28;1.09)	
Heterogeneity		p=0.7225			
Total	47/1039	74/1040		0.61 (0.42;0.88)	0.0078
Latin America					
FIDELIO-DKD	20/274	26/274	58.6%	0.76 (0.42;1.36)	
FIGARO-DKD	16/102	16/101	41.4%	1.00 (0.50;2.00)	
Heterogeneity		p=0.5121			
Total	36/376	42/375		0.85 (0.54;1.33)	0.4699
Others					
FIDELIO-DKD	15/94	6/97	58.0%	2.68 (1.04;6.92)	
FIGARO-DKD	14/62	4/59	42.0%	3.44 (1.13;10.5)	
Heterogeneity		p=0.7274			
Total	29/156	10/156		2.94 (1.43;6.07)	0.0022
Subgroup Heterogeneity		p=0.0022			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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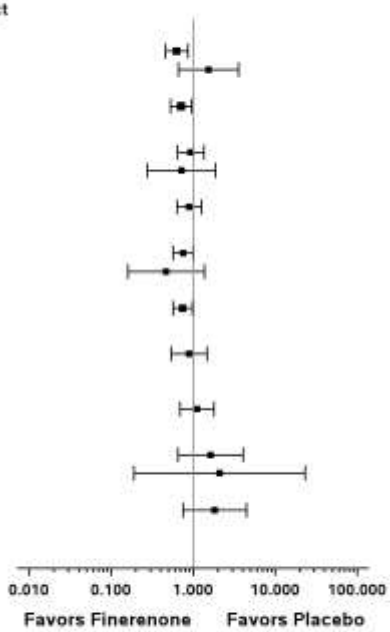
Figure 1.2.2 / 19: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	62/1078	98/1064	87.4%	0.63 (0.46;0.86)	
FIGARO-DKD	14/640	9/639	12.6%	1.53 (0.66;3.55)	
Heterogeneity		p=0.0511			
Total	76/1718	107/1703		0.71 (0.53;0.95)	0.0211
North America					
FIDELIO-DKD	55/425	59/437	87.1%	0.93 (0.64;1.34)	
FIGARO-DKD	7/267	11/271	12.9%	0.72 (0.28;1.86)	
Heterogeneity		p=0.6610			
Total	62/692	70/708		0.89 (0.63;1.25)	0.4977
Asia					
FIDELIO-DKD	88/751	113/748	93.7%	0.75 (0.57;0.99)	
FIGARO-DKD	5/288	10/292	6.3%	0.47 (0.16;1.37)	
Heterogeneity		p=0.3661			
Total	93/1039	123/1040		0.74 (0.57;0.98)	0.0317
Latin America					
FIDELIO-DKD	29/274	32/274	100%	0.89 (0.54;1.47)	
FIGARO-DKD	7/102	0/101		N.C.	
Heterogeneity		p=0.9816			
Total	36/376	32/375		1.11 (0.69;1.78)	0.6761
Others					
FIDELIO-DKD	11/94	8/97	87.5%	1.62 (0.65;4.03)	
FIGARO-DKD	2/62	1/59	12.5%	2.09 (0.19;23.3)	
Heterogeneity		p=0.8669			
Total	13/156	9/156		1.83 (0.75;4.45)	0.1763
Subgroup Heterogeneity		p=0.1775			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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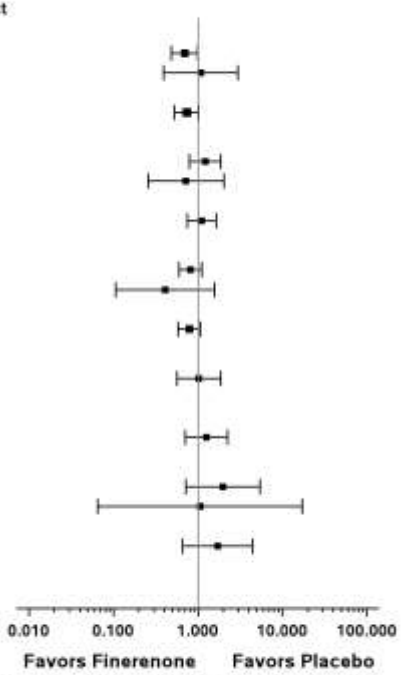
Figure 1.2.2 / 20: Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	52/1078	74/1064	89.1%	0.70 (0.49;0.99)	
FIGARO-DKD	8/640	7/639	10.9%	1.08 (0.39;2.98)	
Heterogeneity		p=0.4300			
Total	60/1718	81/1703		0.74 (0.53;1.03)	0.0703
North America					
FIDELIO-DKD	48/425	39/437	85.7%	1.22 (0.80;1.86)	
FIGARO-DKD	7/267	9/271	14.3%	0.72 (0.26;2.02)	
Heterogeneity		p=0.3951			
Total	55/692	48/708		1.11 (0.75;1.64)	0.6006
Asia					
FIDELIO-DKD	74/751	87/748	95.0%	0.81 (0.60;1.11)	
FIGARO-DKD	3/288	7/292	5.0%	0.41 (0.11;1.59)	
Heterogeneity		p=0.3284			
Total	77/1039	94/1040		0.79 (0.58;1.07)	0.1221
Latin America					
FIDELIO-DKD	22/274	21/274	100%	1.02 (0.56;1.86)	
FIGARO-DKD	5/102	0/101		N.C.	
Heterogeneity		p=0.9840			
Total	27/376	21/375		1.26 (0.71;2.23)	0.4244
Others					
FIDELIO-DKD	10/94	6/97	88.3%	1.97 (0.72;5.44)	
FIGARO-DKD	1/62	1/59	11.7%	1.06 (0.07;17.3)	
Heterogeneity		p=0.7165			
Total	11/156	7/156		1.72 (0.66;4.48)	0.2581
Subgroup Heterogeneity		p=0.1732			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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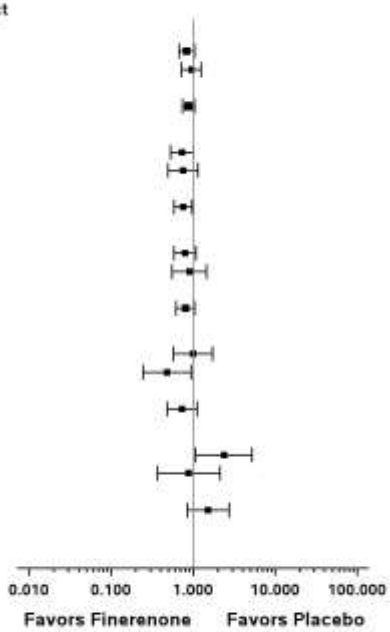
Figure 1.2.2 / 21: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	150/1078	175/1064	60.9%	0.83 (0.67;1.03)	
FIGARO-DKD	101/640	107/639	39.1%	0.95 (0.72;1.24)	
Heterogeneity		p=0.4468			
Total	251/1718	282/1703		0.87 (0.73;1.03)	0.1090
North America					
FIDELIO-DKD	66/425	90/437	63.6%	0.73 (0.53;1.00)	
FIGARO-DKD	38/267	51/271	36.4%	0.75 (0.49;1.15)	
Heterogeneity		p=0.9850			
Total	104/692	141/708		0.75 (0.58;0.96)	0.0238
Asia					
FIDELIO-DKD	73/751	88/748	70.5%	0.79 (0.58;1.08)	
FIGARO-DKD	33/288	34/292	29.5%	0.90 (0.55;1.45)	
Heterogeneity		p=0.5819			
Total	106/1039	122/1040		0.80 (0.62;1.04)	0.0960
Latin America					
FIDELIO-DKD	25/274	25/274	59.2%	0.99 (0.57;1.73)	
FIGARO-DKD	13/102	26/101	40.8%	0.48 (0.24;0.93)	
Heterogeneity		p=0.1059			
Total	38/376	51/375		0.73 (0.48;1.11)	0.1387
Others					
FIDELIO-DKD	19/94	9/97	55.0%	2.37 (1.07;5.24)	
FIGARO-DKD	10/62	10/59	45.0%	0.88 (0.36;2.11)	
Heterogeneity		p=0.1029			
Total	29/156	19/156		1.52 (0.85;2.73)	0.1537
Subgroup Heterogeneity		p=0.2352			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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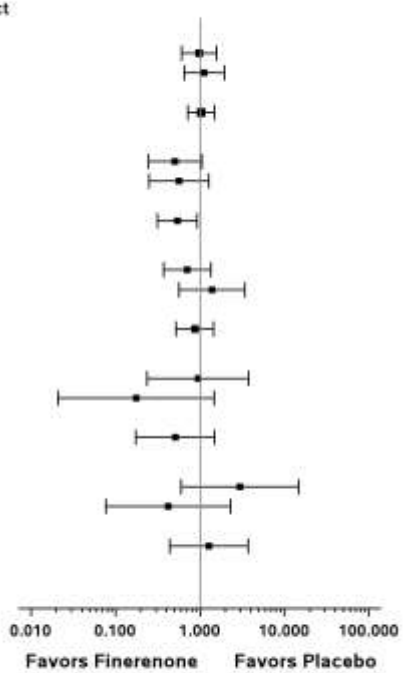
Figure 1.2.2 / 22: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	33/1078	33/1064	56.5%	0.98 (0.60;1.58)	
FIGARO-DKD	27/640	24/639	43.5%	1.12 (0.65;1.94)	
Heterogeneity		p=0.7152			
Total	60/1718	57/1703		1.04 (0.72;1.49)	0.8473
North America					
FIDELIO-DKD	11/425	22/437	56.0%	0.51 (0.25;1.05)	
FIGARO-DKD	9/267	16/271	44.0%	0.57 (0.25;1.29)	
Heterogeneity		p=0.8688			
Total	20/692	38/708		0.54 (0.31;0.93)	0.0233
Asia					
FIDELIO-DKD	16/751	22/748	66.0%	0.71 (0.37;1.35)	
FIGARO-DKD	12/288	8/292	34.0%	1.39 (0.57;3.40)	
Heterogeneity		p=0.2098			
Total	28/1039	30/1040		0.87 (0.52;1.46)	0.6040
Latin America					
FIDELIO-DKD	4/274	4/274	70.2%	0.95 (0.24;3.79)	
FIGARO-DKD	1/102	6/101	29.8%	0.18 (0.02;1.47)	
Heterogeneity		p=0.1834			
Total	5/376	10/375		0.51 (0.17;1.50)	0.2136
Others					
FIDELIO-DKD	6/94	2/97	53.0%	2.98 (0.60;14.8)	
FIGARO-DKD	2/62	4/59	47.0%	0.42 (0.08;2.31)	
Heterogeneity		p=0.0828			
Total	8/156	6/156		1.28 (0.44;3.75)	0.6453
Subgroup Heterogeneity		p=0.2587			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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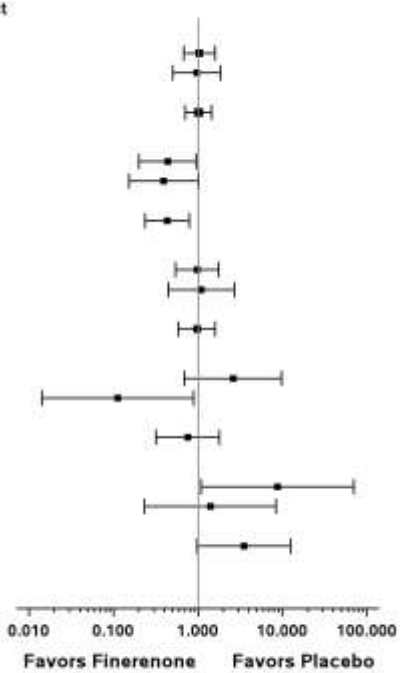
Figure 1.2.2 / 23: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	43/1078	40/1064	69.3%	1.04 (0.68;1.60)	
FIGARO-DKD	18/640	19/639	30.7%	0.97 (0.51;1.85)	
Heterogeneity		p=0.8546			
Total	61/1718	59/1703		1.02 (0.71;1.46)	0.9247
North America					
FIDELIO-DKD	9/425	21/437	59.5%	0.44 (0.20;0.96)	
FIGARO-DKD	6/267	15/271	40.5%	0.39 (0.15;1.02)	
Heterogeneity		p=0.8119			
Total	15/692	36/708		0.43 (0.24;0.79)	0.0050
Asia					
FIDELIO-DKD	22/751	22/748	70.0%	0.97 (0.54;1.76)	
FIGARO-DKD	10/288	9/292	30.0%	1.09 (0.44;2.69)	
Heterogeneity		p=0.7683			
Total	32/1039	31/1040		0.98 (0.59;1.60)	0.9204
Latin America					
FIDELIO-DKD	8/274	3/274	70.8%	2.62 (0.69;9.86)	
FIGARO-DKD	1/102	9/101	29.2%	0.11 (0.01;0.89)	
Heterogeneity		p=0.0116			
Total	9/376	12/375		0.76 (0.32;1.80)	0.5267
Others					
FIDELIO-DKD	8/94	1/97	42.6%	8.78 (1.10;70.3)	
FIGARO-DKD	3/62	2/59	57.4%	1.41 (0.23;8.46)	
Heterogeneity		p=0.2255			
Total	11/156	3/156		3.50 (0.97;12.6)	0.0406
Subgroup Heterogeneity		p=0.0297			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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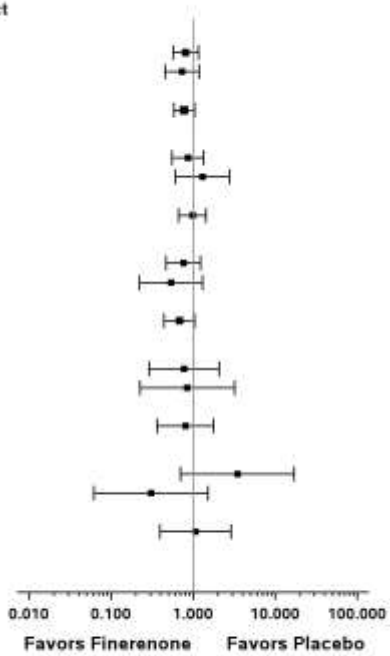
Figure 1.2.2 / 24: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	55/1078	67/1064	64.3%	0.81 (0.57;1.15)	
FIGARO-DKD	29/640	40/639	35.7%	0.73 (0.45;1.17)	
Heterogeneity		p=0.7177			
Total	84/1718	107/1703		0.78 (0.58;1.03)	0.0808
North America					
FIDELIO-DKD	35/425	42/437	74.1%	0.86 (0.55;1.34)	
FIGARO-DKD	15/267	12/271	25.9%	1.30 (0.61;2.78)	
Heterogeneity		p=0.3854			
Total	50/692	54/708		0.97 (0.66;1.43)	0.8948
Asia					
FIDELIO-DKD	29/751	37/748	76.7%	0.76 (0.47;1.23)	
FIGARO-DKD	8/288	13/292	23.3%	0.53 (0.22;1.29)	
Heterogeneity		p=0.5424			
Total	37/1039	50/1040		0.68 (0.44;1.04)	0.0706
Latin America					
FIDELIO-DKD	7/274	9/274	64.2%	0.77 (0.29;2.07)	
FIGARO-DKD	4/102	5/101	35.8%	0.84 (0.22;3.17)	
Heterogeneity		p=0.9187			
Total	11/376	14/375		0.80 (0.36;1.76)	0.5771
Others					
FIDELIO-DKD	6/94	2/97	50.0%	3.45 (0.69;17.1)	
FIGARO-DKD	2/62	6/59	50.0%	0.30 (0.06;1.51)	
Heterogeneity		p=0.0279			
Total	8/156	8/156		1.06 (0.39;2.88)	0.9017
Subgroup Heterogeneity		p=0.7458			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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Figure 1.2.2 / 25: Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Region and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Europe					
FIDELIO-DKD	491/1078	493/1064	60.7%	0.97 (0.86;1.10)	
FIGARO-DKD	315/640	323/639	39.3%	0.95 (0.81;1.11)	
Heterogeneity		p=0.8127			
Total	806/1718	816/1703		0.96 (0.87;1.06)	0.4232
North America					
FIDELIO-DKD	194/425	228/437	63.0%	0.86 (0.71;1.05)	
FIGARO-DKD	131/267	116/271	37.0%	1.26 (0.98;1.62)	
Heterogeneity		p=0.0206			
Total	325/692	344/708		0.99 (0.85;1.16)	0.9449
Asia					
FIDELIO-DKD	358/751	377/748	70.5%	0.92 (0.80;1.06)	
FIGARO-DKD	144/288	166/292	29.5%	0.83 (0.67;1.04)	
Heterogeneity		p=0.5838			
Total	502/1039	543/1040		0.88 (0.78;0.99)	0.0384
Latin America					
FIDELIO-DKD	83/274	85/274	67.1%	0.98 (0.73;1.33)	
FIGARO-DKD	42/102	41/101	32.9%	1.04 (0.67;1.60)	
Heterogeneity		p=0.8052			
Total	125/376	126/375		1.00 (0.78;1.28)	0.9853
Others					
FIDELIO-DKD	50/94	44/97	54.6%	1.31 (0.87;1.98)	
FIGARO-DKD	38/62	41/59	45.4%	0.81 (0.52;1.27)	
Heterogeneity		p=0.1122			
Total	88/156	85/156		1.06 (0.78;1.44)	0.6956
Subgroup Heterogeneity		p=0.6215			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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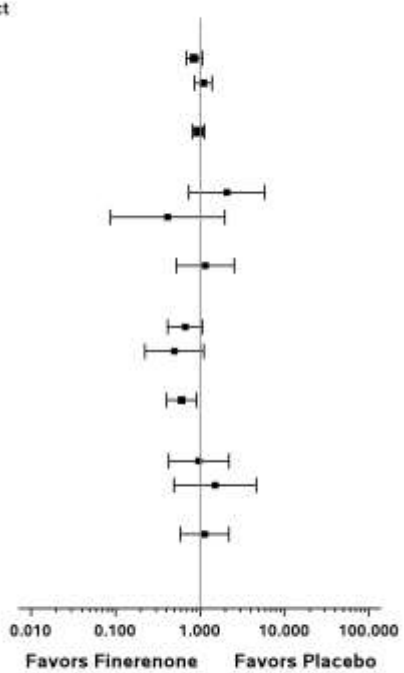
Figure 1.2.2 / 26: Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	145/1637	170/1663	53.7%	0.86 (0.69;1.07)	
FIGARO-DKD	143/1013	128/992	46.3%	1.10 (0.87;1.40)	
Heterogeneity		p=0.1244			
Total	288/2650	298/2655		0.96 (0.82;1.13)	0.6430
Black					
FIDELIO-DKD	16/130	5/115	69.4%	2.08 (0.74;5.87)	
FIGARO-DKD	2/43	8/71	30.6%	0.42 (0.09;1.99)	
Heterogeneity		p=0.0926			
Total	18/173	13/186		1.16 (0.53;2.53)	0.7092
Asian					
FIDELIO-DKD	29/678	43/679	74.5%	0.67 (0.42;1.07)	
FIGARO-DKD	11/251	18/253	25.5%	0.50 (0.22;1.12)	
Heterogeneity		p=0.5939			
Total	40/929	61/932		0.61 (0.40;0.91)	0.0152
Other					
FIDELIO-DKD	12/177	12/163	65.4%	0.97 (0.43;2.20)	
FIGARO-DKD	11/52	5/46	34.6%	1.52 (0.49;4.68)	
Heterogeneity		p=0.5364			
Total	23/229	17/209		1.14 (0.59;2.21)	0.6943
Subgroup Heterogeneity		p=0.1073			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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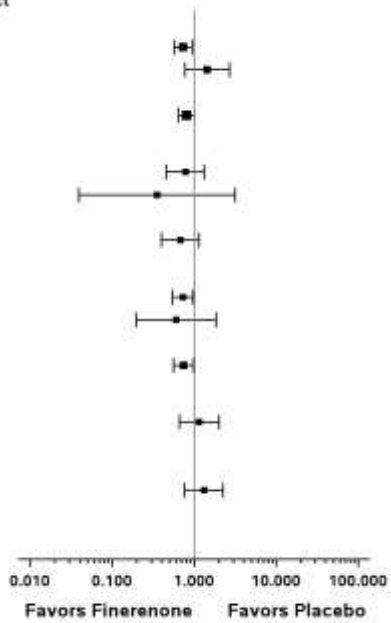
Figure 1.2.2 / 27: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	106/1637	147/1663	86.3%	0.73 (0.57;0.94)	
FIGARO-DKD	24/1013	17/992	13.7%	1.44 (0.77;2.69)	
Heterogeneity		p=0.0439			
Total	130/2650	164/2655		0.80 (0.64;1.01)	0.0642
Black					
FIDELIO-DKD	30/130	28/115	94.4%	0.78 (0.46;1.32)	
FIGARO-DKD	1/43	6/71	5.6%	0.35 (0.04;3.12)	
Heterogeneity		p=0.5521			
Total	31/173	34/186		0.68 (0.40;1.15)	0.1471
Asian					
FIDELIO-DKD	81/678	110/679	93.8%	0.73 (0.54;0.97)	
FIGARO-DKD	5/251	8/253	6.2%	0.60 (0.19;1.83)	
Heterogeneity		p=0.6898			
Total	86/929	118/932		0.74 (0.56;0.98)	0.0333
Other					
FIDELIO-DKD	28/177	25/163	100%	1.15 (0.66;2.00)	
FIGARO-DKD	5/52	0/46		N.C.	
Heterogeneity		p=0.9878			
Total	33/229	25/209		1.31 (0.76;2.25)	0.3276
Subgroup Heterogeneity		p=0.2638			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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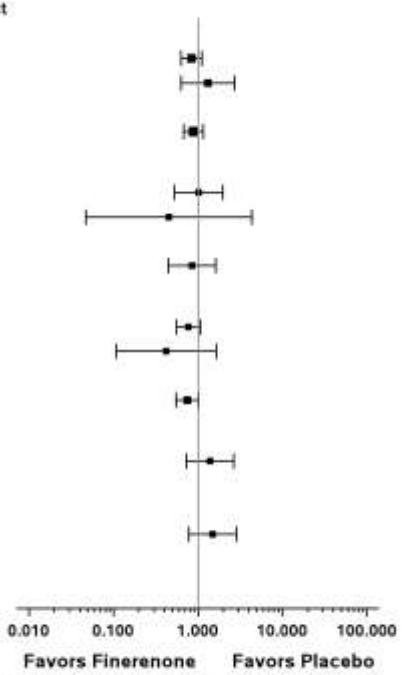
Figure 1.2.2 / 28: Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	91/1637	109/1663	87.3%	0.84 (0.64;1.11)	
FIGARO-DKD	18/1013	13/992	12.7%	1.31 (0.63;2.73)	
Heterogeneity		p=0.2389			
Total	109/2650	122/2655		0.89 (0.68;1.15)	0.3671
Black					
FIDELIO-DKD	25/130	16/115	92.2%	1.03 (0.53;1.98)	
FIGARO-DKD	1/43	4/71	7.8%	0.45 (0.05;4.37)	
Heterogeneity		p=0.5902			
Total	26/173	20/186		0.85 (0.45;1.63)	0.6309
Asian					
FIDELIO-DKD	68/678	85/679	94.8%	0.77 (0.56;1.06)	
FIGARO-DKD	3/251	7/253	5.2%	0.42 (0.11;1.65)	
Heterogeneity		p=0.3969			
Total	71/929	92/932		0.75 (0.55;1.02)	0.0664
Other					
FIDELIO-DKD	22/177	17/163	100%	1.39 (0.72;2.67)	
FIGARO-DKD	2/52	0/46		N.C.	
Heterogeneity		p=0.9899			
Total	24/229	17/209		1.49 (0.78;2.85)	0.2221
Subgroup Heterogeneity		p=0.2964			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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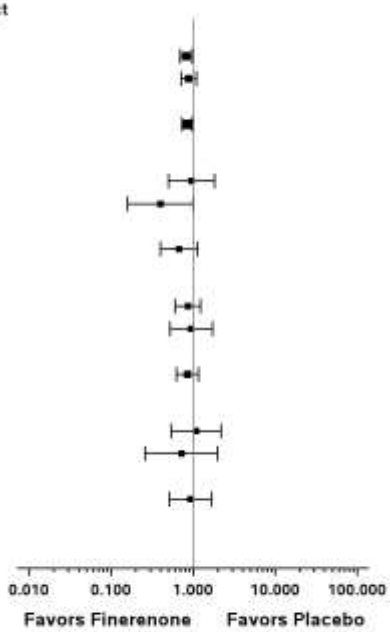
Figure 1.2.2 / 29: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	238/1637	287/1663	61.2%	0.81 (0.68;0.97)	
FIGARO-DKD	158/1013	174/992	38.8%	0.88 (0.71;1.09)	
Heterogeneity		p=0.5696			
Total	396/2650	461/2655		0.84 (0.73;0.96)	0.0109
Black					
FIDELIO-DKD	22/130	19/115	67.2%	0.95 (0.50;1.82)	
FIGARO-DKD	6/43	21/71	32.8%	0.40 (0.16;1.00)	
Heterogeneity		p=0.1317			
Total	28/173	40/186		0.67 (0.40;1.12)	0.1244
Asian					
FIDELIO-DKD	56/678	65/679	73.5%	0.86 (0.60;1.23)	
FIGARO-DKD	22/251	23/253	26.5%	0.94 (0.52;1.71)	
Heterogeneity		p=0.6979			
Total	78/929	88/932		0.85 (0.62;1.16)	0.2985
Other					
FIDELIO-DKD	17/177	16/163	67.9%	1.08 (0.54;2.18)	
FIGARO-DKD	9/52	10/46	32.1%	0.72 (0.26;1.98)	
Heterogeneity		p=0.5391			
Total	26/229	26/209		0.93 (0.52;1.67)	0.8071
Subgroup Heterogeneity		p=0.8249			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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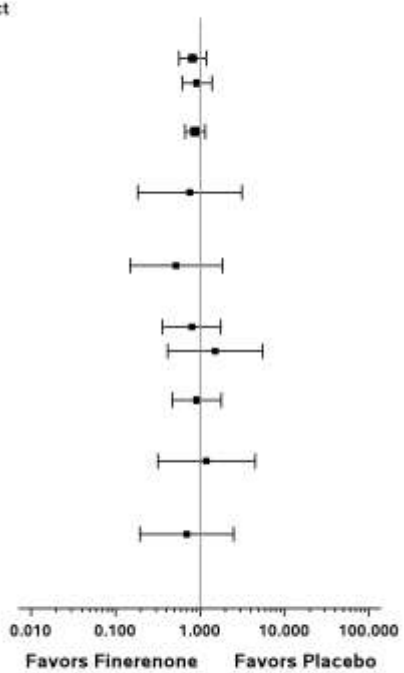
Figure 1.2.2 / 30: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	50/1637	60/1663	54.1%	0.82 (0.56;1.19)	
FIGARO-DKD	45/1013	48/992	45.9%	0.93 (0.62;1.40)	
Heterogeneity		p=0.7014			
Total	95/2650	108/2655		0.88 (0.67;1.16)	0.3568
Black					
FIDELIO-DKD	4/130	4/115	100%	0.76 (0.18;3.13)	
FIGARO-DKD	0/43	3/71		N.C.	
Heterogeneity		p=0.9942			
Total	4/173	7/186		0.52 (0.15;1.84)	0.3043
Asian					
FIDELIO-DKD	11/678	15/679	72.7%	0.80 (0.36;1.76)	
FIGARO-DKD	6/251	4/253	27.3%	1.51 (0.42;5.50)	
Heterogeneity		p=0.3737			
Total	17/929	19/932		0.92 (0.47;1.80)	0.8091
Other					
FIDELIO-DKD	5/177	4/163	100%	1.20 (0.32;4.52)	
FIGARO-DKD	0/52	3/46		N.C.	
Heterogeneity		p=0.9947			
Total	5/229	7/209		0.70 (0.19;2.51)	0.5791
Subgroup Heterogeneity		p=0.8657			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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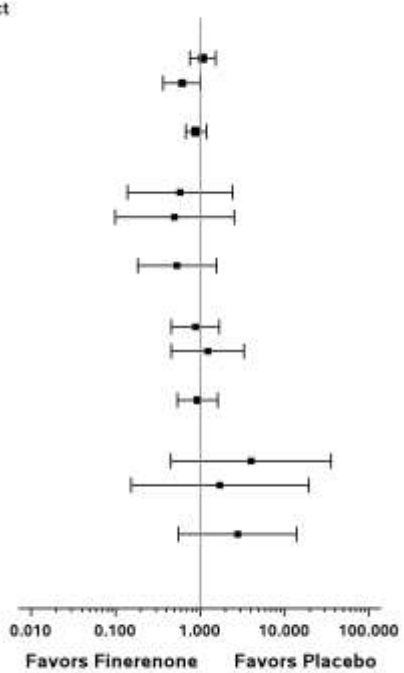
Figure 1.2.2 / 31: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	66/1637	61/1663	68.3%	1.08 (0.76;1.53)	
FIGARO-DKD	24/1013	38/992	31.7%	0.61 (0.37;1.03)	
Heterogeneity		p=0.0708			
Total	90/2650	99/2655		0.90 (0.68;1.20)	0.4718
Black					
FIDELIO-DKD	3/130	6/115	56.3%	0.58 (0.14;2.44)	
FIGARO-DKD	2/43	7/71	43.7%	0.50 (0.10;2.53)	
Heterogeneity		p=0.9206			
Total	5/173	13/186		0.54 (0.18;1.57)	0.2482
Asian					
FIDELIO-DKD	17/678	19/679	69.4%	0.88 (0.46;1.70)	
FIGARO-DKD	9/251	8/253	30.6%	1.24 (0.46;3.33)	
Heterogeneity		p=0.5245			
Total	26/929	27/932		0.94 (0.55;1.62)	0.8295
Other					
FIDELIO-DKD	4/177	1/163	55.0%	4.02 (0.45;36.0)	
FIGARO-DKD	3/52	1/46	45.0%	1.73 (0.15;19.6)	
Heterogeneity		p=0.6311			
Total	7/229	2/209		2.79 (0.56;14.0)	0.1951
Subgroup Heterogeneity		p=0.2015			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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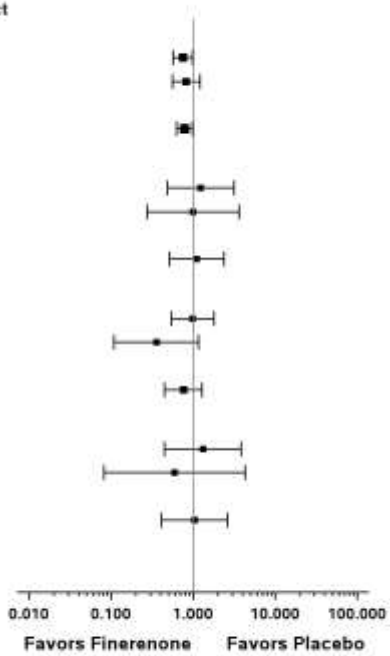
Figure 1.2.2 / 32: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	91/1637	121/1663	66.8%	0.75 (0.57;0.98)	
FIGARO-DKD	48/1013	56/992	33.2%	0.82 (0.56;1.20)	
Heterogeneity		p=0.7523			
Total	139/2650	177/2655		0.78 (0.62;0.97)	0.0269
Black					
FIDELIO-DKD	11/130	8/115	65.7%	1.23 (0.49;3.14)	
FIGARO-DKD	4/43	6/71	34.3%	0.99 (0.27;3.60)	
Heterogeneity		p=0.7845			
Total	15/173	14/186		1.10 (0.52;2.36)	0.8007
Asian					
FIDELIO-DKD	22/678	22/679	80.2%	0.99 (0.55;1.78)	
FIGARO-DKD	4/251	10/253	19.8%	0.35 (0.11;1.17)	
Heterogeneity		p=0.1438			
Total	26/929	32/932		0.76 (0.45;1.28)	0.2964
Other					
FIDELIO-DKD	8/177	6/163	77.3%	1.31 (0.45;3.83)	
FIGARO-DKD	2/52	4/46	22.7%	0.59 (0.08;4.27)	
Heterogeneity		p=0.5217			
Total	10/229	10/209		1.04 (0.41;2.63)	0.9349
Subgroup Heterogeneity		p=0.8709			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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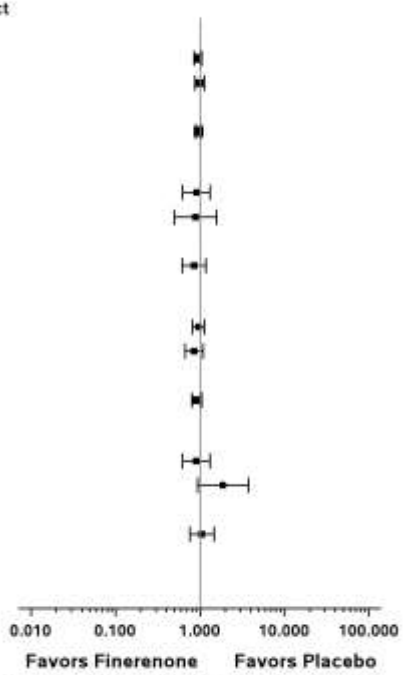
Figure 1.2.2 / 33: Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Race (4 categories) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
White					
FIDELIO-DKD	735/1637	778/1663	60.5%	0.94 (0.85;1.04)	
FIGARO-DKD	496/1013	499/992	39.5%	0.99 (0.88;1.13)	
Heterogeneity		p=0.5765			
Total	1231/2650	1277/2655		0.96 (0.89;1.04)	0.3565
Black					
FIDELIO-DKD	61/130	60/115	70.8%	0.91 (0.63;1.31)	
FIGARO-DKD	20/43	35/71	29.2%	0.89 (0.50;1.58)	
Heterogeneity		p=0.8959			
Total	81/173	95/186		0.85 (0.62;1.17)	0.3244
Asian					
FIDELIO-DKD	321/678	328/679	71.9%	0.96 (0.82;1.12)	
FIGARO-DKD	122/251	135/253	28.1%	0.85 (0.67;1.10)	
Heterogeneity		p=0.4964			
Total	443/929	463/932		0.92 (0.80;1.05)	0.2023
Other					
FIDELIO-DKD	59/177	61/163	77.7%	0.91 (0.62;1.32)	
FIGARO-DKD	32/52	18/46	22.3%	1.87 (0.93;3.76)	
Heterogeneity		p=0.0463			
Total	91/229	79/209		1.06 (0.76;1.48)	0.7435
Subgroup Heterogeneity		p=0.7454			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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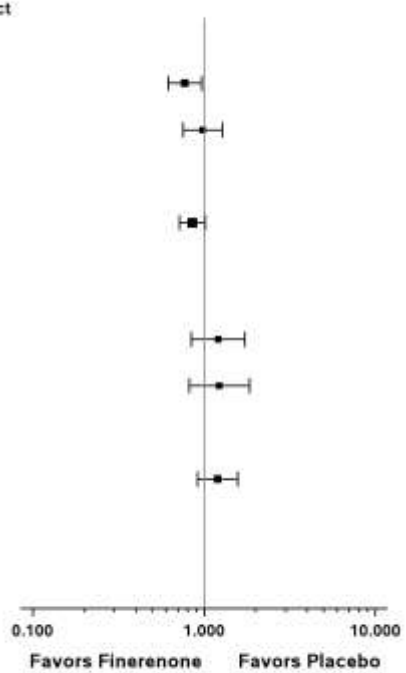
Figure 1.2.2 / 34: Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	133/1800	175/1876	57.4%	0.77 (0.61;0.97)	
FIGARO-DKD	111/917	115/937	42.6%	0.98 (0.76;1.27)	
Heterogeneity		p=0.1596			
Total	244/2717	290/2813		0.85 (0.72;1.01)	0.0650
Female					
FIDELIO-DKD	69/822	55/744	55.8%	1.20 (0.84;1.72)	
FIGARO-DKD	56/442	44/425	44.2%	1.23 (0.82;1.84)	
Heterogeneity		p=0.8681			
Total	125/1264	99/1169		1.20 (0.91;1.57)	0.1900
Subgroup Heterogeneity		p=0.0304			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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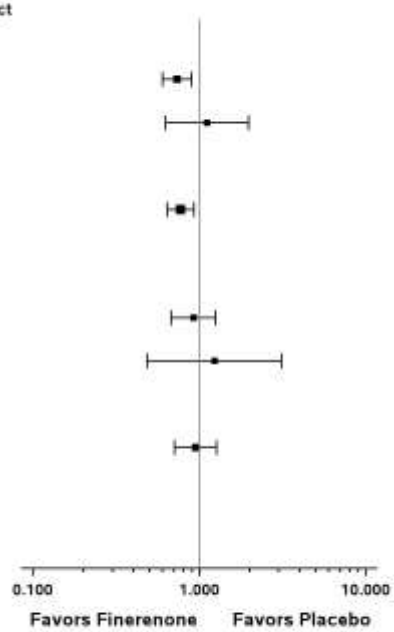
Figure 1.2.2 / 35: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	166/1800	225/1876	89.1%	0.73 (0.60;0.89)	
FIGARO-DKD	24/917	23/937	10.9%	1.11 (0.62;1.97)	
Heterogeneity		p=0.2065			
Total	190/2717	248/2813		0.77 (0.64;0.93)	0.0065
Female					
FIDELIO-DKD	79/822	85/744	90.1%	0.92 (0.67;1.25)	
FIGARO-DKD	11/442	8/425	9.9%	1.23 (0.48;3.13)	
Heterogeneity		p=0.4370			
Total	90/1264	93/1169		0.95 (0.71;1.27)	0.7094
Subgroup Heterogeneity		p=0.2310			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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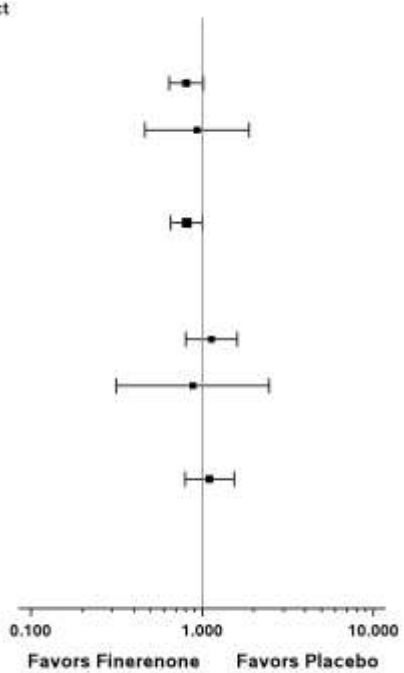
Figure 1.2.2 / 36: Forest plot of onset of kidney failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	137/1800	166/1876	90.5%	0.81 (0.64;1.01)	
FIGARO-DKD	16/917	17/937	9.5%	0.93 (0.46;1.88)	
Heterogeneity		p=0.6978			
Total	153/2717	183/2813		0.81 (0.65;1.01)	0.0607
Female					
FIDELIO-DKD	69/822	61/744	89.8%	1.13 (0.80;1.60)	
FIGARO-DKD	8/442	7/425	10.2%	0.88 (0.31;2.47)	
Heterogeneity		p=0.7630			
Total	77/1264	68/1169		1.10 (0.79;1.54)	0.5570
Subgroup Heterogeneity		p=0.1287			



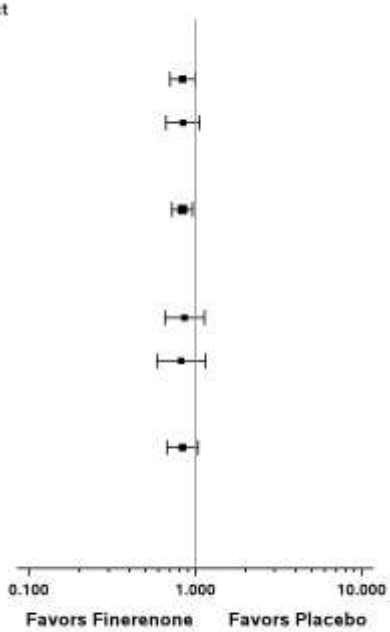
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 37: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	235/1800	280/1876	64.6%	0.84 (0.70;1.00)	
FIGARO-DKD	130/917	154/937	35.4%	0.84 (0.66;1.06)	
Heterogeneity		p=0.9432			
Total	365/2717	434/2813		0.83 (0.72;0.96)	0.0099
Female					
FIDELIO-DKD	98/822	107/744	60.1%	0.86 (0.65;1.14)	
FIGARO-DKD	65/442	74/425	39.9%	0.82 (0.58;1.15)	
Heterogeneity		p=0.8664			
Total	163/1264	181/1169		0.84 (0.68;1.04)	0.1060
Subgroup Heterogeneity		p=0.9989			



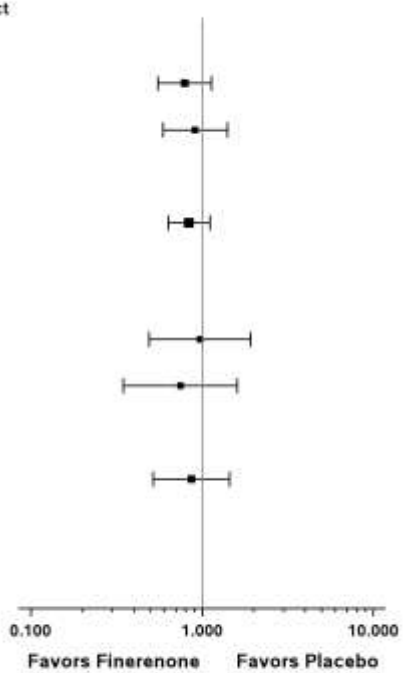
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 38: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	53/1800	67/1876	59.3%	0.79 (0.55;1.13)	
FIGARO-DKD	39/917	43/937	40.7%	0.91 (0.59;1.41)	
Heterogeneity		p=0.6320			
Total	92/2717	110/2813		0.84 (0.63;1.11)	0.2107
Female					
FIDELIO-DKD	17/822	16/744	55.6%	0.97 (0.49;1.92)	
FIGARO-DKD	12/442	15/425	44.4%	0.75 (0.35;1.60)	
Heterogeneity		p=0.6102			
Total	29/1264	31/1169		0.86 (0.52;1.44)	0.5774
Subgroup Heterogeneity		p=0.9705			

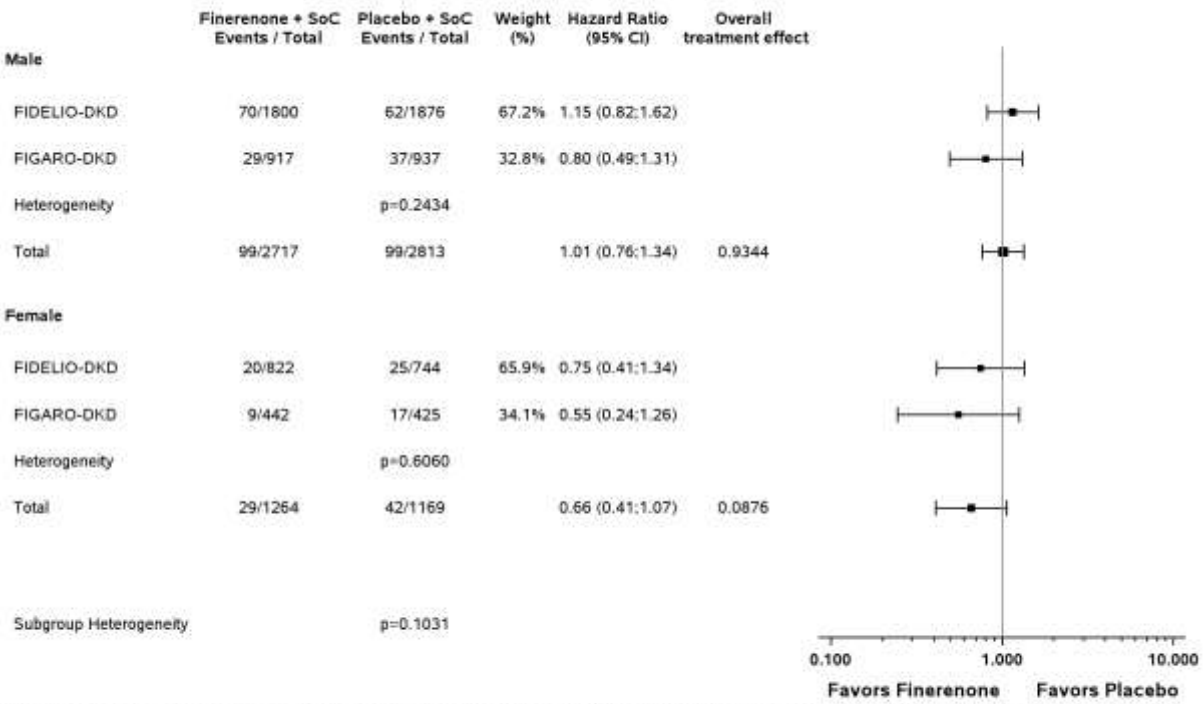


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 39: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

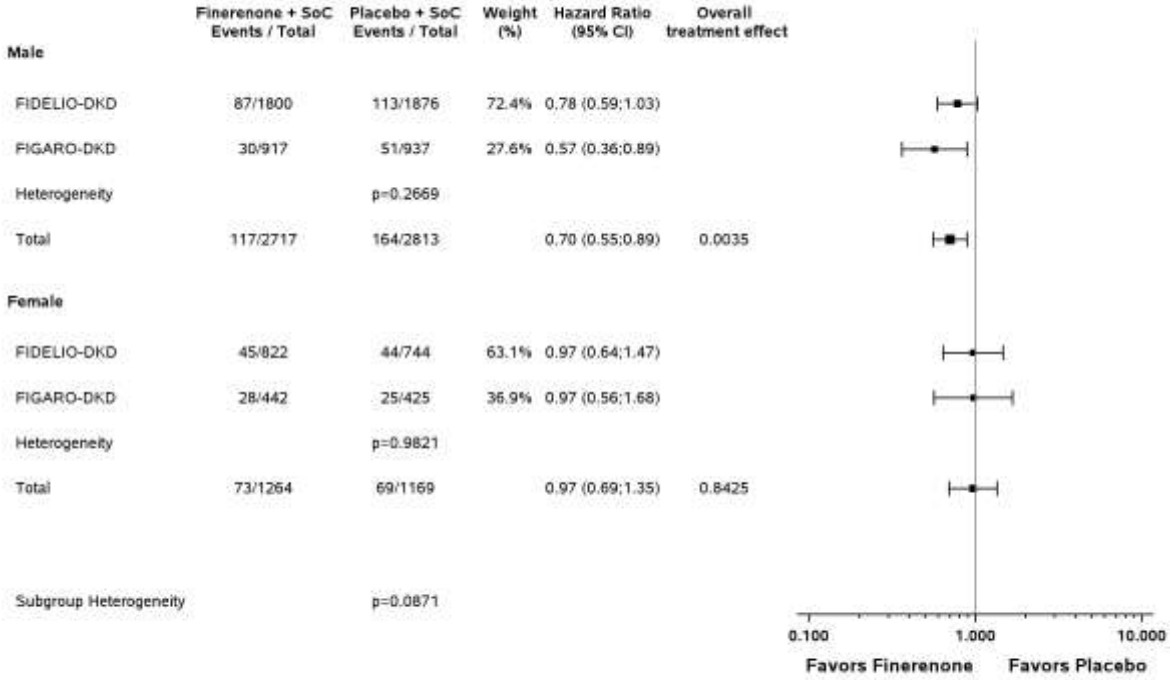


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 40: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



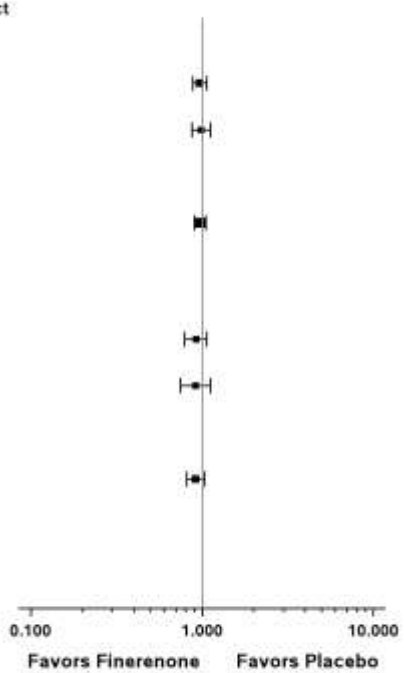
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 41: Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Sex and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
Male					
FIDELIO-DKD	836/1800	887/1876	64.5%	0.97 (0.88;1.07)	
FIGARO-DKD	472/917	485/937	35.5%	0.99 (0.87;1.12)	
Heterogeneity		p=0.7461			
Total	1308/2717	1372/2813		0.97 (0.90;1.05)	0.4424
Female					
FIDELIO-DKD	340/822	340/744	63.3%	0.92 (0.79;1.07)	
FIGARO-DKD	198/442	202/425	36.7%	0.91 (0.75;1.12)	
Heterogeneity		p=0.9865			
Total	538/1264	542/1169		0.91 (0.81;1.03)	0.1530
Subgroup Heterogeneity		p=0.3172			



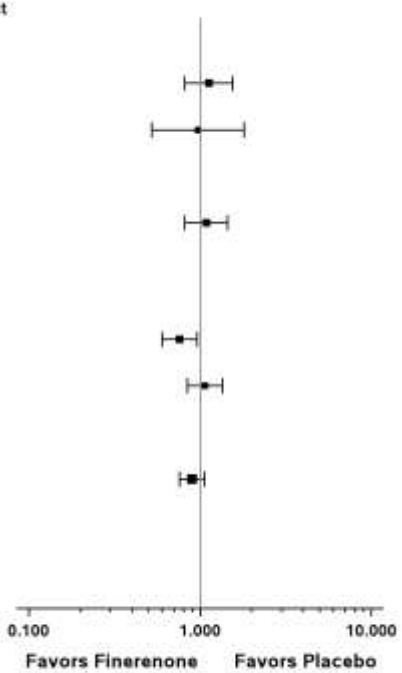
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 42: Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	79/1106	69/1078	78.5%	1.12 (0.81;1.55)	
FIGARO-DKD	20/337	21/336	21.5%	0.97 (0.52;1.81)	
Heterogeneity		p=0.7224			
Total	99/1443	90/1414		1.08 (0.81;1.45)	0.5809
>= 65 years					
FIDELIO-DKD	123/1516	161/1542	49.5%	0.76 (0.60;0.96)	
FIGARO-DKD	147/1022	138/1026	50.5%	1.06 (0.84;1.34)	
Heterogeneity		p=0.0371			
Total	270/2538	299/2568		0.90 (0.76;1.06)	0.1923
Subgroup Heterogeneity		p=0.2408			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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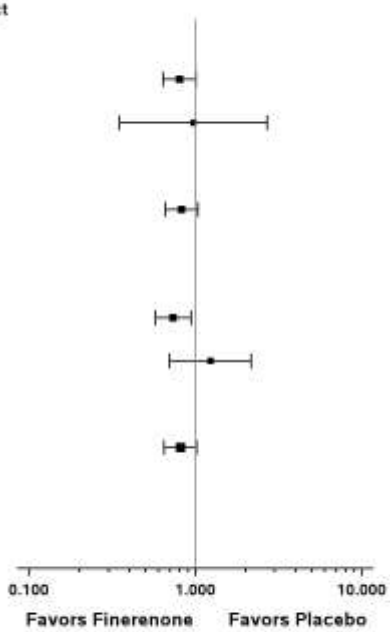
Figure 1.2.2 / 43: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	135/1106	162/1078	95.2%	0.80 (0.64;1.01)	
FIGARO-DKD	7/337	9/336	4.8%	0.97 (0.35;2.70)	
Heterogeneity		p=0.6606			
Total	142/1443	171/1414		0.82 (0.66;1.03)	0.0917
>= 65 years					
FIDELIO-DKD	110/1516	148/1542	83.9%	0.73 (0.57;0.94)	
FIGARO-DKD	28/1022	22/1026	16.1%	1.23 (0.70;2.16)	
Heterogeneity		p=0.1079			
Total	138/2538	170/2568		0.81 (0.65;1.02)	0.0675
Subgroup Heterogeneity		p=0.9717			



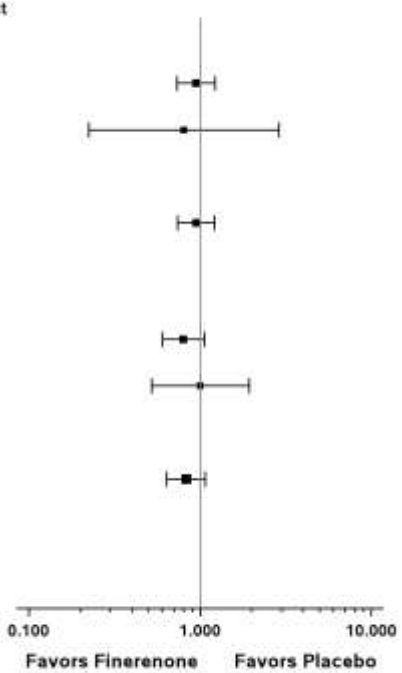
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 44: Forest plot of onset of kidney failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	118/1106	118/1078	96.1%	0.95 (0.73;1.22)	
FIGARO-DKD	4/337	6/336	3.9%	0.80 (0.22;2.88)	
Heterogeneity		p=0.8935			
Total	122/1443	124/1414		0.95 (0.73;1.22)	0.6659
>= 65 years					
FIDELIO-DKD	88/1516	109/1542	84.3%	0.80 (0.60;1.06)	
FIGARO-DKD	20/1022	18/1026	15.7%	1.00 (0.52;1.93)	
Heterogeneity		p=0.5422			
Total	108/2538	127/2568		0.83 (0.64;1.07)	0.1522
Subgroup Heterogeneity		p=0.5203			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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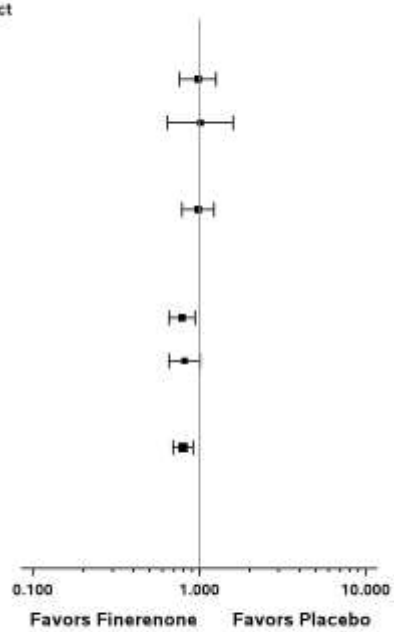
Figure 1.2.2 / 45: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

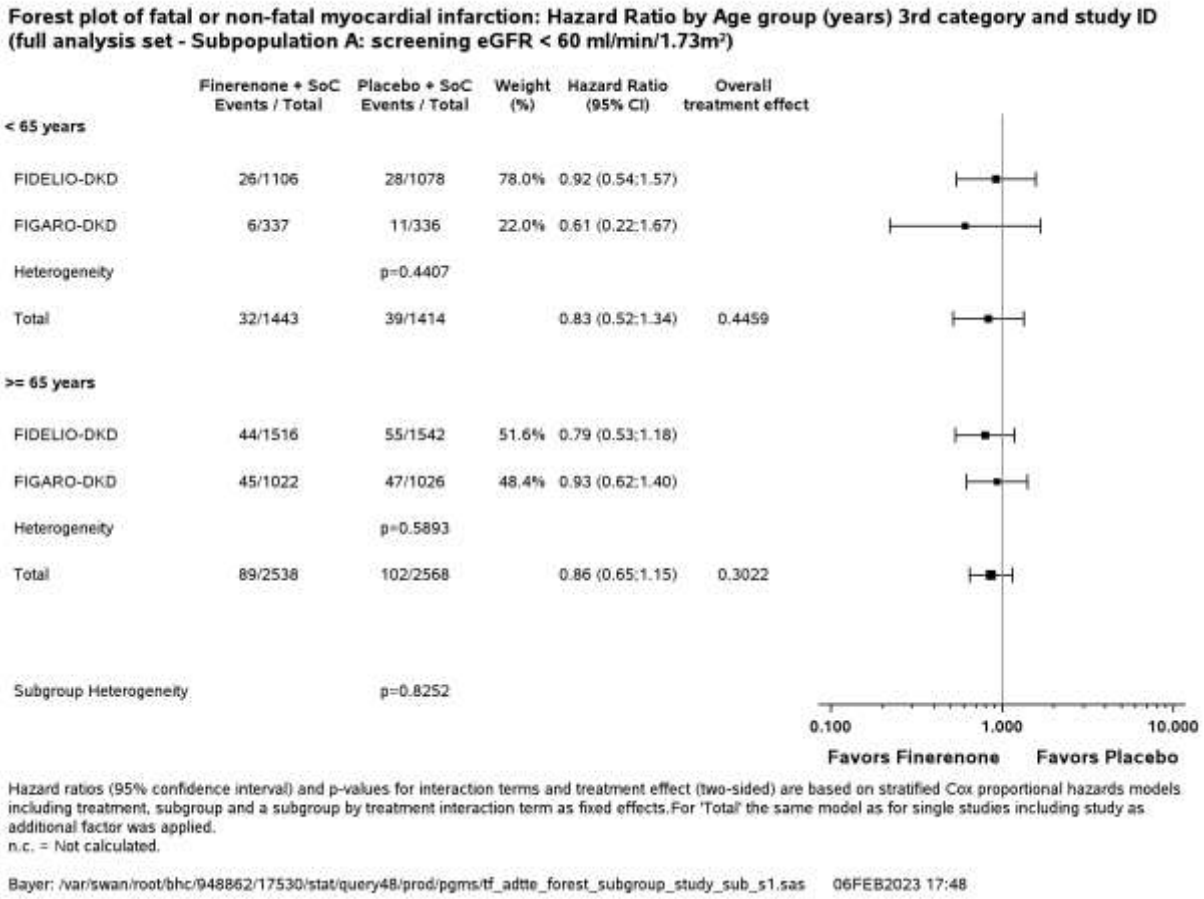
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	122/1106	122/1078	76.4%	0.98 (0.76;1.26)	
FIGARO-DKD	39/337	40/336	23.6%	1.01 (0.64;1.60)	
Heterogeneity		p=0.8655			
Total	161/1443	162/1414		0.98 (0.78;1.22)	0.8334
>= 65 years					
FIDELIO-DKD	211/1516	265/1542	58.0%	0.78 (0.65;0.94)	
FIGARO-DKD	156/1022	188/1026	42.0%	0.81 (0.66;1.00)	
Heterogeneity		p=0.7889			
Total	367/2538	453/2568		0.79 (0.69;0.91)	0.0010
Subgroup Heterogeneity		p=0.1315			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 46: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



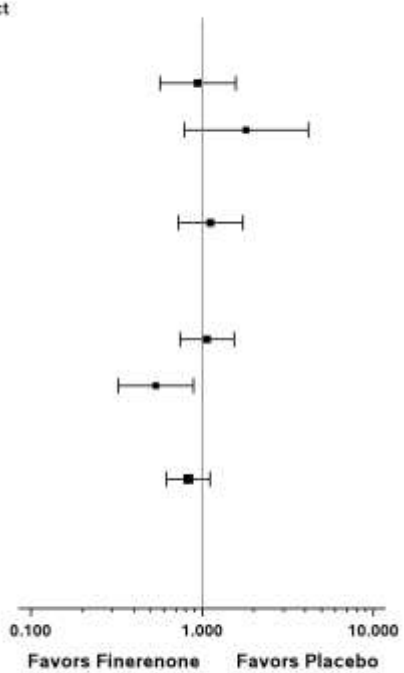
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 47: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

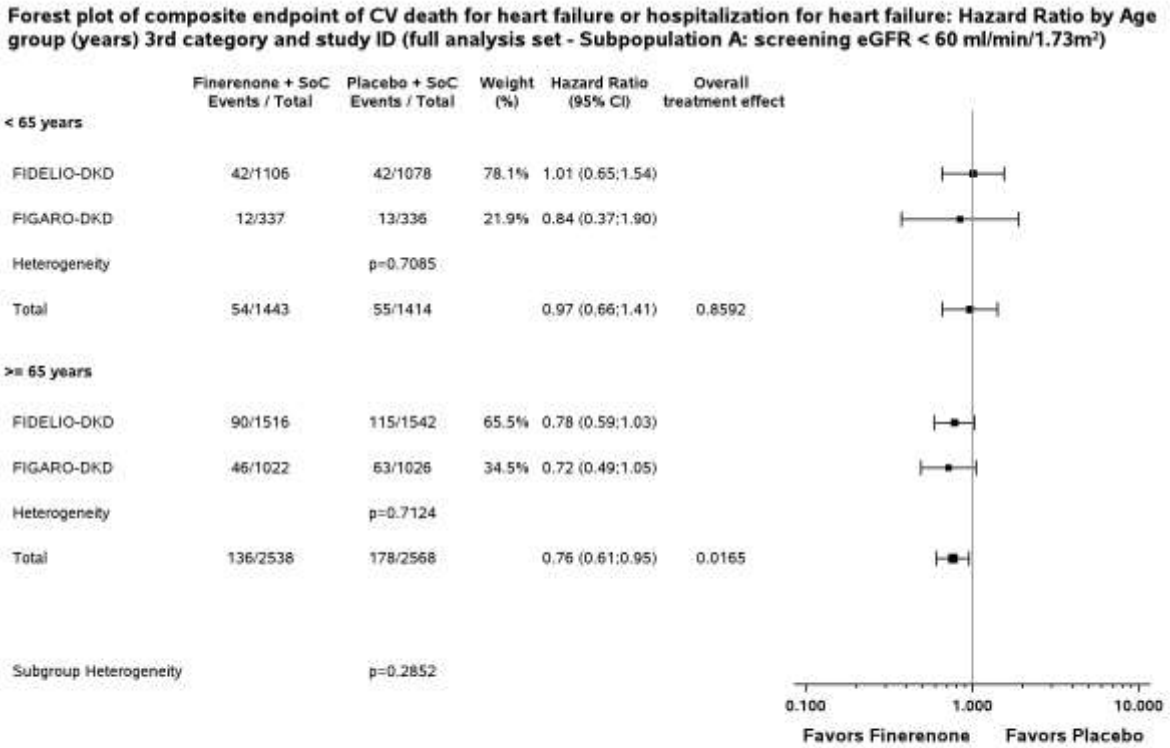
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	30/1106	31/1078	72.9%	0.94 (0.57;1.57)	
FIGARO-DKD	15/337	10/336	27.1%	1.80 (0.78;4.16)	
Heterogeneity		p=0.2222			
Total	45/1443	41/1414		1.12 (0.73;1.73)	0.6112
>= 65 years					
FIDELIO-DKD	60/1516	56/1542	65.9%	1.07 (0.74;1.54)	
FIGARO-DKD	23/1022	44/1026	34.1%	0.54 (0.32;0.89)	
Heterogeneity		p=0.0336			
Total	83/2538	100/2568		0.83 (0.62;1.11)	0.2046
Subgroup Heterogeneity		p=0.3391			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 48: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



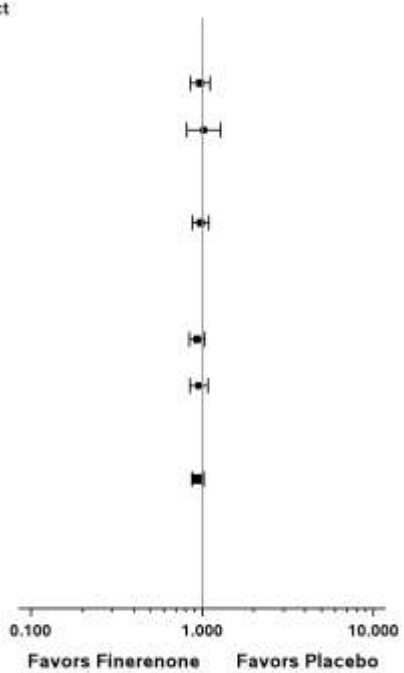
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 49: Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Age group (years) 3rd category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 65 years					
FIDELIO-DKD	472/1106	473/1078	76.0%	0.97 (0.86;1.11)	
FIGARO-DKD	157/337	153/336	24.0%	1.02 (0.81;1.28)	
Heterogeneity		p=0.7237			
Total	629/1443	626/1414		0.98 (0.87;1.10)	0.7136
>= 65 years					
FIDELIO-DKD	704/1516	754/1542	58.2%	0.93 (0.84;1.03)	
FIGARO-DKD	513/1022	534/1026	41.8%	0.95 (0.84;1.08)	
Heterogeneity		p=0.7606			
Total	1217/2538	1288/2568		0.94 (0.87;1.02)	0.1370
Subgroup Heterogeneity		p=0.6808			



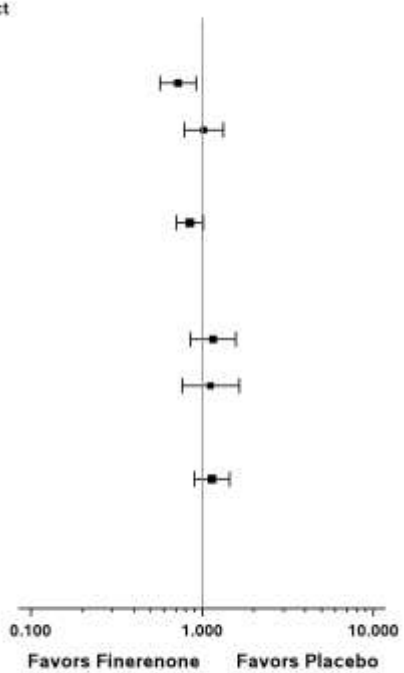
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 50: Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	112/1215	152/1213	53.8%	0.72 (0.57;0.92)	
FIGARO-DKD	113/865	108/851	46.2%	1.02 (0.78;1.33)	
Heterogeneity		p=0.0554			
Total	225/2080	260/2064		0.85 (0.71;1.01)	0.0677
absent					
FIDELIO-DKD	90/1407	78/1407	61.4%	1.16 (0.85;1.57)	
FIGARO-DKD	54/494	51/511	38.6%	1.12 (0.76;1.64)	
Heterogeneity		p=0.9018			
Total	144/1901	129/1918		1.14 (0.90;1.45)	0.2741
Subgroup Heterogeneity		p=0.0491			



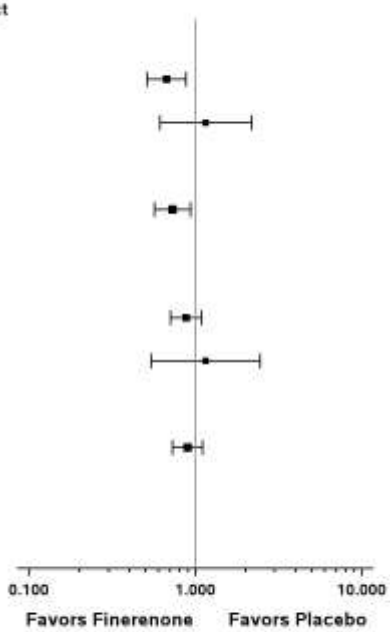
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 51: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	91/1215	129/1213	84.6%	0.67 (0.51;0.88)	
FIGARO-DKD	21/865	18/851	15.4%	1.15 (0.61;2.17)	
Heterogeneity		p=0.1158			
Total	112/2080	147/2064		0.73 (0.57;0.93)	0.0109
absent					
FIDELIO-DKD	154/1407	181/1407	92.5%	0.88 (0.71;1.09)	
FIGARO-DKD	14/494	13/511	7.5%	1.15 (0.54;2.45)	
Heterogeneity		p=0.4795			
Total	168/1901	194/1918		0.89 (0.73;1.10)	0.2908
Subgroup Heterogeneity		p=0.2060			



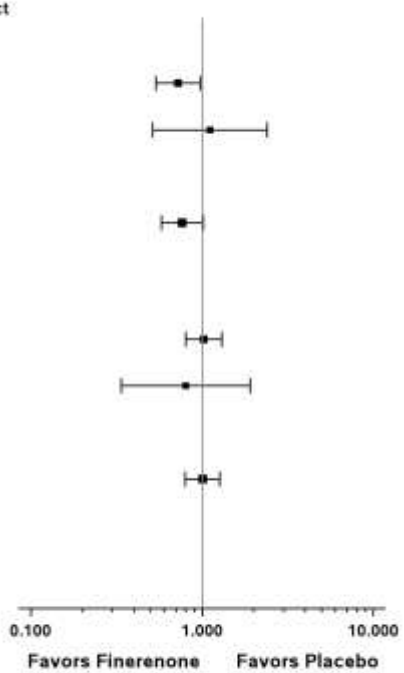
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 52: Forest plot of onset of kidney failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

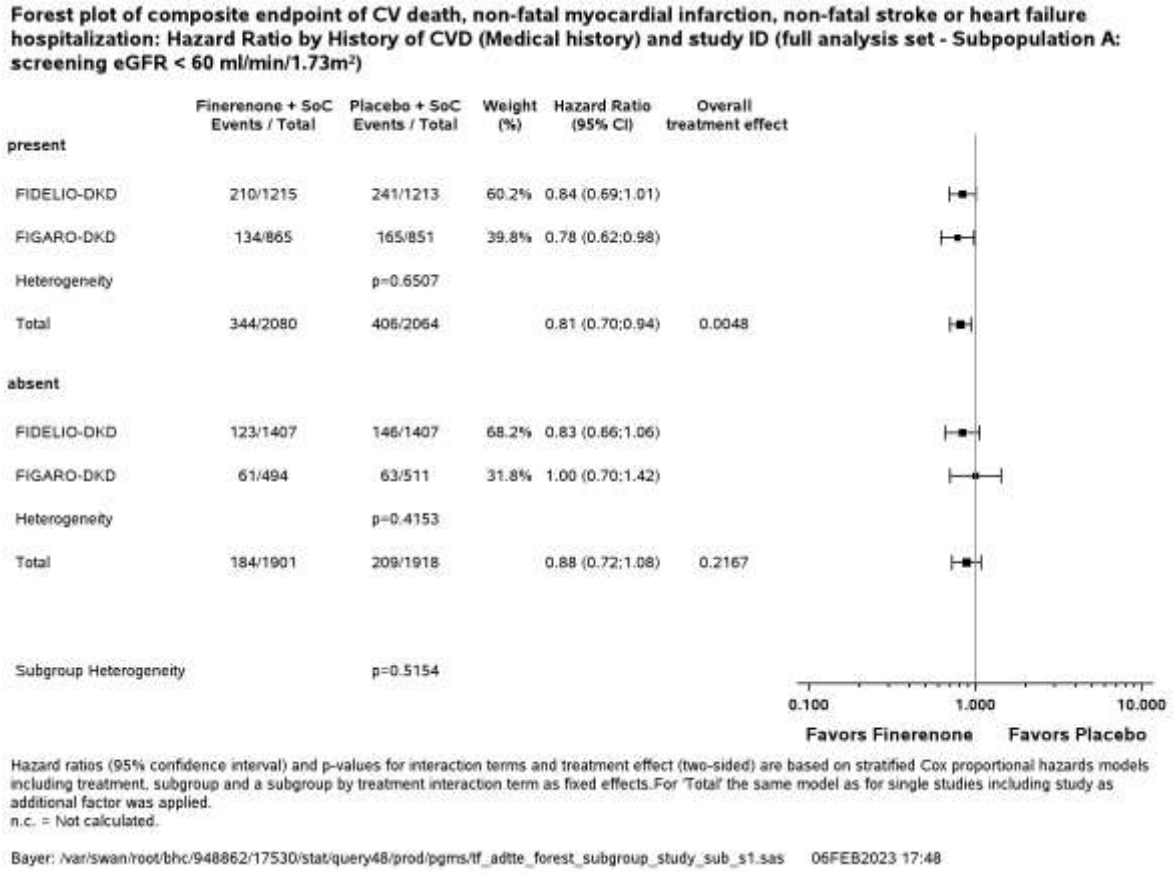
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	76/1215	98/1213	86.9%	0.72 (0.53;0.98)	
FIGARO-DKD	14/865	12/851	13.1%	1.11 (0.51;2.40)	
Heterogeneity		p=0.3066			
Total	90/2080	110/2064		0.76 (0.58;1.01)	0.0584
absent					
FIDELIO-DKD	130/1407	129/1407	92.6%	1.02 (0.80;1.31)	
FIGARO-DKD	10/494	12/511	7.4%	0.80 (0.34;1.90)	
Heterogeneity		p=0.6233			
Total	140/1901	141/1918		1.00 (0.79;1.27)	0.9720
Subgroup Heterogeneity		p=0.1428			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 53: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



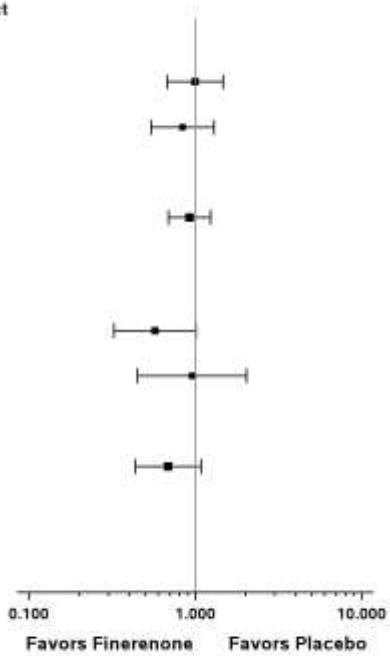
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 54: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	51/1215	51/1213	55.5%	0.99 (0.67;1.47)	
FIGARO-DKD	38/865	44/851	44.5%	0.84 (0.54;1.29)	
Heterogeneity		p=0.5663			
Total	89/2080	95/2064		0.92 (0.69;1.23)	0.5739
absent					
FIDELIO-DKD	19/1407	32/1407	63.8%	0.57 (0.32;1.01)	
FIGARO-DKD	13/494	14/511	36.2%	0.95 (0.45;2.03)	
Heterogeneity		p=0.2981			
Total	32/1901	46/1918		0.68 (0.44;1.08)	0.0982
Subgroup Heterogeneity		p=0.2798			



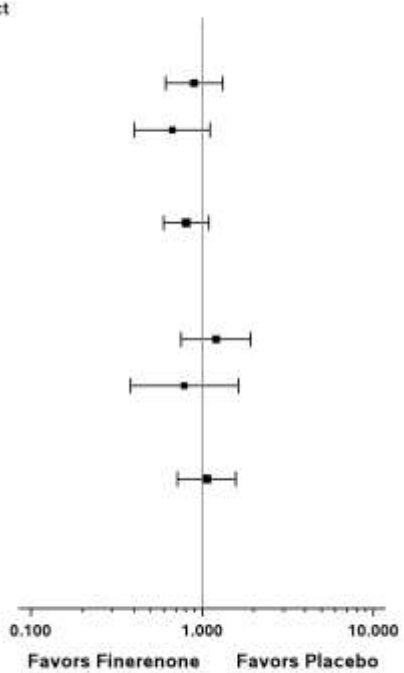
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 55: Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

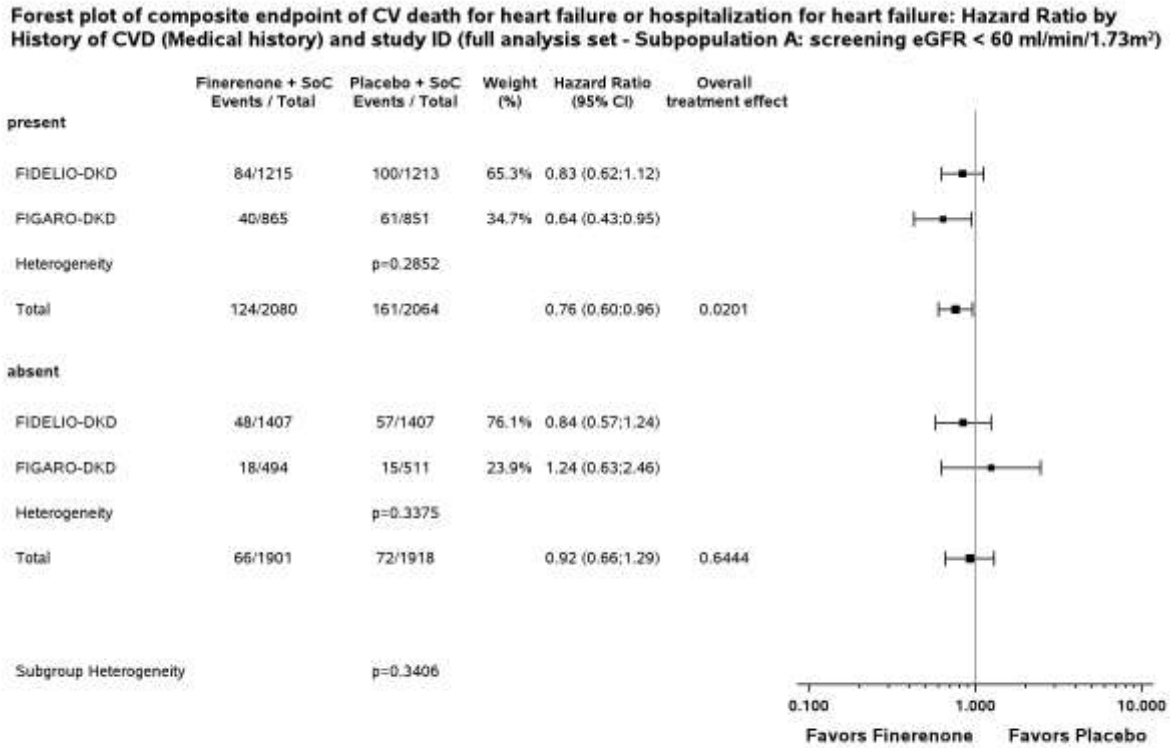
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	51/1215	55/1213	63.9%	0.90 (0.61;1.32)	
FIGARO-DKD	25/865	37/851	36.1%	0.67 (0.40;1.11)	
Heterogeneity		p=0.3633			
Total	76/2080	92/2064		0.81 (0.59;1.09)	0.1629
absent					
FIDELIO-DKD	39/1407	32/1407	70.5%	1.21 (0.75;1.92)	
FIGARO-DKD	13/494	17/511	29.5%	0.79 (0.38;1.62)	
Heterogeneity		p=0.3172			
Total	52/1901	49/1918		1.06 (0.72;1.57)	0.7639
Subgroup Heterogeneity		p=0.2753			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 56: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



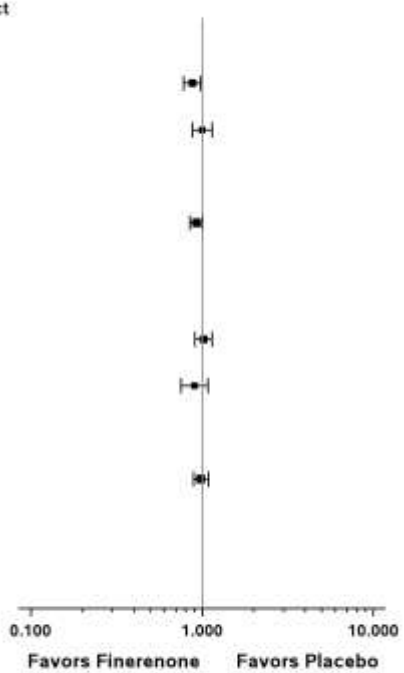
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 57: Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by History of CVD (Medical history) and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
present					
FIDELIO-DKD	601/1215	647/1213	58.5%	0.87 (0.78;0.98)	
FIGARO-DKD	443/865	435/851	41.5%	1.00 (0.88;1.14)	
Heterogeneity		p=0.1318			
Total	1044/2080	1082/2064		0.93 (0.85;1.01)	0.0750
absent					
FIDELIO-DKD	575/1407	580/1407	70.7%	1.02 (0.91;1.14)	
FIGARO-DKD	227/494	252/511	29.3%	0.90 (0.75;1.08)	
Heterogeneity		p=0.2890			
Total	802/1901	832/1918		0.98 (0.89;1.08)	0.7238
Subgroup Heterogeneity		p=0.3627			



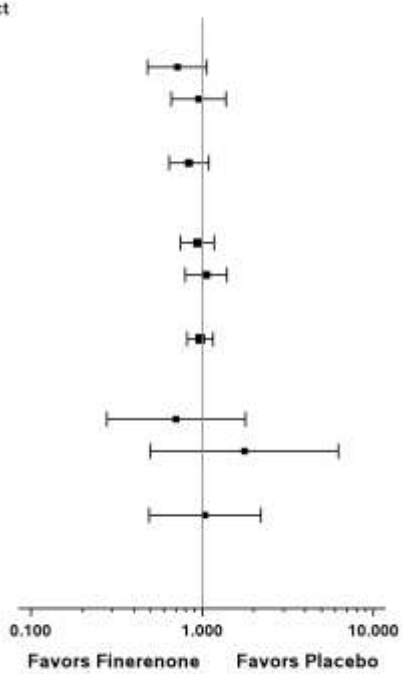
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 58: Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	43/724	59/724	46.1%	0.71 (0.48;1.06)	
FIGARO-DKD	58/494	59/497	53.9%	0.95 (0.66;1.37)	
Heterogeneity		p=0.2482			
Total	101/1218	118/1221		0.84 (0.64;1.10)	0.1958
130 - < 160 mmHg					
FIDELIO-DKD	149/1762	160/1766	61.6%	0.94 (0.75;1.17)	
FIGARO-DKD	99/831	95/830	38.4%	1.05 (0.80;1.40)	
Heterogeneity		p=0.4502			
Total	248/2593	255/2596		0.97 (0.82;1.16)	0.7655
>= 160 mmHg					
FIDELIO-DKD	8/133	11/128	64.7%	0.70 (0.28;1.79)	
FIGARO-DKD	10/34	5/35	35.3%	1.76 (0.50;6.23)	
Heterogeneity		p=0.2964			
Total	18/167	16/163		1.04 (0.49;2.21)	0.9212
Subgroup Heterogeneity		p=0.5831			



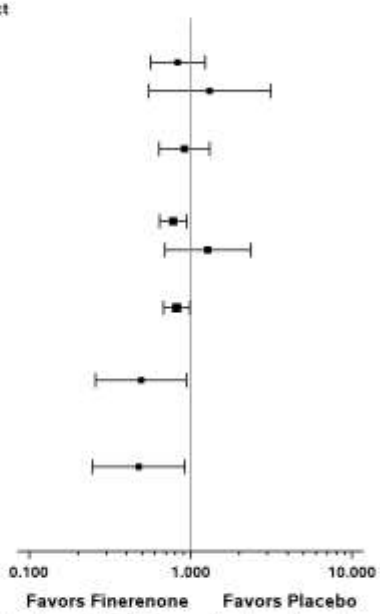
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 59: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	47/724	55/724	83.2%	0.83 (0.56;1.23)	
FIGARO-DKD	12/494	9/497	16.8%	1.31 (0.55;3.14)	
Heterogeneity		p=0.3672			
Total	59/1218	64/1221		0.91 (0.64;1.31)	0.6268
130 - < 160 mmHg					
FIDELIO-DKD	178/1762	228/1766	90.7%	0.78 (0.64;0.95)	
FIGARO-DKD	23/831	19/830	9.3%	1.28 (0.69;2.36)	
Heterogeneity		p=0.1258			
Total	201/2593	247/2596		0.82 (0.68;0.99)	0.0351
>= 160 mmHg					
FIDELIO-DKD	19/133	27/128	100%	0.49 (0.26;0.94)	
FIGARO-DKD	0/34	3/35		N.C.	
Heterogeneity		p=0.9920			
Total	19/167	30/163		0.48 (0.25;0.92)	0.0252
Subgroup Heterogeneity		p=0.1644			



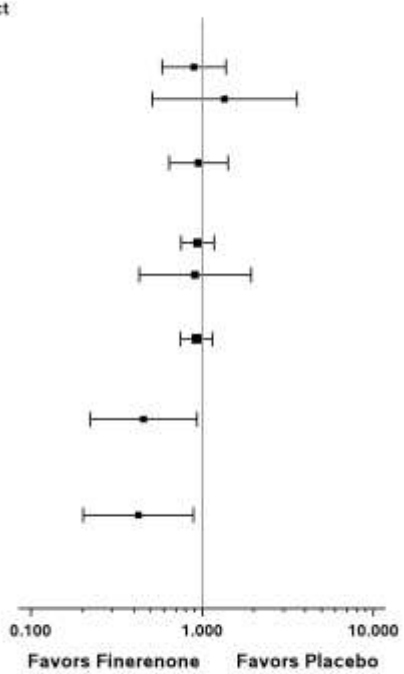
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 60: Forest plot of onset of kidney failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	40/724	43/724	83.6%	0.89 (0.58;1.38)	
FIGARO-DKD	10/494	7/497	16.4%	1.35 (0.51;3.57)	
Heterogeneity		p=0.4431			
Total	50/1218	50/1221		0.95 (0.64;1.41)	0.8106
130 - < 160 mmHg					
FIDELIO-DKD	152/1762	161/1766	91.9%	0.94 (0.75;1.17)	
FIGARO-DKD	14/831	15/830	8.1%	0.91 (0.43;1.93)	
Heterogeneity		p=0.9872			
Total	166/2593	176/2596		0.93 (0.75;1.15)	0.4993
>= 160 mmHg					
FIDELIO-DKD	13/133	23/128	100%	0.45 (0.22;0.93)	
FIGARO-DKD	0/34	2/35		N.C.	
Heterogeneity		p=0.9943			
Total	13/167	25/163		0.42 (0.20;0.89)	0.0205
Subgroup Heterogeneity		p=0.0430			



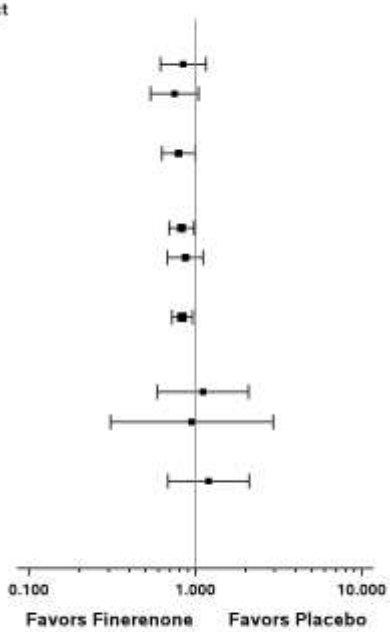
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 61: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	72/724	85/724	52.3%	0.84 (0.61;1.16)	
FIGARO-DKD	64/494	82/497	47.7%	0.75 (0.54;1.04)	
Heterogeneity		p=0.6706			
Total	136/1218	167/1221		0.79 (0.63;0.99)	0.0428
130 - < 160 mmHg					
FIDELIO-DKD	238/1762	282/1766	66.8%	0.82 (0.69;0.98)	
FIGARO-DKD	122/831	138/830	33.2%	0.87 (0.68;1.11)	
Heterogeneity		p=0.6305			
Total	360/2593	420/2596		0.83 (0.72;0.96)	0.0103
>= 160 mmHg					
FIDELIO-DKD	21/133	19/128	76.1%	1.11 (0.59;2.08)	
FIGARO-DKD	9/34	8/35	23.9%	0.95 (0.31;2.93)	
Heterogeneity		p=0.6408			
Total	30/167	27/163		1.20 (0.68;2.10)	0.5265
Subgroup Heterogeneity		p=0.4736			



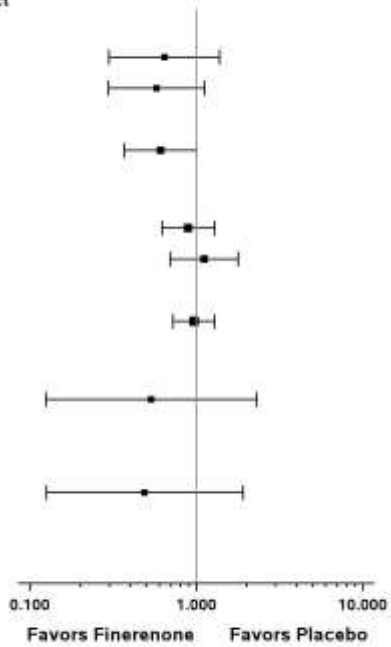
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 62: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	11/724	17/724	43.3%	0.64 (0.30;1.37)	
FIGARO-DKD	14/494	23/497	56.7%	0.57 (0.29;1.12)	
Heterogeneity		p=0.7063			
Total	25/1218	40/1221		0.61 (0.37;1.00)	0.0488
130 - < 160 mmHg					
FIDELIO-DKD	55/1762	61/1766	62.6%	0.89 (0.62;1.28)	
FIGARO-DKD	37/831	33/830	37.4%	1.11 (0.69;1.77)	
Heterogeneity		p=0.4641			
Total	92/2593	94/2596		0.96 (0.72;1.28)	0.7975
>= 160 mmHg					
FIDELIO-DKD	3/133	5/128	100%	0.53 (0.12;2.30)	
FIGARO-DKD	0/34	2/35		N.C.	
Heterogeneity		p=0.9948			
Total	3/167	7/163		0.49 (0.12;1.90)	0.2907
Subgroup Heterogeneity		p=0.1804			



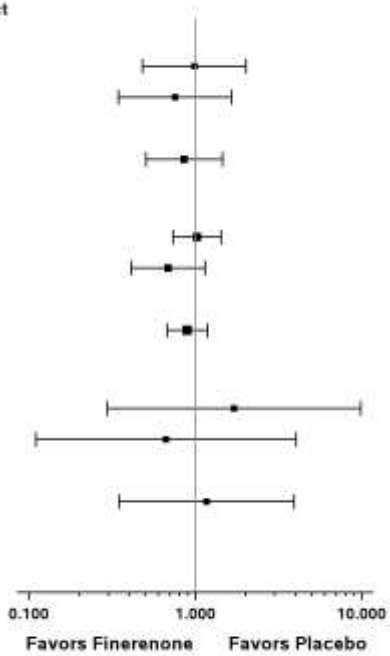
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 63: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	15/724	15/724	54.2%	0.98 (0.48;2.02)	
FIGARO-DKD	11/494	15/497	45.8%	0.75 (0.34;1.64)	
Heterogeneity		p=0.6706			
Total	26/1218	30/1221		0.86 (0.50;1.45)	0.5604
130 - < 160 mmHg					
FIDELIO-DKD	71/1762	69/1766	70.5%	1.02 (0.73;1.42)	
FIGARO-DKD	25/831	36/830	29.5%	0.68 (0.41;1.14)	
Heterogeneity		p=0.2177			
Total	96/2593	105/2596		0.89 (0.68;1.18)	0.4185
>= 160 mmHg					
FIDELIO-DKD	4/133	2/128	51.4%	1.70 (0.29;9.84)	
FIGARO-DKD	2/34	3/35	48.6%	0.66 (0.11;4.02)	
Heterogeneity		p=0.3967			
Total	6/167	5/163		1.17 (0.35;3.93)	0.8011
Subgroup Heterogeneity		p=0.9140			



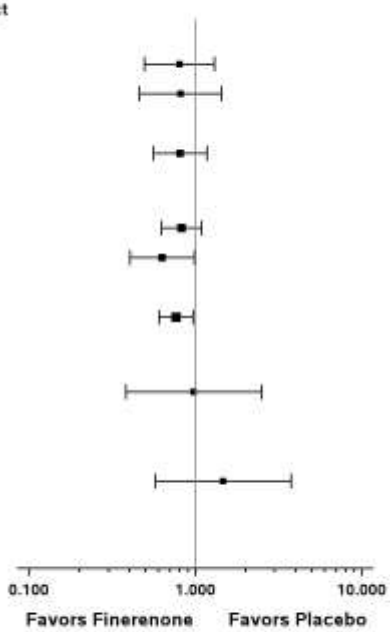
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 64: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	30/724	37/724	58.1%	0.80 (0.49;1.30)	
FIGARO-DKD	22/494	27/497	41.9%	0.81 (0.46;1.44)	
Heterogeneity		p=0.9920			
Total	52/1218	64/1221		0.81 (0.56;1.17)	0.2619
130 - < 160 mmHg					
FIDELIO-DKD	92/1762	111/1766	72.5%	0.82 (0.62;1.09)	
FIGARO-DKD	32/831	49/830	27.5%	0.63 (0.40;0.99)	
Heterogeneity		p=0.3479			
Total	124/2593	160/2596		0.76 (0.60;0.96)	0.0224
>= 160 mmHg					
FIDELIO-DKD	9/133	9/128	100%	0.98 (0.38;2.50)	
FIGARO-DKD	4/34	0/35		N.C.	
Heterogeneity		p=0.9936			
Total	13/167	9/163		1.47 (0.57;3.76)	0.4218
Subgroup Heterogeneity		p=0.3340			



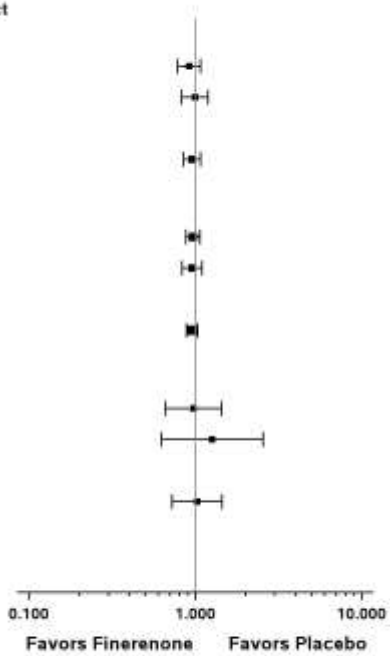
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 65: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline systolic blood pressure (mmHg) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
< 130 mmHg					
FIDELIO-DKD	303/724	328/724	57.2%	0.91 (0.78;1.07)	
FIGARO-DKD	235/494	238/497	42.8%	0.99 (0.83;1.19)	
Heterogeneity		p=0.4250			
Total	538/1218	566/1221		0.95 (0.84;1.07)	0.4261
130 - < 160 mmHg					
FIDELIO-DKD	817/1762	841/1766	66.8%	0.96 (0.88;1.06)	
FIGARO-DKD	414/831	423/830	33.2%	0.95 (0.83;1.09)	
Heterogeneity		p=0.9983			
Total	1231/2593	1264/2596		0.95 (0.88;1.03)	0.2243
>= 160 mmHg					
FIDELIO-DKD	54/133	56/128	76.6%	0.97 (0.66;1.44)	
FIGARO-DKD	21/34	26/35	23.4%	1.26 (0.62;2.55)	
Heterogeneity		p=0.5185			
Total	75/167	82/163		1.02 (0.72;1.45)	0.8951
Subgroup Heterogeneity		p=0.8756			



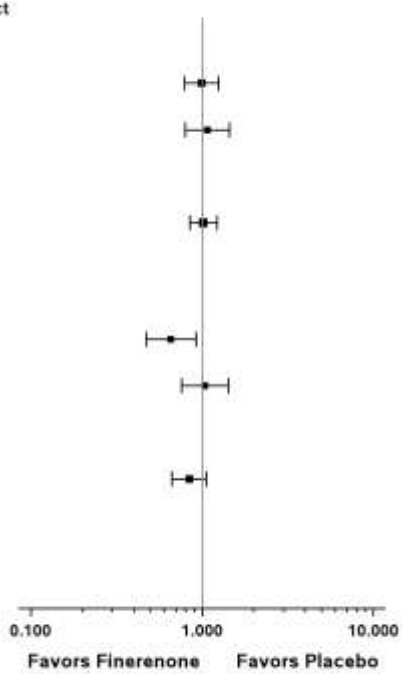
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 66: Forest plot of all-cause mortality: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	145/1558	145/1546	62.9%	0.99 (0.79;1.25)	
FIGARO-DKD	90/639	82/629	37.1%	1.07 (0.80;1.45)	
Heterogeneity		p=0.6171			
Total	235/2197	227/2175		1.02 (0.85;1.22)	0.8661
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	56/1062	85/1071	46.9%	0.66 (0.47;0.92)	
FIGARO-DKD	77/720	76/731	53.1%	1.04 (0.76;1.43)	
Heterogeneity		p=0.0549			
Total	133/1782	161/1802		0.84 (0.67;1.05)	0.1315
Subgroup Heterogeneity		p=0.2005			



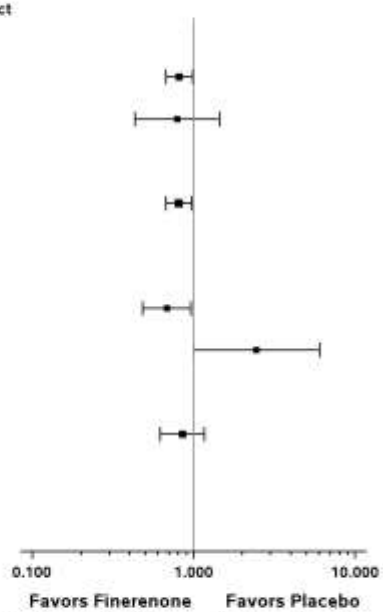
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 67: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	190/1558	228/1546	90.7%	0.81 (0.67;0.99)	
FIGARO-DKD	19/639	24/629	9.3%	0.79 (0.43;1.44)	
Heterogeneity		p=0.9506			
Total	209/2197	252/2175		0.81 (0.67;0.97)	0.0237
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	55/1062	82/1071	87.3%	0.68 (0.48;0.96)	
FIGARO-DKD	16/720	7/731	12.7%	2.45 (1.00;6.01)	
Heterogeneity		p=0.0112			
Total	71/1782	89/1802		0.85 (0.62;1.17)	0.3146
Subgroup Heterogeneity		p=0.7873			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 68: Forest plot of onset of kidney failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

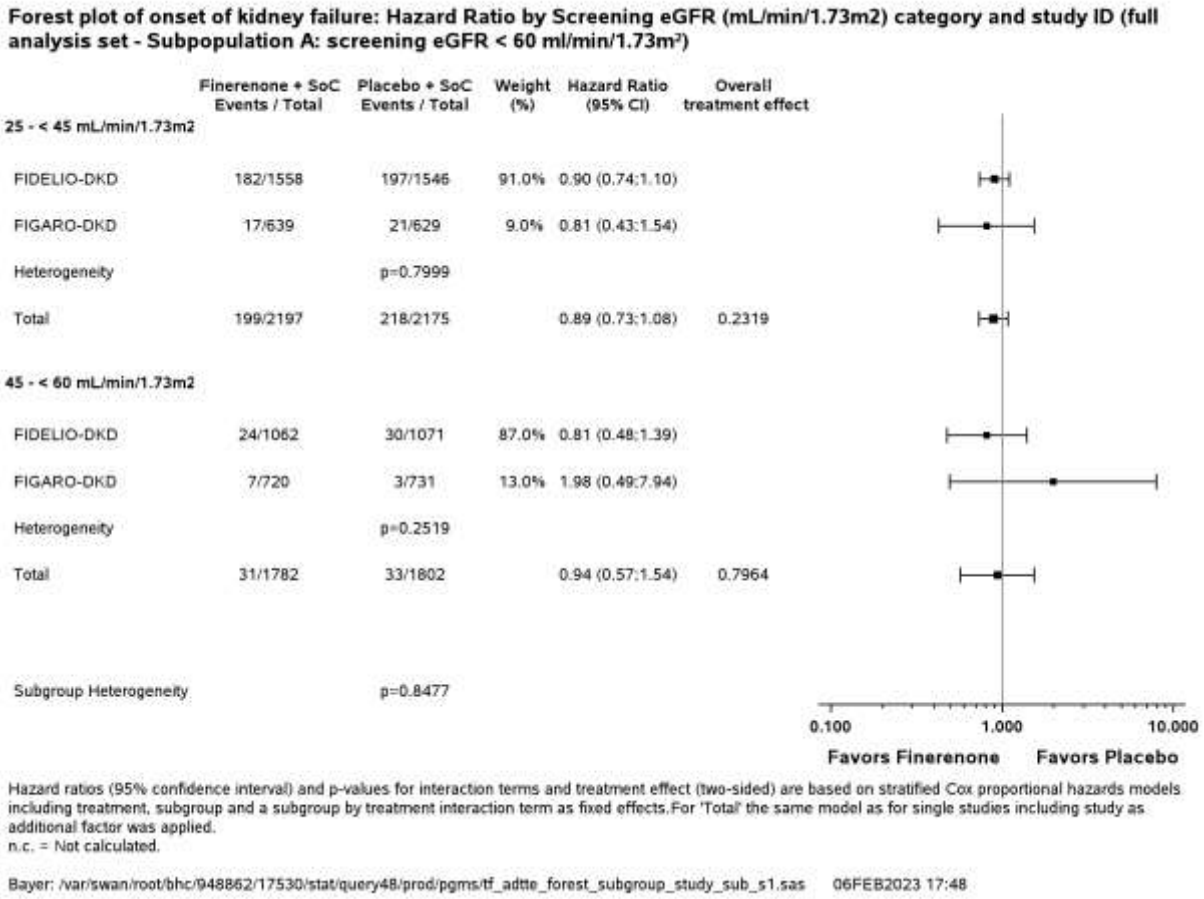
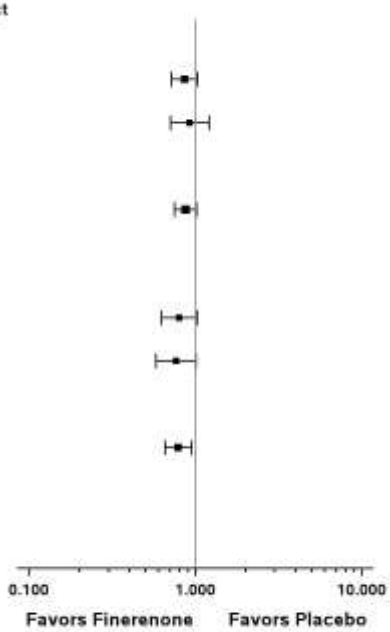


Figure 1.2.2 / 69: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	220/1558	248/1546	68.4%	0.86 (0.72;1.03)	
FIGARO-DKD	105/639	111/629	31.6%	0.92 (0.70;1.20)	
Heterogeneity		p=0.6160			
Total	325/2197	359/2175		0.87 (0.75;1.01)	0.0686
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	112/1062	139/1071	55.1%	0.80 (0.62;1.02)	
FIGARO-DKD	90/720	116/731	44.9%	0.76 (0.58;1.01)	
Heterogeneity		p=0.7913			
Total	202/1782	255/1802		0.79 (0.65;0.95)	0.0106
Subgroup Heterogeneity		p=0.4051			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

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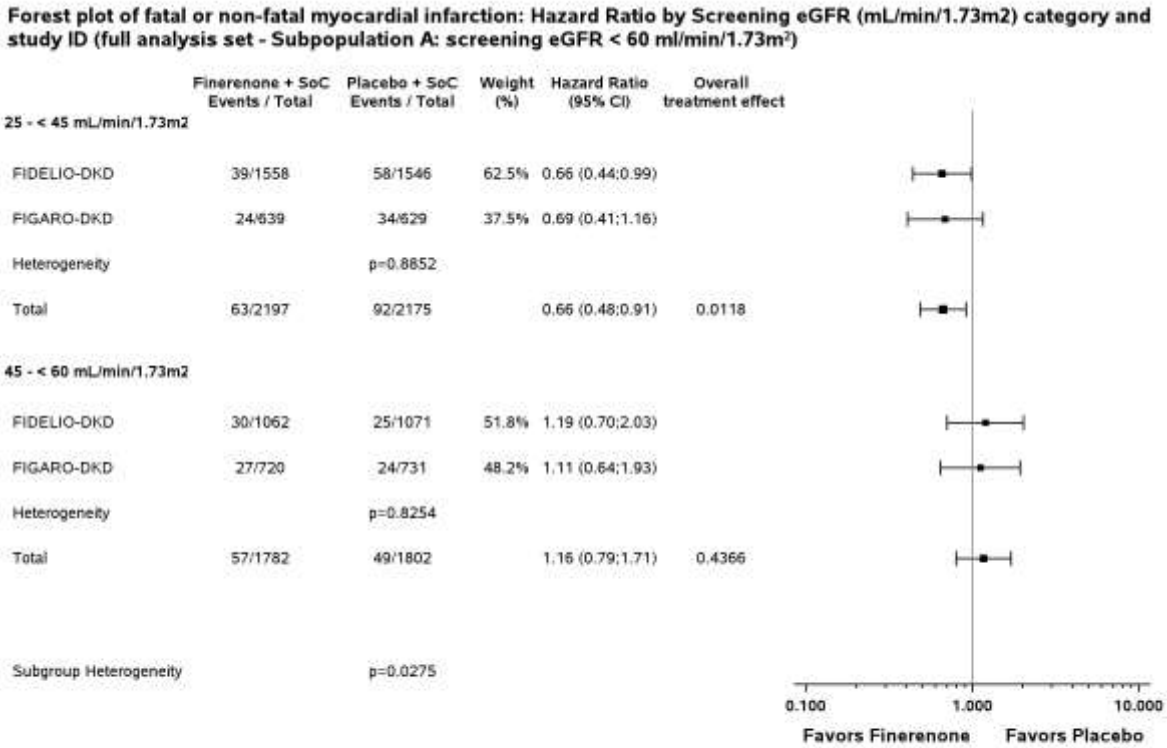
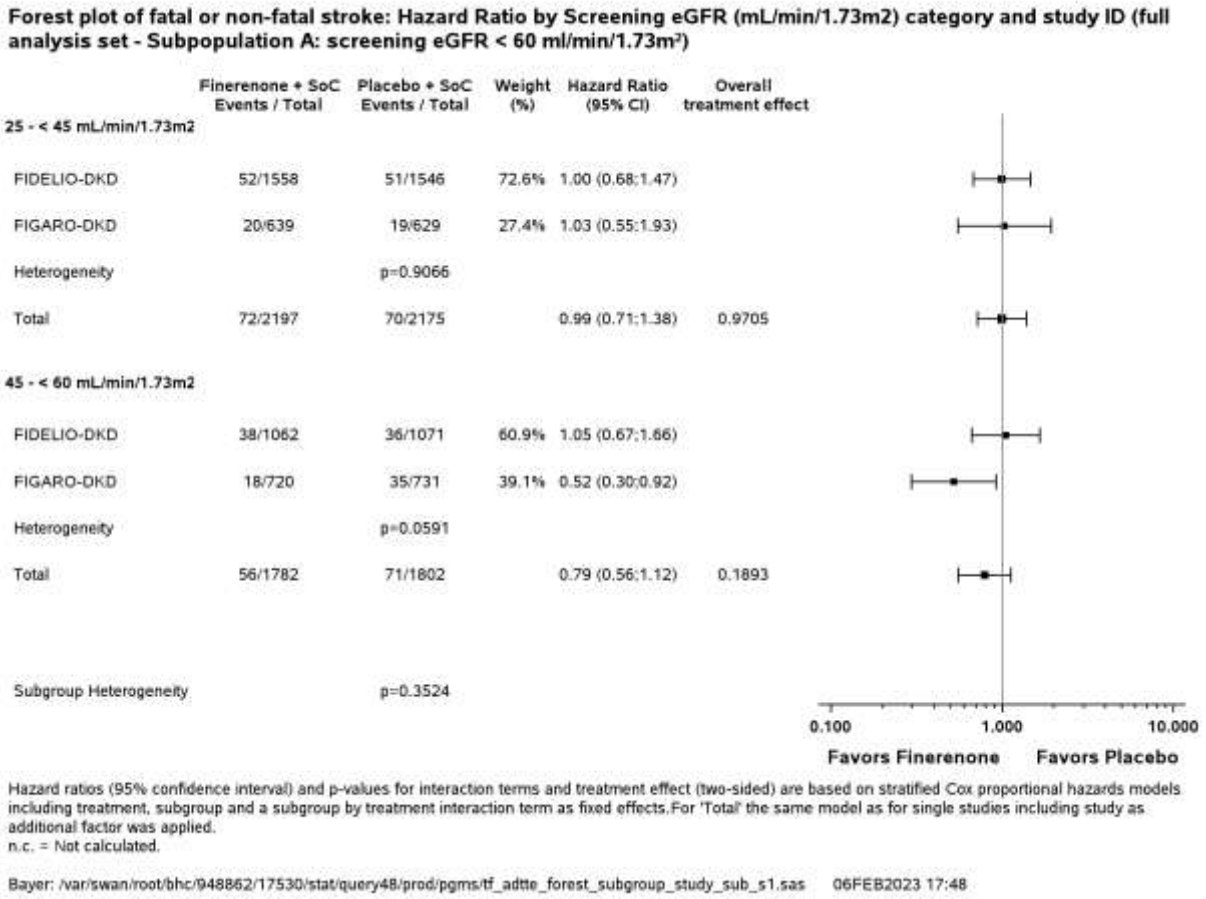
Figure 1.2.2 / 70: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 71: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



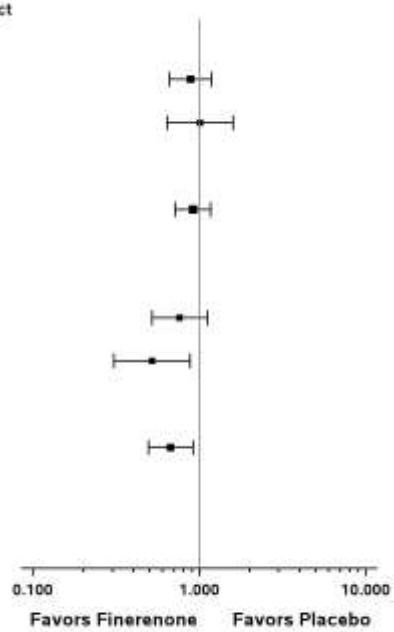
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 72: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	86/1558	96/1546	71.4%	0.88 (0.66;1.18)	
FIGARO-DKD	37/639	36/629	28.6%	1.01 (0.64;1.60)	
Heterogeneity		p=0.6154			
Total	123/2197	132/2175		0.91 (0.71;1.17)	0.4585
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	46/1062	61/1071	65.6%	0.76 (0.52;1.11)	
FIGARO-DKD	21/720	40/731	34.4%	0.52 (0.30;0.88)	
Heterogeneity		p=0.2322			
Total	67/1782	101/1802		0.67 (0.49;0.91)	0.0107
Subgroup Heterogeneity		p=0.1276			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 73: Forest plot of all-cause hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Screening eGFR (mL/min/1.73m2) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
25 - < 45 mL/min/1.73m2					
FIDELIO-DKD	730/1558	751/1546	69.4%	0.96 (0.87;1.06)	
FIGARO-DKD	329/639	328/629	30.6%	0.99 (0.85;1.16)	
Heterogeneity		p=0.6671			
Total	1059/2197	1079/2175		0.96 (0.88;1.05)	0.3816
45 - < 60 mL/min/1.73m2					
FIDELIO-DKD	445/1062	473/1071	56.7%	0.93 (0.82;1.06)	
FIGARO-DKD	341/720	359/731	43.3%	0.94 (0.81;1.09)	
Heterogeneity		p=0.8926			
Total	786/1782	832/1802		0.93 (0.85;1.03)	0.1718
Subgroup Heterogeneity		p=0.6484			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 74: Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

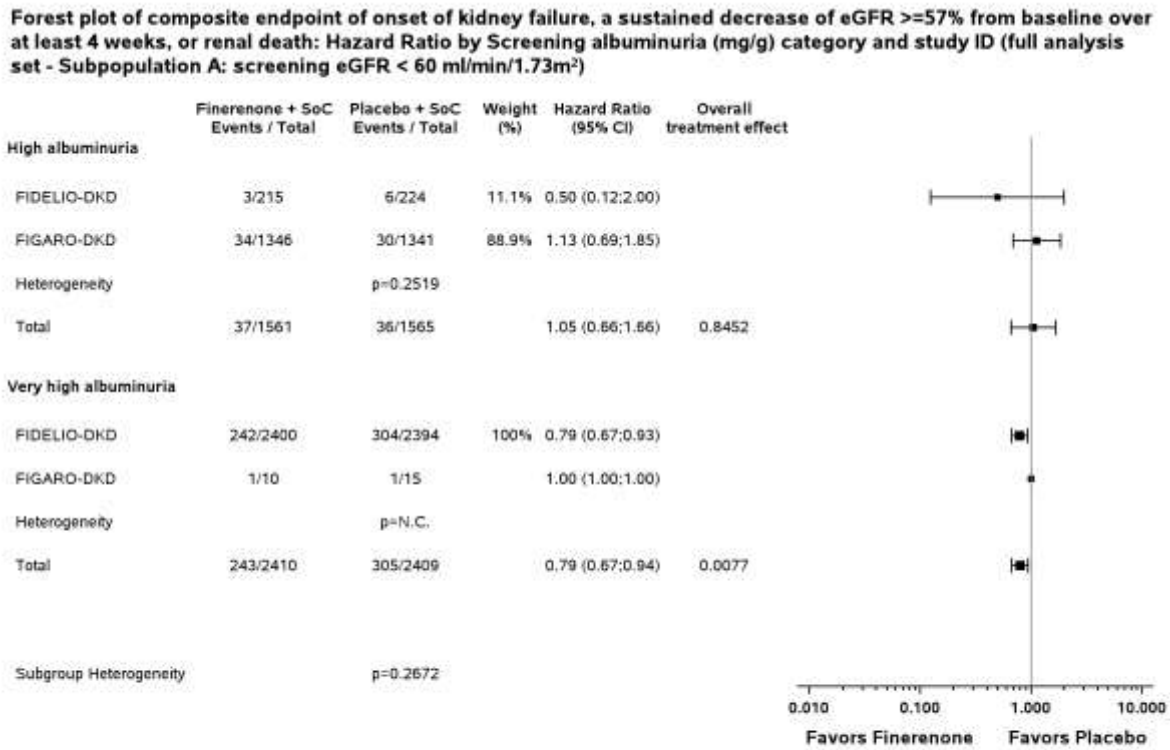
Forest plot of all-cause mortality: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	10/215	21/224	7.4%	0.55 (0.25;1.20)	
FIGARO-DKD	166/1346	156/1341	92.6%	1.06 (0.85;1.32)	
Heterogeneity		p=0.1309			
Total	176/1561	177/1565		1.02 (0.83;1.26)	0.8563
Very high albuminuria					
FIDELIO-DKD	191/2400	209/2394	100%	0.91 (0.75;1.11)	
FIGARO-DKD	1/10	3/15			
Heterogeneity		p=0.9622			
Total	192/2410	212/2409		0.89 (0.73;1.08)	0.2294
Subgroup Heterogeneity		p=0.4323			

Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

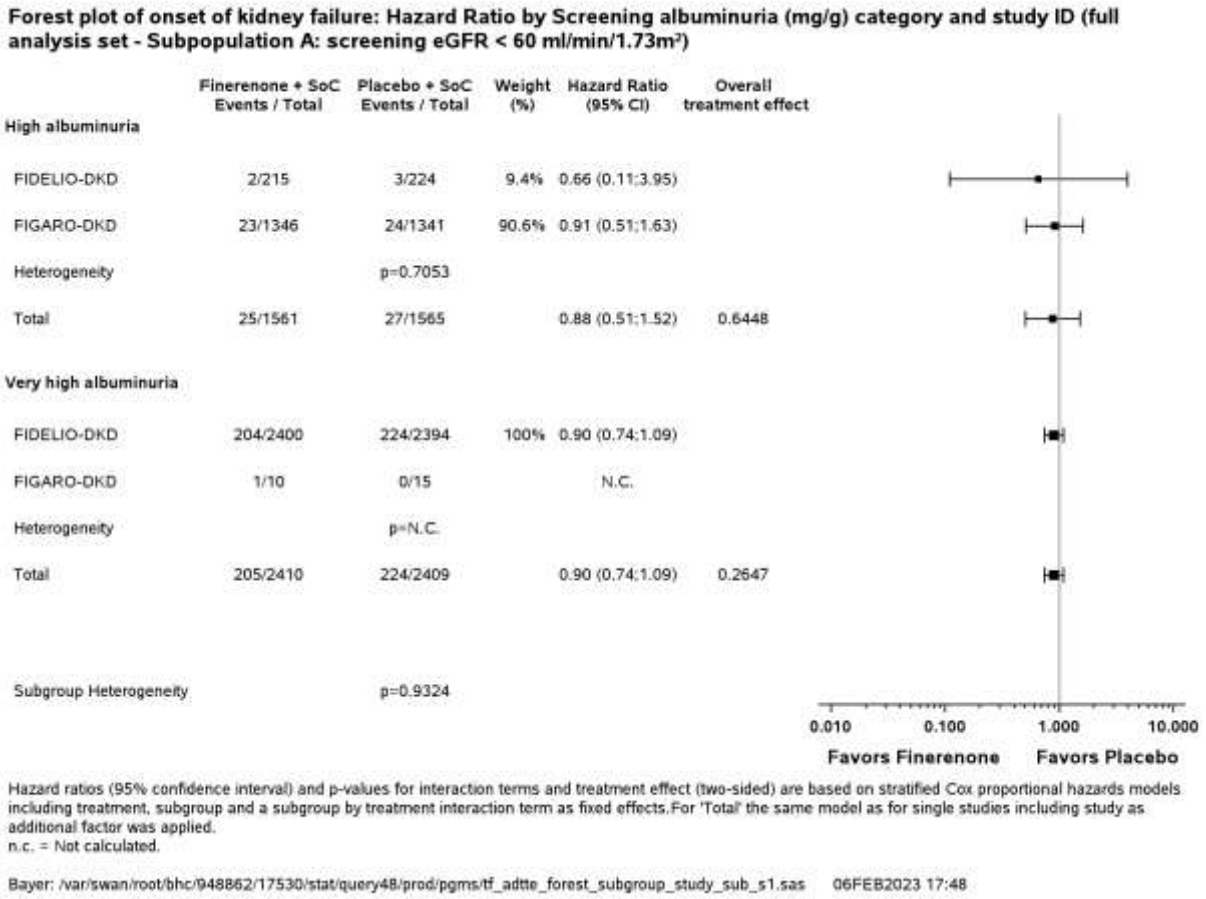
Figure 1.2.2 / 75: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 76: Forest plot of onset of kidney failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



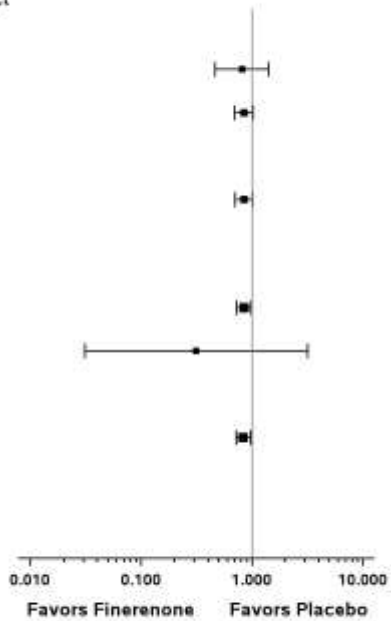
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 77: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	23/215	29/224	10.7%	0.81 (0.46;1.42)	
FIGARO-DKD	193/1346	223/1341	89.3%	0.85 (0.70;1.03)	
Heterogeneity		p=0.9256			
Total	216/1561	252/1565		0.85 (0.70;1.02)	0.0719
Very high albuminuria					
FIDELIO-DKD	308/2400	358/2394	99.6%	0.85 (0.73;0.99)	
FIGARO-DKD	2/10	4/15	0.4%	0.31 (0.03;3.17)	
Heterogeneity		p=0.4079			
Total	310/2410	362/2409		0.83 (0.72;0.97)	0.0188
Subgroup Heterogeneity		p=0.9711			



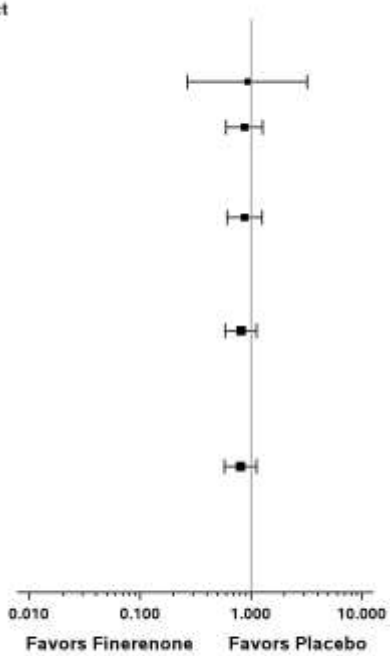
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 78: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

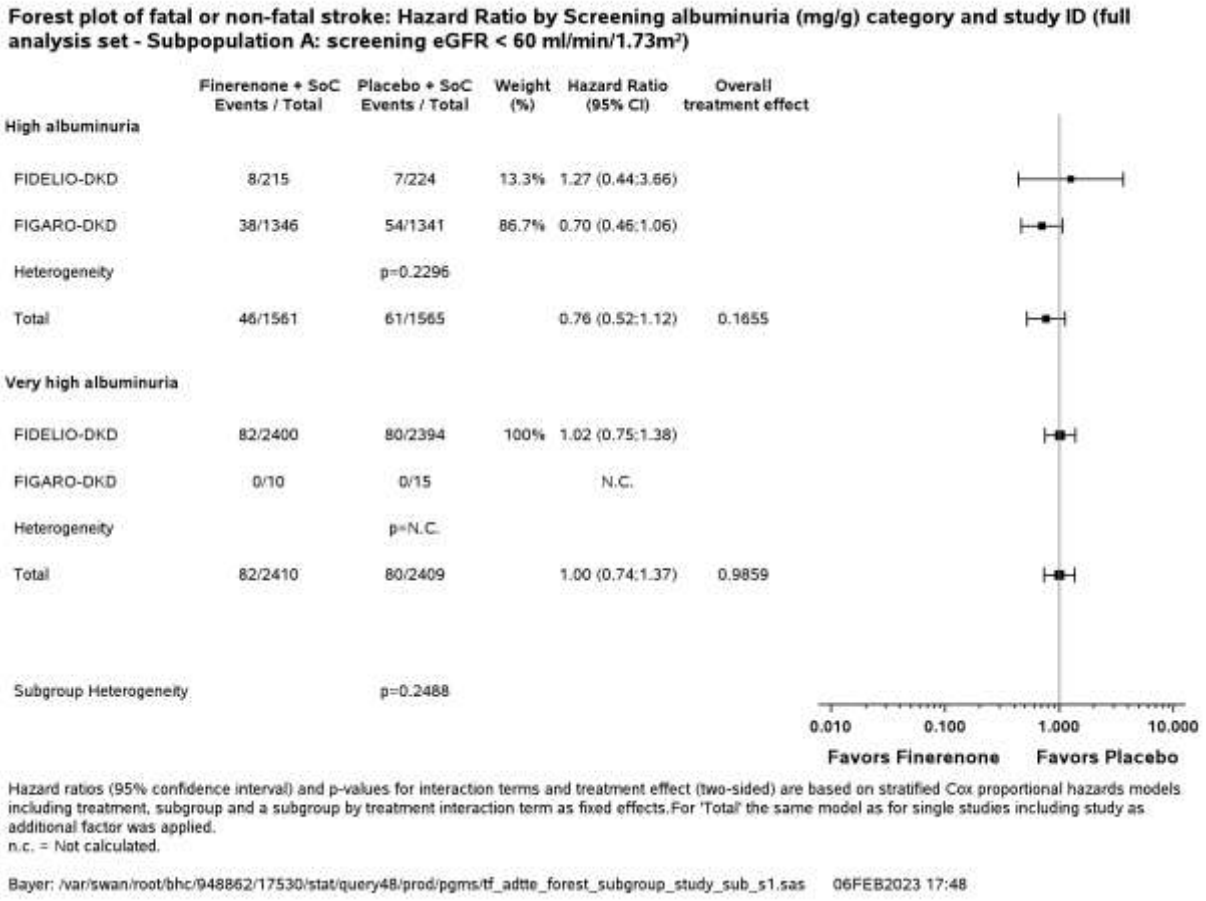
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	5/215	5/224	8.5%	0.93 (0.27;3.21)	
FIGARO-DKD	51/1346	57/1341	91.5%	0.87 (0.60;1.27)	
Heterogeneity		p=0.8243			
Total	56/1561	62/1565		0.88 (0.61;1.26)	0.4724
Very high albuminuria					
FIDELIO-DKD	64/2400	78/2394	100%	0.81 (0.58;1.13)	
FIGARO-DKD	0/10	1/15		N.C.	
Heterogeneity		p=0.9811			
Total	64/2410	79/2409		0.81 (0.58;1.12)	0.2021
Subgroup Heterogeneity		p=0.7472			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 79: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



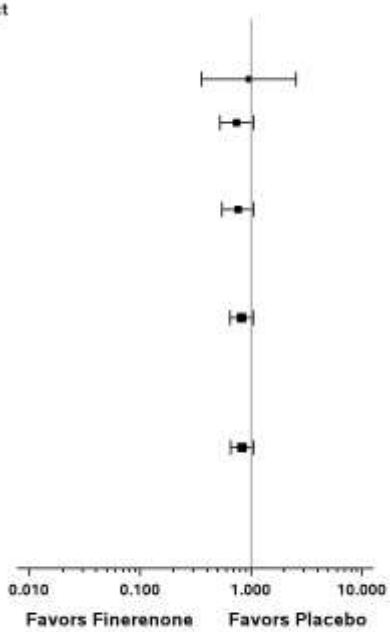
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 80: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

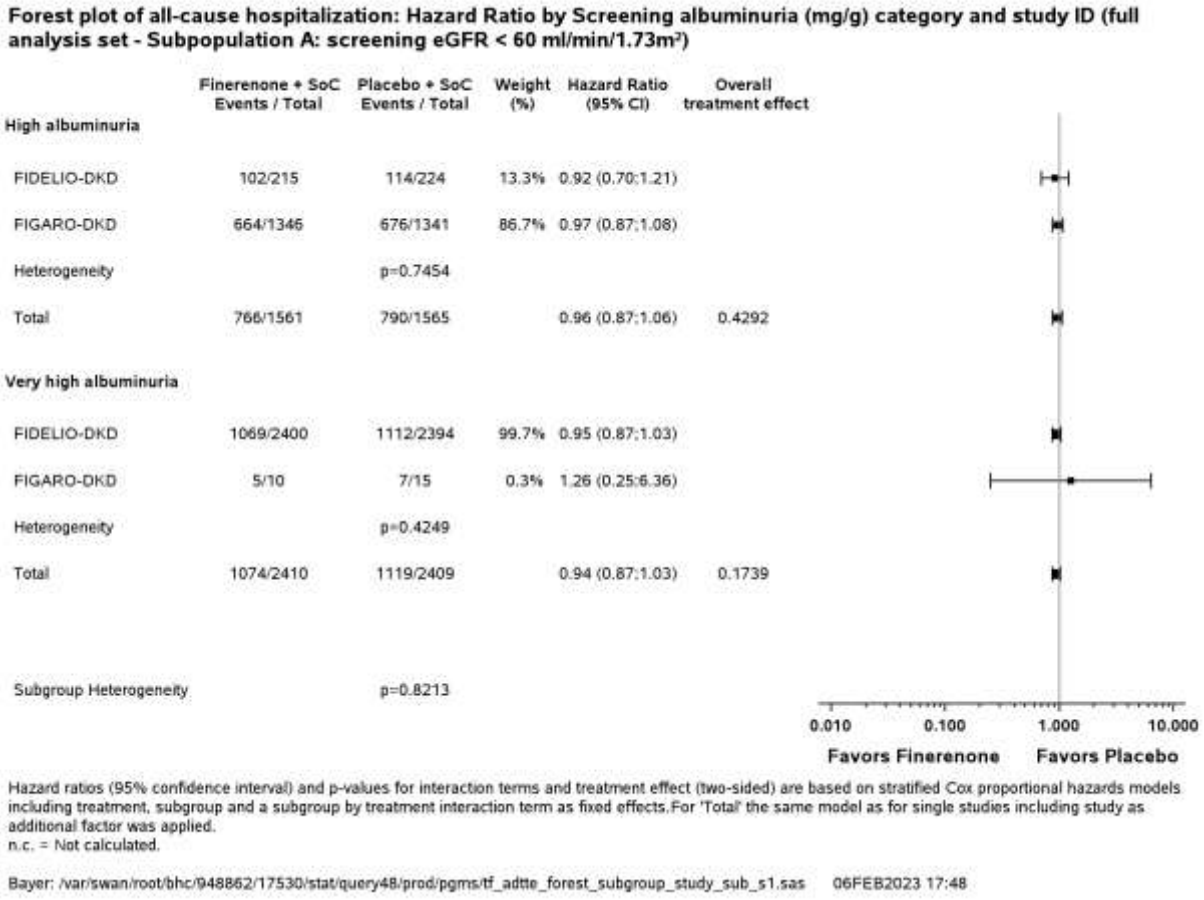
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
High albuminuria					
FIDELIO-DKD	8/215	8/224	11.1%	0.96 (0.36;2.56)	
FIGARO-DKD	56/1346	74/1341	88.9%	0.75 (0.53;1.05)	
Heterogeneity		p=0.5762			
Total	64/1561	82/1565		0.76 (0.55;1.06)	0.1037
Very high albuminuria					
FIDELIO-DKD	123/2400	149/2394	100%	0.83 (0.65;1.05)	
FIGARO-DKD	2/10	1/15			
Heterogeneity		p=0.9665			
Total	125/2410	150/2409		0.84 (0.66;1.06)	0.1397
Subgroup Heterogeneity		p=0.6448			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 81: Forest plot of all-cause hospitalization: Hazard Ratio by Screening albuminuria (mg/g) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



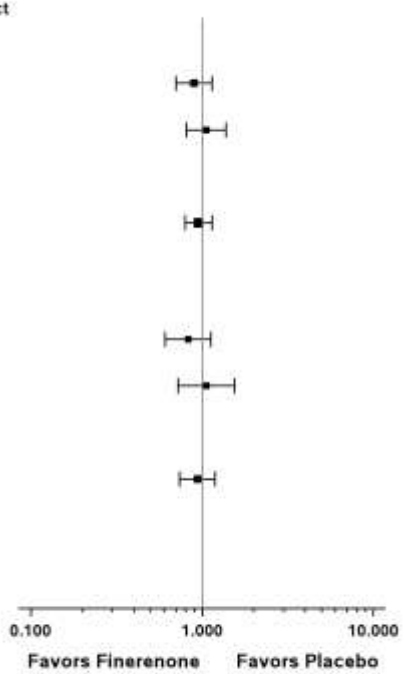
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 82: Forest plot of all-cause mortality: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause mortality: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	127/1737	138/1703	55.3%	0.90 (0.70;1.14)	
FIGARO-DKD	110/924	105/932	44.7%	1.05 (0.81;1.38)	
Heterogeneity		p=0.3410			
Total	237/2661	243/2635		0.96 (0.80;1.14)	0.6175
> 4.5 mmol/L					
FIDELIO-DKD	74/884	92/916	60.4%	0.83 (0.61;1.13)	
FIGARO-DKD	57/435	53/429	39.6%	1.05 (0.72;1.54)	
Heterogeneity		p=0.3662			
Total	131/1319	145/1345		0.94 (0.74;1.19)	0.6059
Subgroup Heterogeneity		p=0.9282			



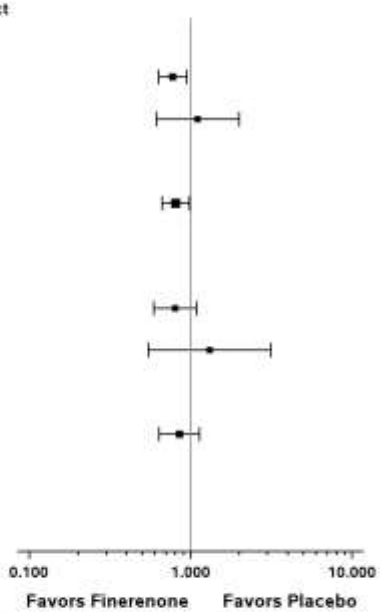
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 83: Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of onset of kidney failure, a sustained decrease of eGFR >=57% from baseline over at least 4 weeks, or renal death: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	171/1737	211/1703	89.6%	0.77 (0.63;0.95)	
FIGARO-DKD	23/924	22/932	10.4%	1.10 (0.61;2.00)	
Heterogeneity		p=0.2565			
Total	194/2661	233/2635		0.81 (0.67;0.98)	0.0276
> 4.5 mmol/L					
FIDELIO-DKD	74/884	99/916	89.3%	0.80 (0.59;1.08)	
FIGARO-DKD	12/435	9/429	10.7%	1.31 (0.55;3.14)	
Heterogeneity		p=0.3262			
Total	86/1319	108/1345		0.85 (0.64;1.13)	0.2706
Subgroup Heterogeneity		p=0.8298			



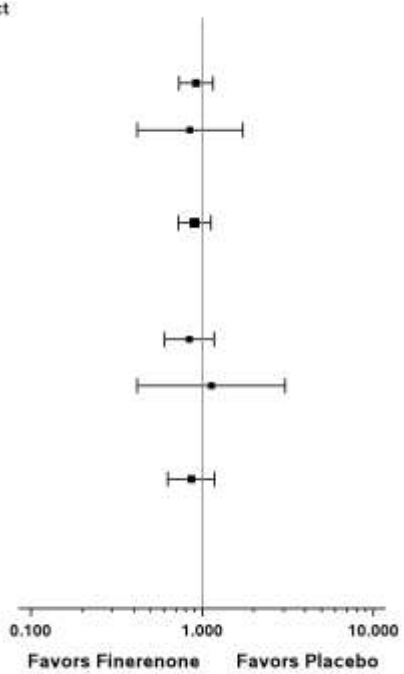
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 84: Forest plot of onset of kidney failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of onset of kidney failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	143/1737	148/1703	90.5%	0.92 (0.73;1.16)	
FIGARO-DKD	14/924	17/932	9.5%	0.85 (0.42;1.73)	
Heterogeneity		p=0.9391			
Total	157/2661	165/2635		0.90 (0.73;1.13)	0.3662
> 4.5 mmol/L					
FIDELIO-DKD	63/884	79/916	89.9%	0.84 (0.60;1.17)	
FIGARO-DKD	10/435	7/429	10.1%	1.13 (0.42;3.06)	
Heterogeneity		p=0.6032			
Total	73/1319	86/1345		0.86 (0.63;1.19)	0.3622
Subgroup Heterogeneity		p=0.7589			



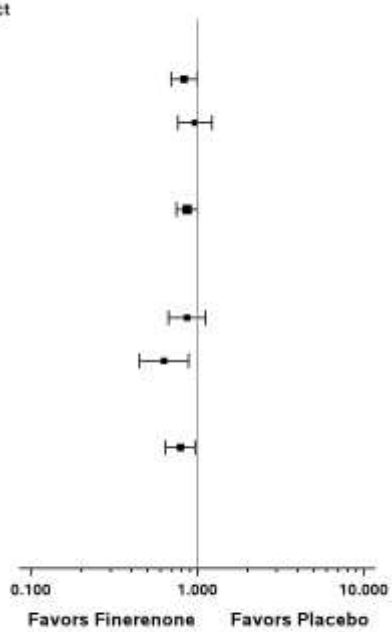
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 85: Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death, non-fatal myocardial infarction, non-fatal stroke or heart failure hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

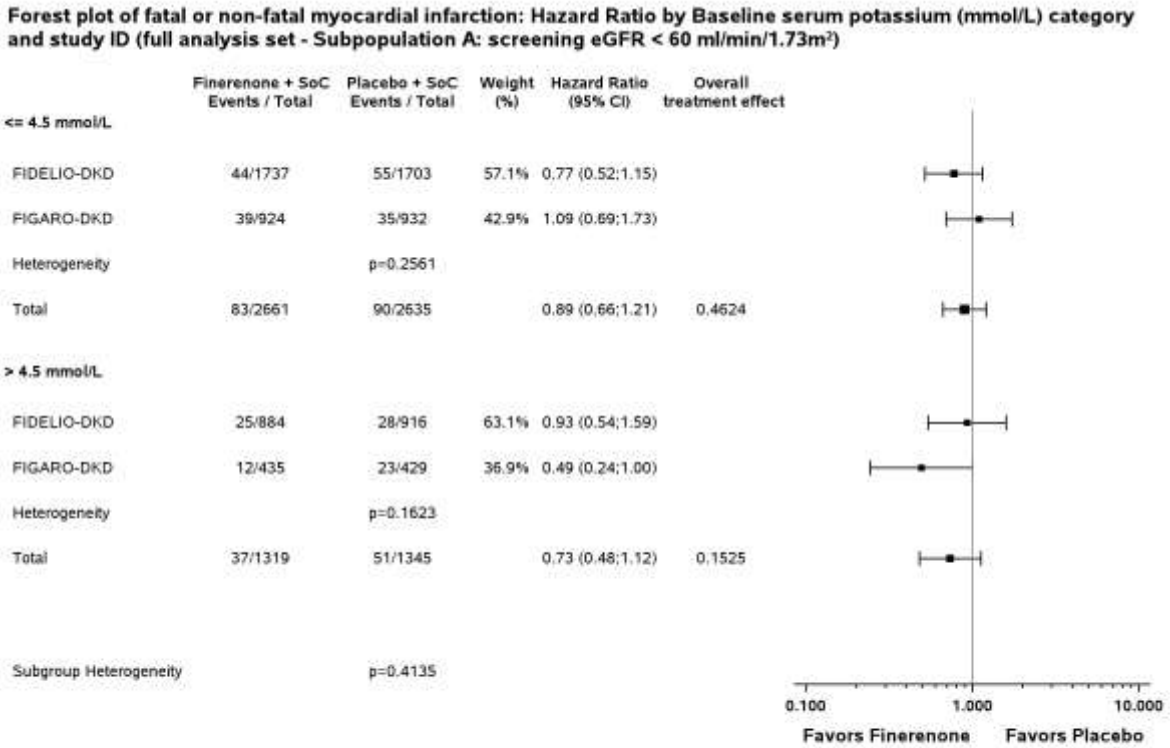
	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	222/1737	256/1703	63.3%	0.83 (0.69;0.99)	
FIGARO-DKD	137/924	140/932	36.7%	0.97 (0.76;1.22)	
Heterogeneity		p=0.2651			
Total	359/2661	396/2635		0.86 (0.75;1.00)	0.0472
> 4.5 mmol/L					
FIDELIO-DKD	110/884	131/916	63.7%	0.86 (0.67;1.12)	
FIGARO-DKD	58/435	87/429	36.3%	0.63 (0.45;0.88)	
Heterogeneity		p=0.1262			
Total	168/1319	218/1345		0.79 (0.64;0.97)	0.0225
Subgroup Heterogeneity		p=0.4195			



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

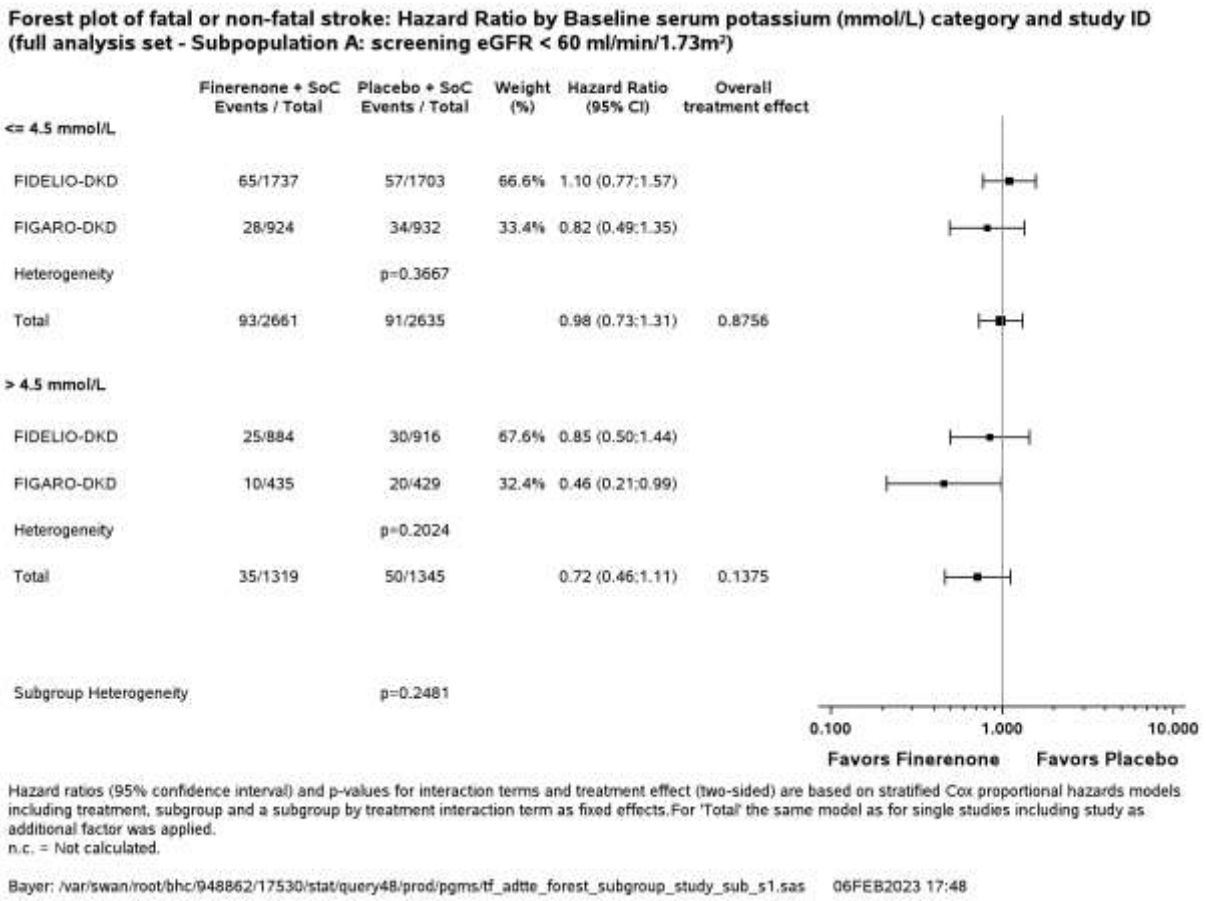
Figure 1.2.2 / 86: Forest plot of fatal or non-fatal myocardial infarction: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 87: Forest plot of fatal or non-fatal stroke: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)



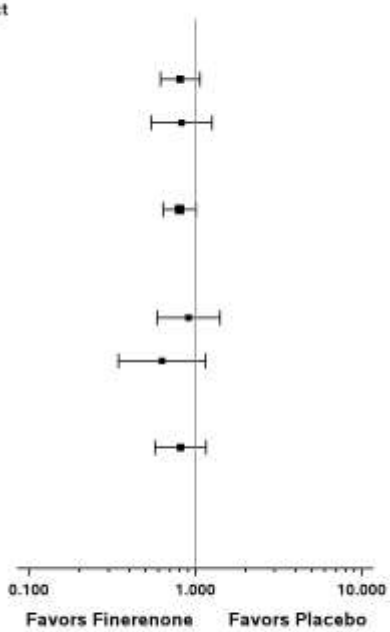
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 88: Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of composite endpoint of CV death for heart failure or hospitalization for heart failure: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	94/1737	113/1703	70.3%	0.81 (0.61;1.06)	
FIGARO-DKD	40/924	48/932	29.7%	0.82 (0.54;1.25)	
Heterogeneity		p=0.8972			
Total	134/2661	161/2635		0.80 (0.64;1.01)	0.0595
> 4.5 mmol/L					
FIDELIO-DKD	38/884	44/916	65.5%	0.91 (0.59;1.41)	
FIGARO-DKD	18/435	28/429	34.5%	0.63 (0.34;1.15)	
Heterogeneity		p=0.3014			
Total	56/1319	72/1345		0.81 (0.57;1.16)	0.2507
Subgroup Heterogeneity		p=0.9737			



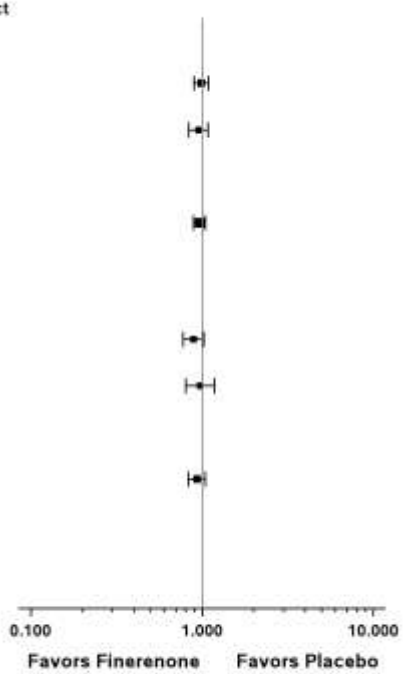
Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure 1.2.2 / 89: Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

Forest plot of all-cause hospitalization: Hazard Ratio by Baseline serum potassium (mmol/L) category and study ID (full analysis set - Subpopulation A: screening eGFR < 60 ml/min/1.73m²)

	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Hazard Ratio (95% CI)	Overall treatment effect
<= 4.5 mmol/L					
FIDELIO-DKD	792/1737	789/1703	63.4%	0.99 (0.89;1.09)	
FIGARO-DKD	456/924	469/932	36.6%	0.95 (0.84;1.08)	
Heterogeneity		p=0.8319			
Total	1248/2661	1258/2635		0.96 (0.89;1.04)	0.3688
> 4.5 mmol/L					
FIDELIO-DKD	383/884	437/916	66.0%	0.89 (0.78;1.02)	
FIGARO-DKD	214/435	218/429	34.0%	0.97 (0.80;1.18)	
Heterogeneity		p=0.5301			
Total	597/1319	655/1345		0.93 (0.83;1.04)	0.2179
Subgroup Heterogeneity		p=0.5393			

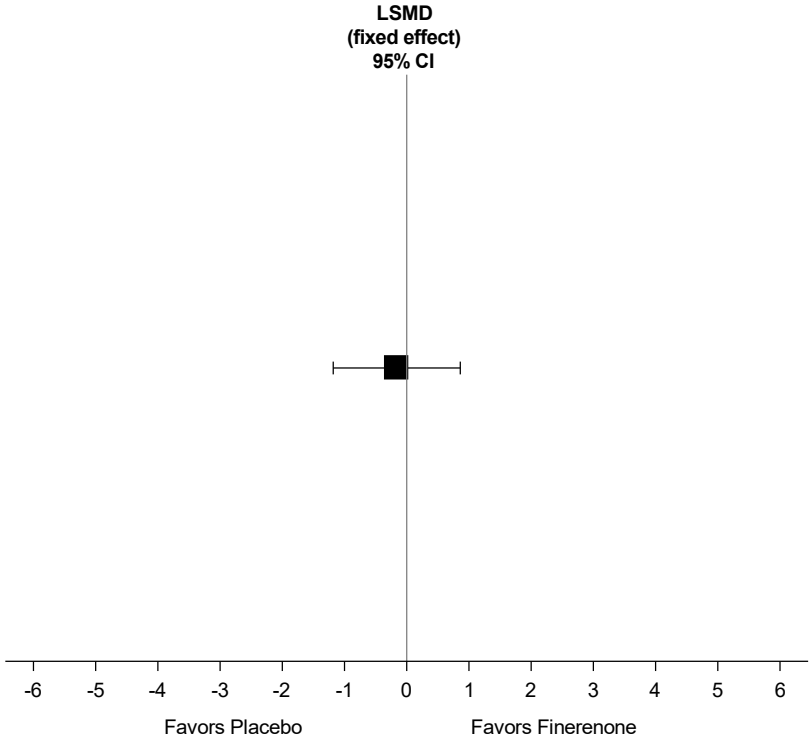


Hazard ratios (95% confidence interval) and p-values for interaction terms and treatment effect (two-sided) are based on stratified Cox proportional hazards models including treatment, subgroup and a subgroup by treatment interaction term as fixed effects.For 'Total' the same model as for single studies including study as additional factor was applied.
n.c. = Not calculated.

Bayer: /var/swan/root/bhc/948862/17530/stat/query48/prod/pgms/tf_adtte_forest_subgroup_study_sub_s1.sas 06FEB2023 17:48

Figure A3.0.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

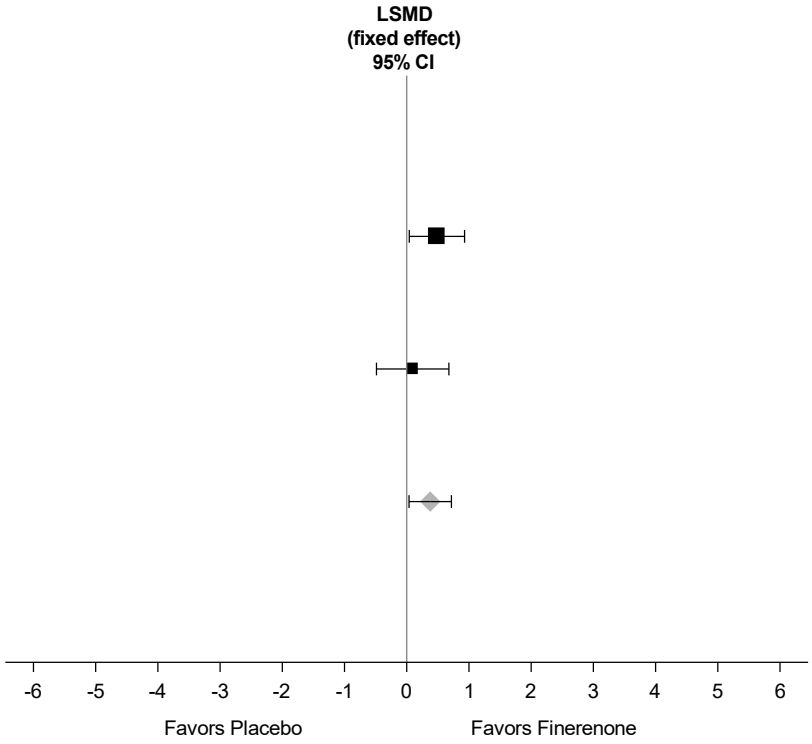
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2386	2366	0	-	
FIGARO-DKD	1245	1234	100.0	-0.16 [-1.18,0.86]	
Total	3631	3600		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the LSMD is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.0.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

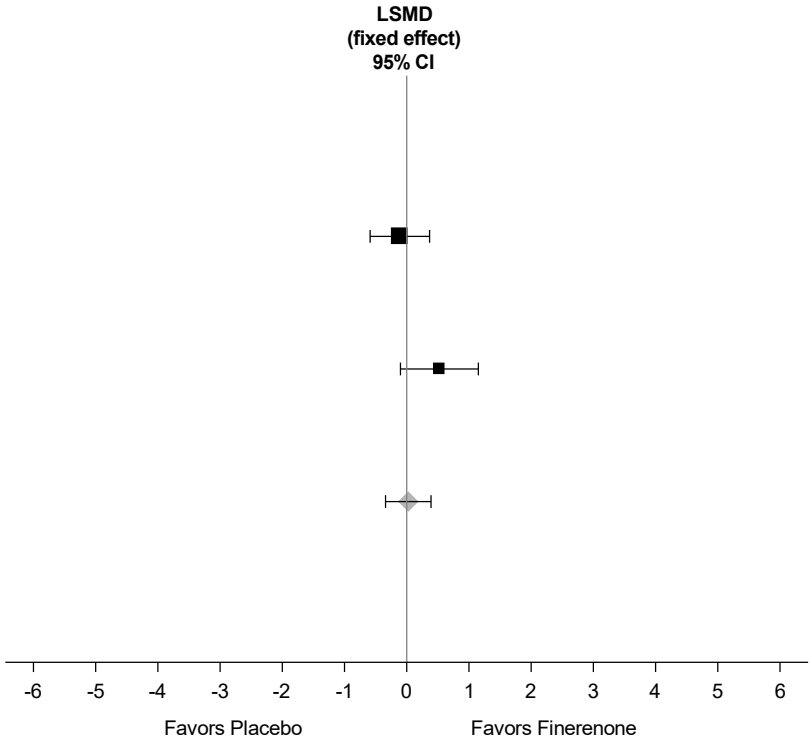
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2360	2333	63.2	0.49 [0.04,0.93]	
FIGARO-DKD	1237	1223	36.8	0.10 [-0.49,0.68]	
Total	3597	3556		0.38 [0.04,0.72]	Z=2.17, p=0.0297
Heterogeneity:	Q=1.13 (df=1)	p=0.2880	I^2=11.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate,
KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.0.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

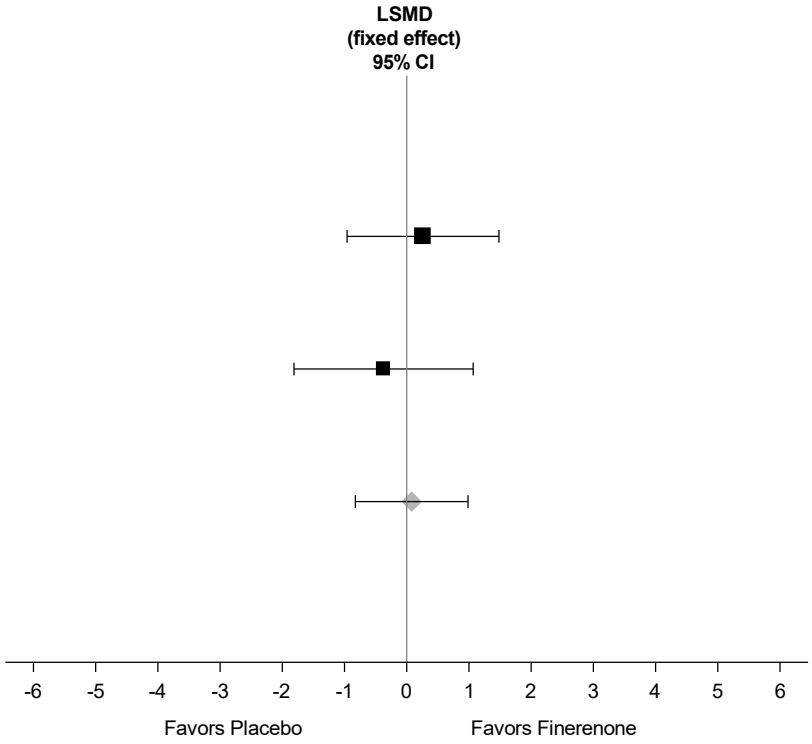
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2360	2333	63.2	-0.11 [-0.59,0.37]	
FIGARO-DKD	1237	1223	36.8	0.53 [-0.10,1.15]	
Total	3597	3556		0.02 [-0.34,0.39]	Z=0.13, p=0.8937
Heterogeneity:	Q=2.77 (df=1)	p=0.0963	I^2=63.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate,
KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.0.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

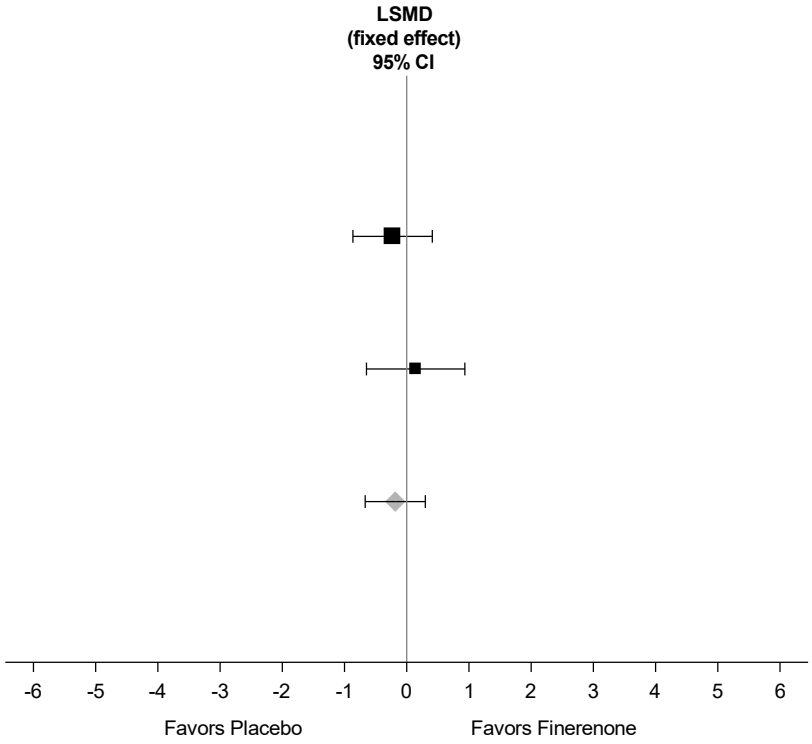
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2381	2361	58.2	0.26 [-0.96,1.48]	
FIGARO-DKD	1247	1236	41.8	-0.37 [-1.81,1.07]	
Total	3628	3597		0.08 [-0.83,0.99]	Z=0.17, p=0.8631
Heterogeneity:	Q=0.46 (df=1)	p=0.4959	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate,
KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.0.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

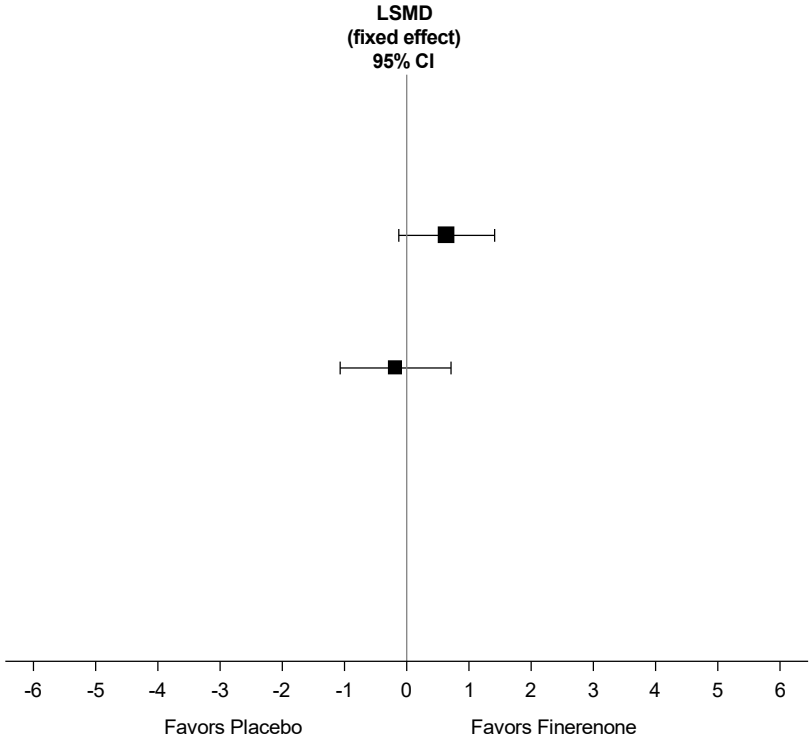
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2383	2366	60.5	-0.23 [-0.87,0.41]	
FIGARO-DKD	1248	1238	39.5	0.14 [-0.65,0.93]	
Total	3631	3604		-0.18 [-0.67,0.30]	Z=-0.75, p=0.4537
Heterogeneity:	Q=0.68 (df=1)	p=0.4097	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate,
KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.0.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

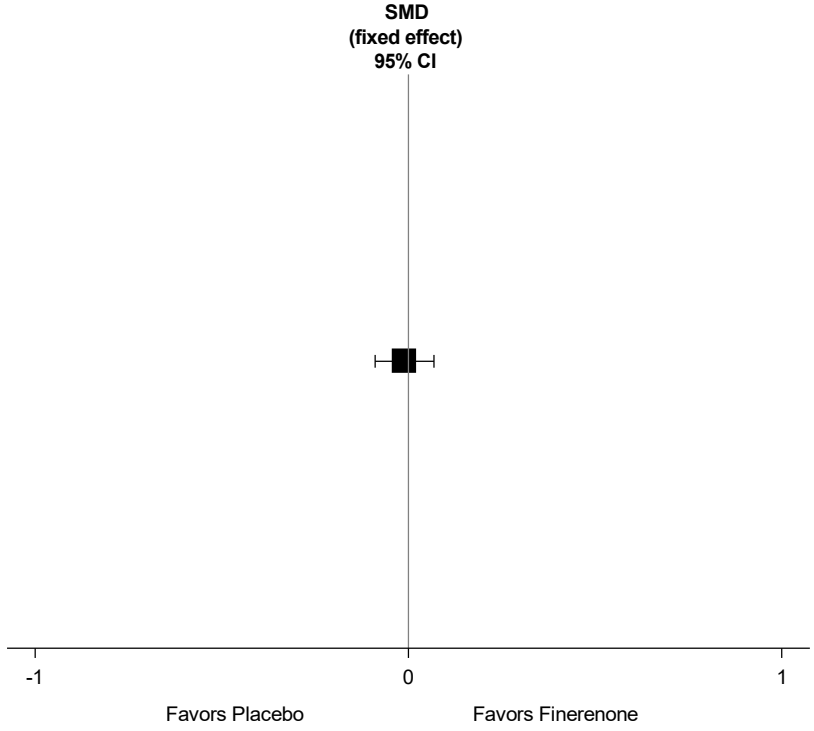
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	LSMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2375	2358	57.2	0.64 [-0.13,1.41]	
FIGARO-DKD	1246	1236	42.8	-0.18 [-1.07,0.71]	
Total	3621	3594		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate,
KDQoL=Kidney Disease Quality of Life, LSMD=least-squares mean difference, MMRM=Mixed Model Repeated Measures, N=number of subjects, SoC=standard of care.
Note: For 'Total' the LSMD is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.1: EQ-5D VAS - Forest Plot for MMRM of Change from Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

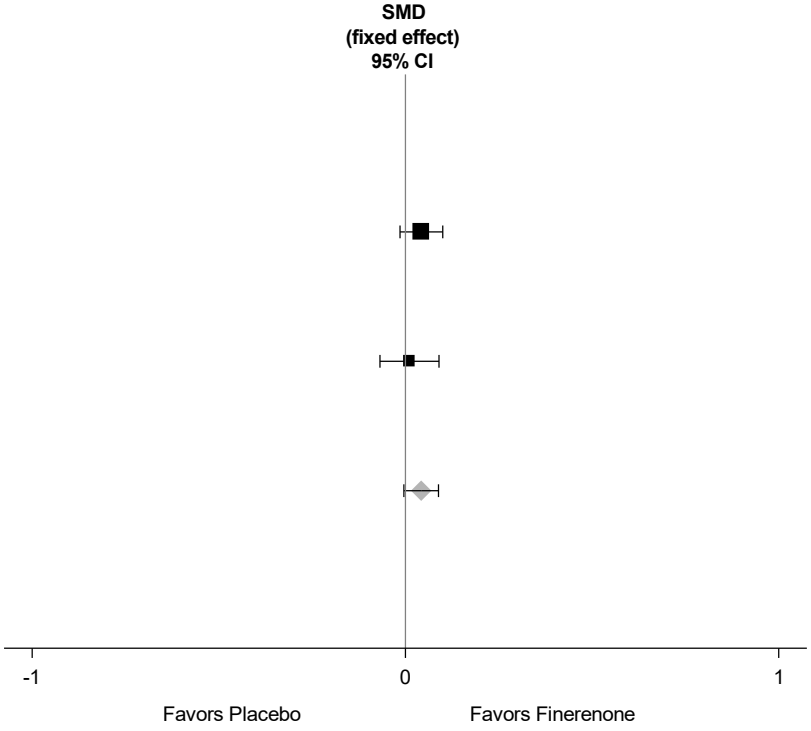
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2386	2366	0	-	
FIGARO-DKD	1245	1234	100.0	-0.01 [-0.09,0.07]	
Total	3631	3600		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care, VAS=Visual Analogue Scale.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.2: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Physical Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

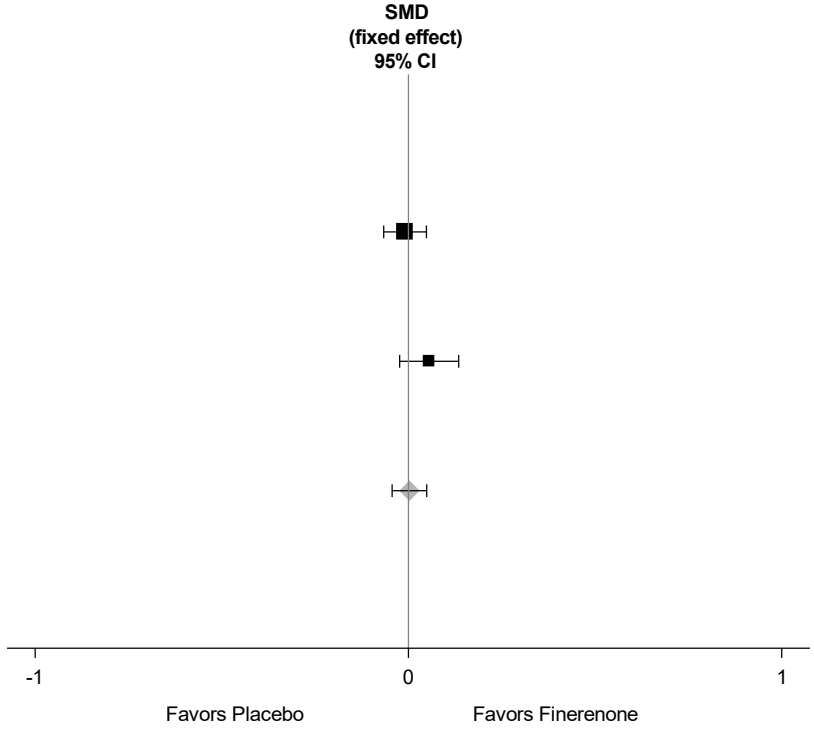
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2360	2333	65.6	0.04 [-0.01,0.10]	
FIGARO-DKD	1237	1223	34.4	0.01 [-0.07,0.09]	
Total	3597	3556		0.04 [0.00,0.09]	Z=1.78, p=0.0747
Heterogeneity:	Q=0.60 (df=1)	p=0.4369	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.3: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Mental Component Summary
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

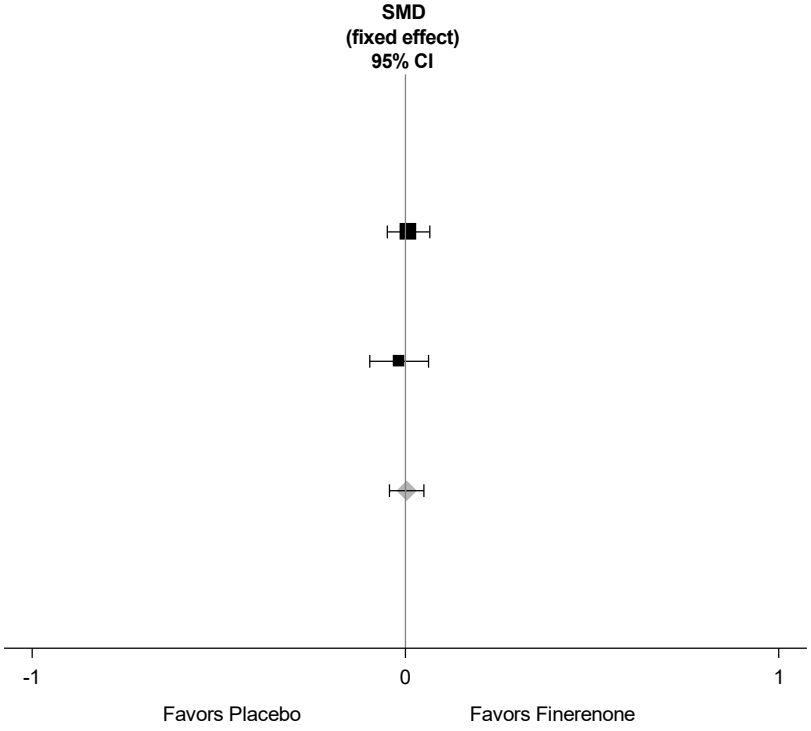
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2360	2333	65.6	-0.01 [-0.07,0.05]	
FIGARO-DKD	1237	1223	34.4	0.06 [-0.02,0.13]	
Total	3597	3556		0.00 [-0.04,0.05]	Z=0.11, p=0.9131
Heterogeneity:	Q=1.88 (df=1)	p=0.1701	I^2=46.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.4: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Burden of Kidney Disease
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

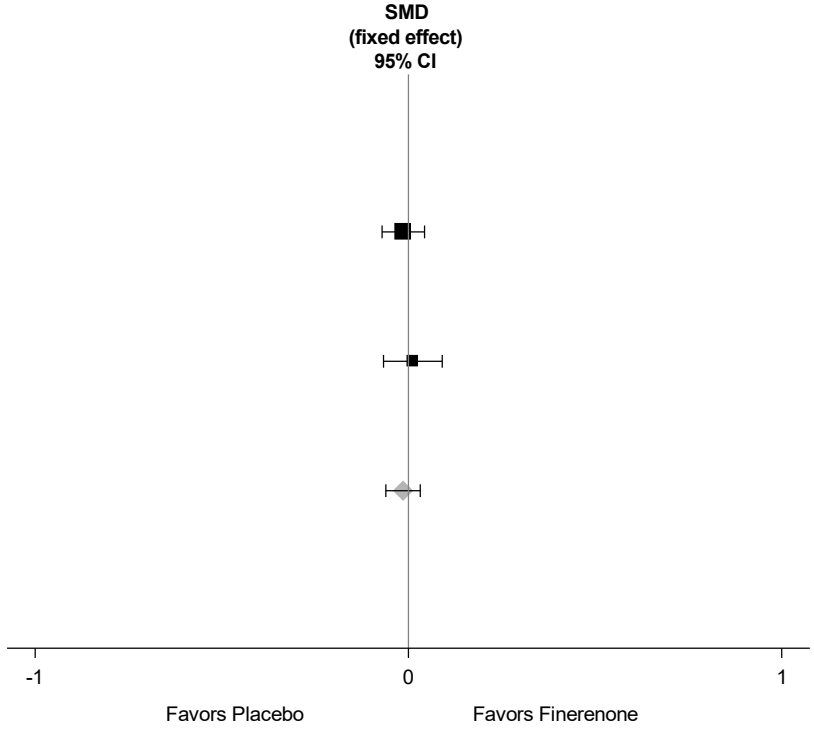
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2381	2361	65.6	0.01 [-0.05,0.07]	
FIGARO-DKD	1247	1236	34.4	-0.02 [-0.10,0.06]	
Total	3628	3597		0.00 [-0.04,0.05]	Z=0.14, p=0.8883
Heterogeneity:	Q=0.28 (df=1)	p=0.5957	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.5: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Symptoms and Problems
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

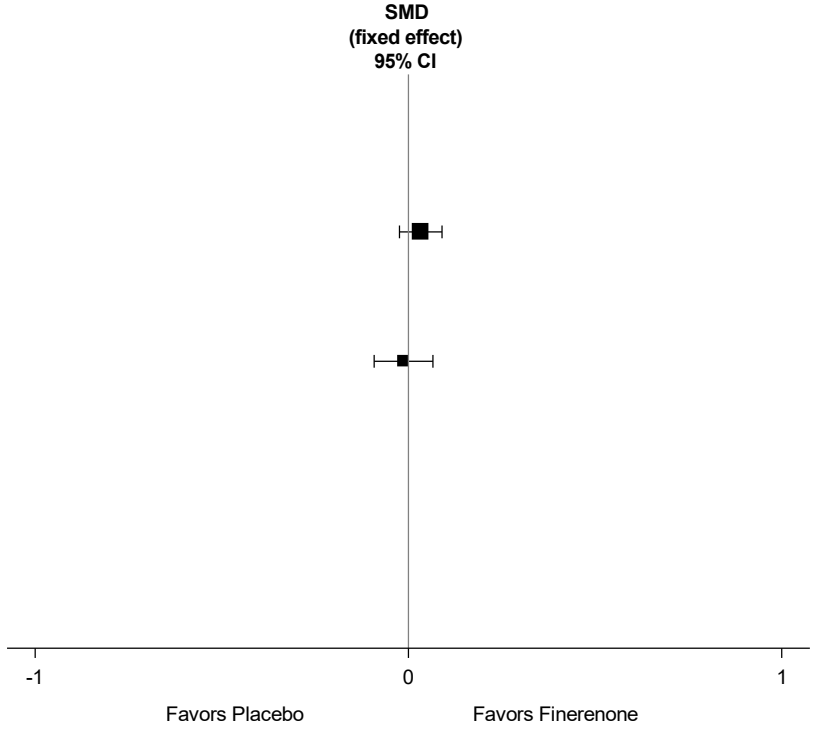
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2383	2366	65.6	-0.01 [-0.07,0.04]	
FIGARO-DKD	1248	1238	34.4	0.01 [-0.07,0.09]	
Total	3631	3604		-0.01 [-0.06,0.03]	Z=-0.61, p=0.5392
Heterogeneity:	Q=0.43 (df=1)	p=0.5115	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.1.6: KDQoL-36 - Forest Plot for MMRM of Change from Baseline of Effects of Kidney Disease on Daily Life
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

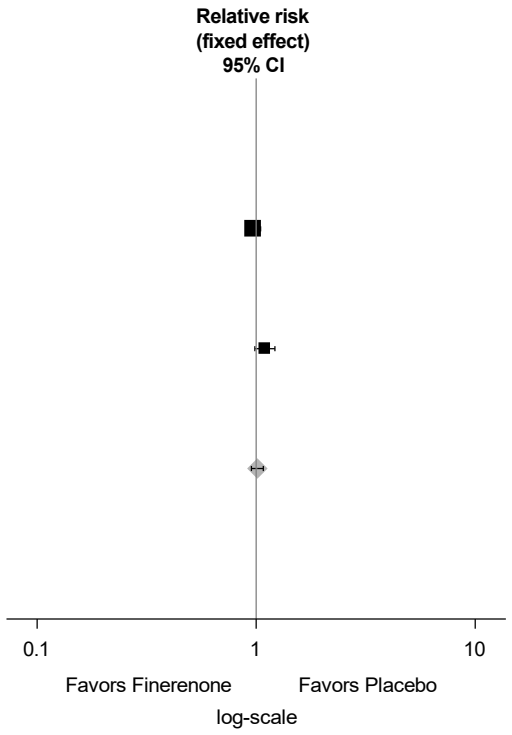
Subgroup Study	Finerenone + SoC N	Placebo + SoC N	Weight (%)	SMD (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2375	2358	65.6	0.03 [-0.02,0.09]	
FIGARO-DKD	1246	1236	34.4	-0.01 [-0.09,0.07]	
Total	3621	3594		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, KDQoL=Kidney Disease Quality of Life, MMRM=Mixed Model Repeated Measures, N=number of subjects, SMD=standardized mean difference, SoC=standard of care.
Note: SMD is estimated by Hedges g. For 'Total' this is estimated by a MIXED Model with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history, study, time, treatment*time, baseline value and baseline value*time as covariate using separate unstructured covariance patterns for each treatment group.
For FIDELIO-DKD and 'Total' Visits 5, 8, 11 were included in the model and for FIGARO-DKD additionally Visit 14.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

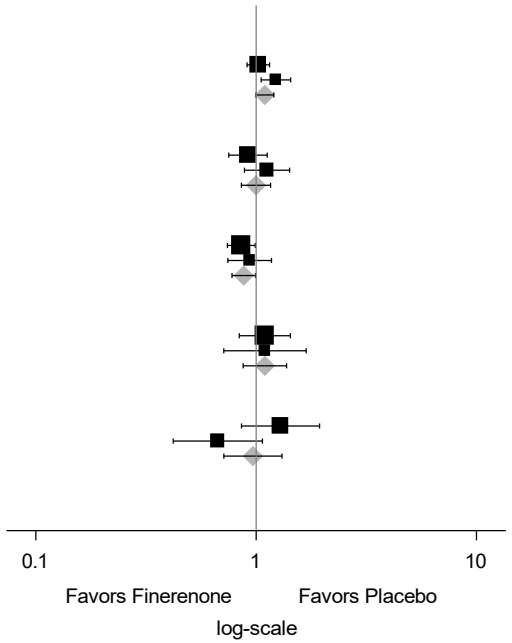
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	840 / 2622	865 / 2620	64.7	0.97 [0.90,1.05]	
FIGARO-DKD	480 / 1359	439 / 1362	35.3	1.10 [0.99,1.22]	
Total	1320 / 3981	1304 / 3982		1.01 [0.95,1.08]	Z=0.39, p=0.6980
Heterogeneity:	Q=3.36 (df=1)	p=0.0667	I^2=70.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.1.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

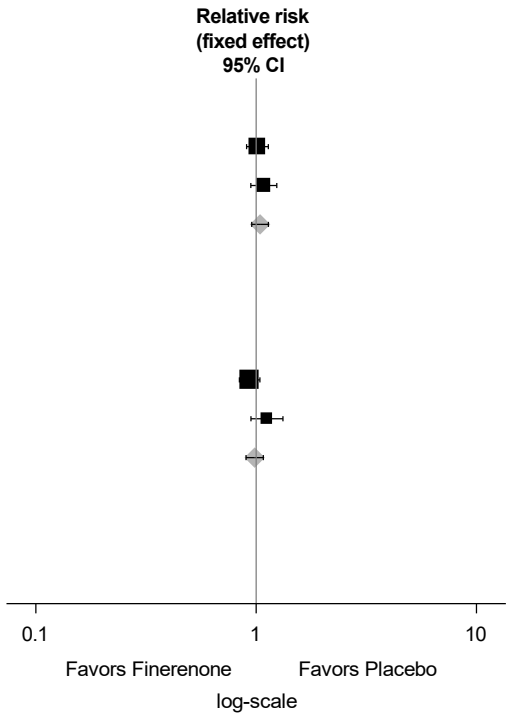
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	372 / 1078	359 / 1064	63.1	1.02 [0.91,1.15]	
FIGARO-DKD	240 / 640	195 / 639	36.9	1.23 [1.05,1.43]	
Total	612 / 1718	554 / 1703		1.10 [1.00,1.20]	Z=1.90, p=0.0568
Heterogeneity:	Q=3.45 (df=1)	p=0.0633	I^2=71.0%		
North America					
FIDELIO-DKD	125 / 425	140 / 437	58.0	0.92 [0.75,1.12]	
FIGARO-DKD	96 / 267	87 / 271	42.0	1.12 [0.88,1.42]	
Total	221 / 692	227 / 708		1.00 [0.86,1.16]	Z=-0.02, p=0.9804
Heterogeneity:	Q=1.58 (df=1)	p=0.2084	I^2=36.8%		
Asia					
FIDELIO-DKD	227 / 751	264 / 748	71.0	0.86 [0.74,0.99]	
FIGARO-DKD	94 / 288	102 / 292	29.0	0.93 [0.74,1.17]	
Total	321 / 1039	366 / 1040		0.88 [0.78,0.99]	Z=-2.07, p=0.0382
Heterogeneity:	Q=0.40 (df=1)	p=0.5281	I^2=0.0%		
Latin America					
FIDELIO-DKD	81 / 274	74 / 274	72.2	1.09 [0.84,1.43]	
FIGARO-DKD	31 / 102	28 / 101	27.8	1.10 [0.71,1.69]	
Total	112 / 376	102 / 375		1.10 [0.87,1.37]	Z=0.78, p=0.4328
Heterogeneity:	Q=0.00 (df=1)	p=0.9952	I^2=0.0%		
Others					
FIDELIO-DKD	35 / 94	28 / 97	56.6	1.29 [0.86,1.94]	
FIGARO-DKD	19 / 62	27 / 59	43.4	0.67 [0.42,1.07]	
Total	54 / 156	55 / 156		0.97 [0.71,1.31]	Z=-0.22, p=0.8265
Heterogeneity:	Q=4.30 (df=1)	p=0.0381	I^2=76.8%		
Subgroup Heterogeneity:	Q=8.44 (df=4)	p=0.0766	I^2=52.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.1.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

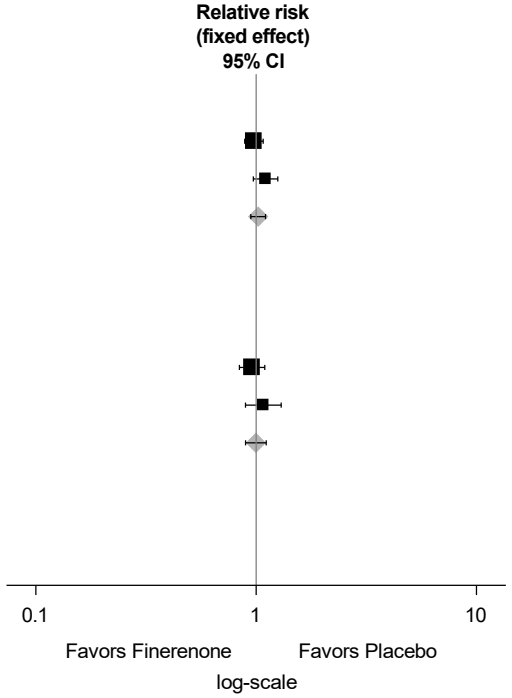
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	402 / 1215	396 / 1213	58.7	1.01 [0.90,1.14]	
FIGARO-DKD	295 / 865	268 / 851	41.3	1.08 [0.95,1.24]	
Total	697 / 2080	664 / 2064		1.04 [0.95,1.14]	Z=0.92, p=0.3589
Heterogeneity:	Q=0.54 (df=1)	p=0.4630	I^2=0.0%		
Absent					
FIDELIO-DKD	438 / 1407	469 / 1407	70.8	0.93 [0.84,1.04]	
FIGARO-DKD	185 / 494	171 / 511	29.2	1.12 [0.95,1.32]	
Total	623 / 1901	640 / 1918		0.98 [0.90,1.08]	Z=-0.34, p=0.7345
Heterogeneity:	Q=3.19 (df=1)	p=0.0742	I^2=68.6%		
Subgroup Heterogeneity:	Q=0.78 (df=1)	p=0.3782	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.1.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

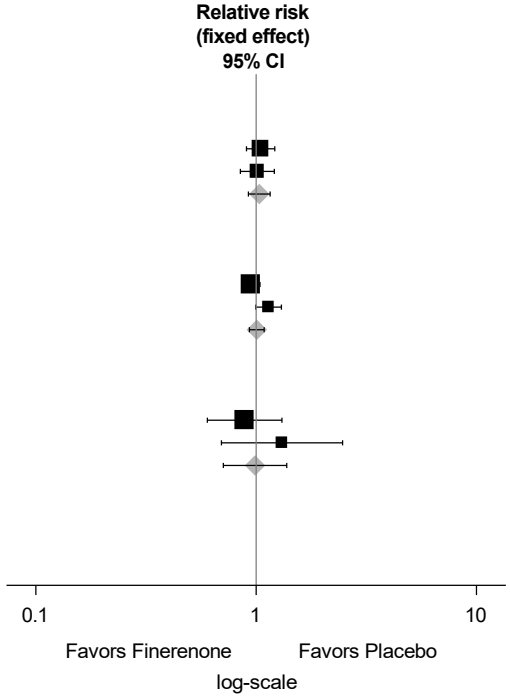
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	557 / 1737	559 / 1703	63.7	0.98 [0.89,1.08]	
FIGARO-DKD	327 / 924	299 / 932	36.3	1.10 [0.97,1.25]	
Total	884 / 2661	858 / 2635		1.02 [0.95,1.10]	Z=0.53, p=0.5957
Heterogeneity:	Q=2.21 (df=1)	p=0.1368	I^2=54.8%		
> 4.5					
FIDELIO-DKD	283 / 884	306 / 916	66.4	0.96 [0.84,1.09]	
FIGARO-DKD	153 / 435	140 / 429	33.6	1.08 [0.89,1.30]	
Total	436 / 1319	446 / 1345		1.00 [0.89,1.11]	Z=-0.06, p=0.9554
Heterogeneity:	Q=1.01 (df=1)	p=0.3142	I^2=1.3%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7237	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.1.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

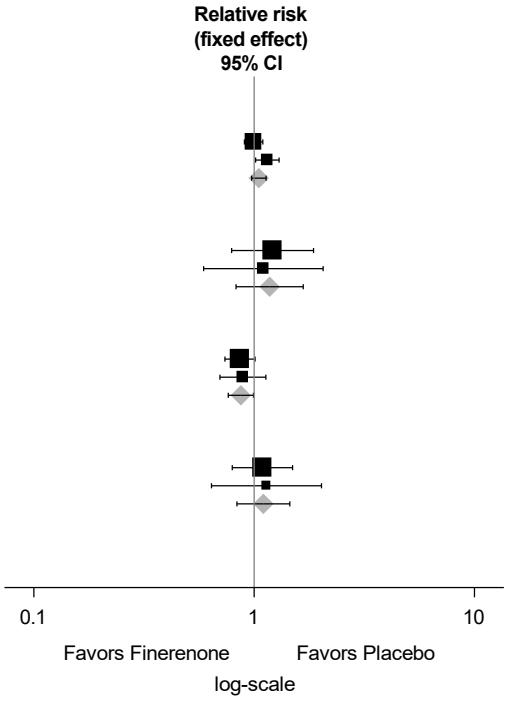
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	242 / 724	231 / 724	59.0	1.05 [0.90,1.21]	
FIGARO-DKD	164 / 494	163 / 497	41.0	1.01 [0.85,1.21]	
Total	406 / 1218	394 / 1221		1.03 [0.92,1.16]	Z=0.56, p=0.5758
Heterogeneity:	Q=0.08 (df=1)	p=0.7707	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	563 / 1762	596 / 1766	66.8	0.95 [0.86,1.04]	
FIGARO-DKD	302 / 831	265 / 830	33.2	1.14 [1.00,1.30]	
Total	865 / 2593	861 / 2596		1.01 [0.93,1.09]	Z=0.17, p=0.8677
Heterogeneity:	Q=4.85 (df=1)	p=0.0277	I^2=79.4%		
>= 160					
FIDELIO-DKD	35 / 133	38 / 128	72.5	0.89 [0.60,1.31]	
FIGARO-DKD	14 / 34	11 / 35	27.5	1.31 [0.70,2.47]	
Total	49 / 167	49 / 163		0.99 [0.71,1.38]	Z=-0.07, p=0.9438
Heterogeneity:	Q=1.06 (df=1)	p=0.3030	I^2=5.7%		
Subgroup Heterogeneity:	Q=0.16 (df=2)	p=0.9229	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.1.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

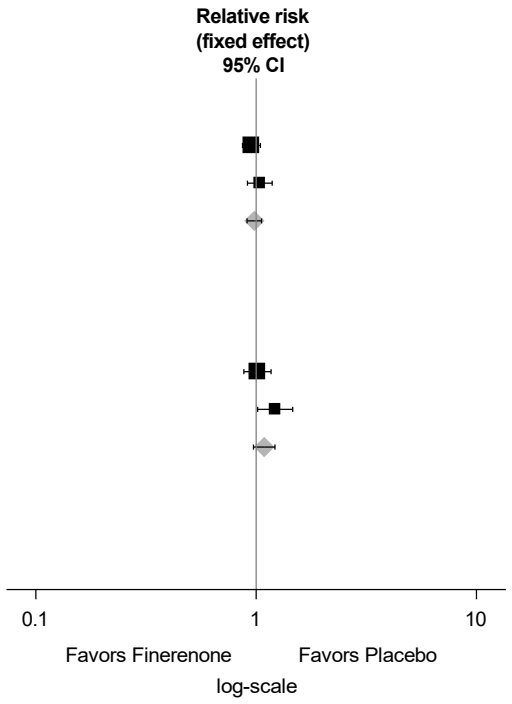
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	547 / 1637	559 / 1663	61.9	0.99 [0.90,1.09]	
FIGARO-DKD	368 / 1013	314 / 992	38.1	1.15 [1.02,1.30]	
Total	915 / 2650	873 / 2655		1.05 [0.97,1.13]	Z=1.27, p=0.2034
Heterogeneity:	Q=3.27 (df=1)	p=0.0705	I^2=69.4%		
Black					
FIDELIO-DKD	37 / 130	27 / 115	68.1	1.21 [0.79,1.86]	
FIGARO-DKD	12 / 43	18 / 71	31.9	1.10 [0.59,2.06]	
Total	49 / 173	45 / 186		1.18 [0.83,1.67]	Z=0.90, p=0.3670
Heterogeneity:	Q=0.06 (df=1)	p=0.8028	I^2=0.0%		
Asian					
FIDELIO-DKD	198 / 678	230 / 679	69.9	0.86 [0.74,1.01]	
FIGARO-DKD	82 / 251	93 / 253	30.1	0.89 [0.70,1.13]	
Total	280 / 929	323 / 932		0.87 [0.76,0.99]	Z=-2.07, p=0.0382
Heterogeneity:	Q=0.04 (df=1)	p=0.8356	I^2=0.0%		
Others					
FIDELIO-DKD	58 / 177	49 / 163	76.9	1.09 [0.80,1.49]	
FIGARO-DKD	18 / 52	14 / 46	23.1	1.14 [0.64,2.02]	
Total	76 / 229	63 / 209		1.10 [0.84,1.45]	Z=0.68, p=0.4955
Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.04 (df=3)	p=0.0705	I^2=57.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.1.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

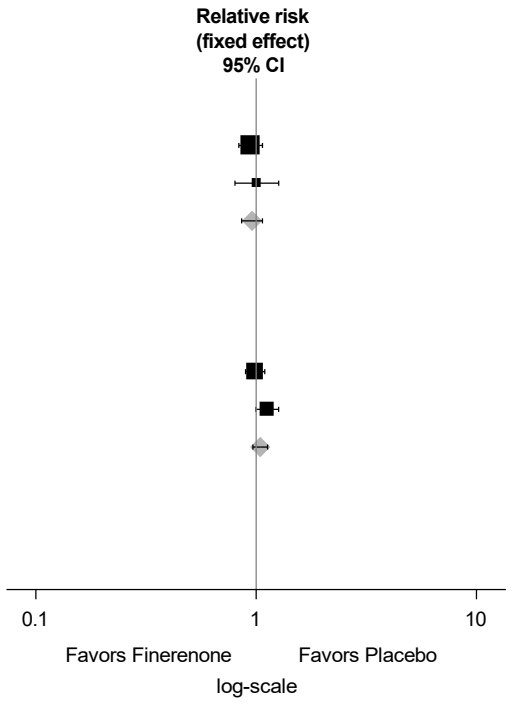
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	569 / 1800	623 / 1876	65.7	0.95 [0.87,1.05]	
FIGARO-DKD	310 / 917	305 / 937	34.3	1.04 [0.91,1.18]	
Total	879 / 2717	928 / 2813		0.98 [0.91,1.06]	Z=-0.50, p=0.6153
Heterogeneity:	Q=1.15 (df=1)	p=0.2842	I^2=12.8%		
Female					
FIDELIO-DKD	271 / 822	242 / 744	62.4	1.01 [0.88,1.17]	
FIGARO-DKD	170 / 442	134 / 425	37.6	1.22 [1.02,1.47]	
Total	441 / 1264	376 / 1169		1.09 [0.97,1.22]	Z=1.46, p=0.1431
Heterogeneity:	Q=2.45 (df=1)	p=0.1173	I^2=59.2%		
Subgroup Heterogeneity:	Q=2.24 (df=1)	p=0.1349	I^2=55.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.1.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

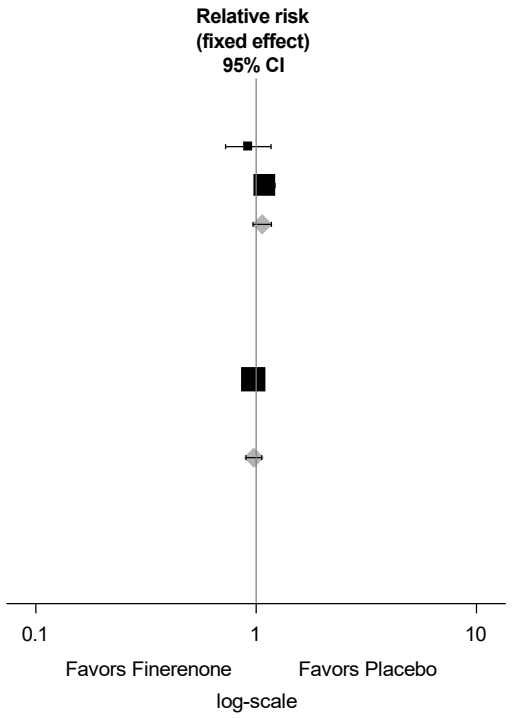
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	339 / 1106	350 / 1078	77.3	0.94 [0.83,1.07]	
FIGARO-DKD	103 / 337	102 / 336	22.7	1.01 [0.80,1.27]	
Total	442 / 1443	452 / 1414		0.96 [0.86,1.07]	Z=-0.78, p=0.4381
Heterogeneity:	Q=0.24 (df=1)	p=0.6270	I^2=0.0%		
>= 65					
FIDELIO-DKD	501 / 1516	515 / 1542	58.2	0.99 [0.89,1.09]	
FIGARO-DKD	377 / 1022	337 / 1026	41.8	1.12 [1.00,1.26]	
Total	878 / 2538	852 / 2568		1.04 [0.97,1.13]	Z=1.09, p=0.2779
Heterogeneity:	Q=2.55 (df=1)	p=0.1105	I^2=60.7%		
Subgroup Heterogeneity:	Q=1.59 (df=1)	p=0.2080	I^2=36.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.1.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

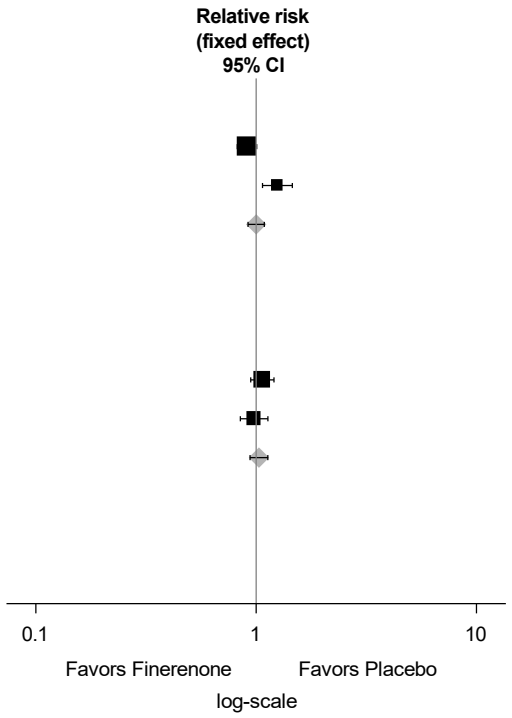
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	79 / 210	87 / 213	16.4	0.92 [0.73,1.17]	
FIGARO-DKD	480 / 1359	439 / 1362	83.6	1.10 [0.99,1.22]	
Total	559 / 1569	526 / 1575		1.06 [0.97,1.17]	Z=1.28, p=0.2003
Heterogeneity:	Q=1.72 (df=1)	p=0.1901	I^2=41.8%		
Very High					
FIDELIO-DKD	761 / 2412	778 / 2407	100.0	0.98 [0.90,1.06]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	761 / 2412	778 / 2407		0.98 [0.90,1.06]	Z=-0.57, p=0.5656
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.81 (df=1)	p=0.1781	I^2=44.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.1.9: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

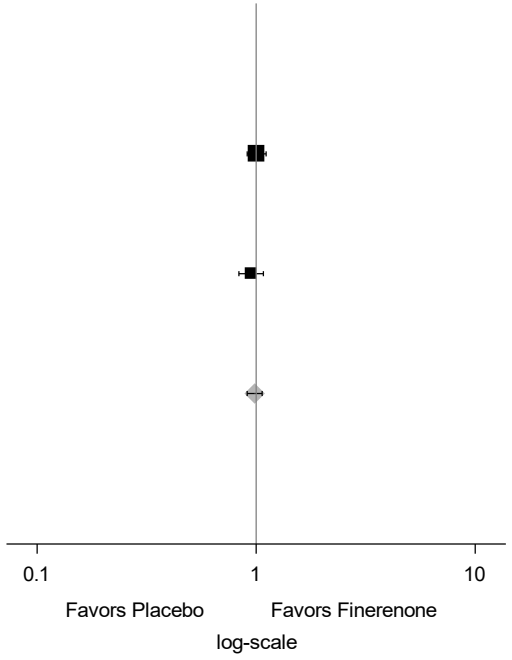
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	480 / 1559	525 / 1549	70.1	0.91 [0.82,1.01]	
FIGARO-DKD	239 / 639	189 / 631	29.9	1.25 [1.07,1.46]	
Total	719 / 2198	714 / 2180		1.00 [0.92,1.09]	Z=0.00, p=0.9989
Heterogeneity:	Q=11.22 (df=1)	p=0.0008	I^2=91.1%		
45 - < 60					
FIDELIO-DKD	360 / 1063	340 / 1071	58.4	1.07 [0.94,1.20]	
FIGARO-DKD	241 / 720	250 / 731	41.6	0.98 [0.85,1.13]	
Total	601 / 1783	590 / 1802		1.03 [0.94,1.13]	Z=0.61, p=0.5430
Heterogeneity:	Q=0.80 (df=1)	p=0.3700	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6544	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

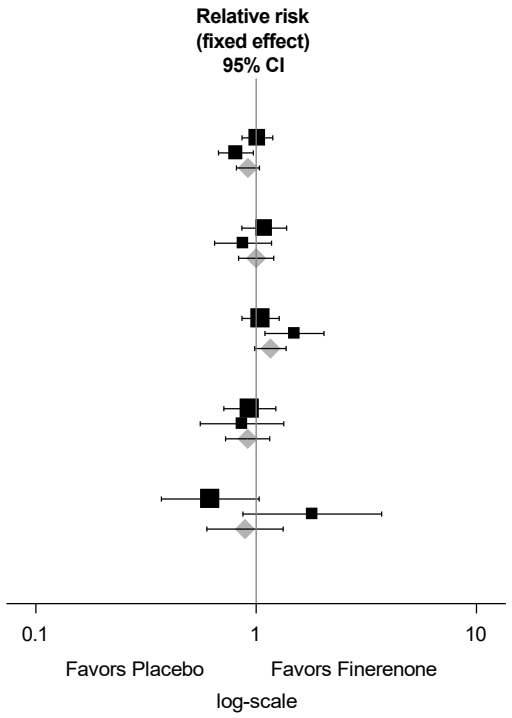
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	600 / 2622	597 / 2620	62.7	1.01 [0.91,1.11]	
FIGARO-DKD	337 / 1359	354 / 1362	37.3	0.95 [0.83,1.08]	
Total	937 / 3981	951 / 3982		0.98 [0.91,1.06]	Z=-0.40, p=0.6911
Heterogeneity:	Q=0.49 (df=1)	p=0.4841	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.2.1: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

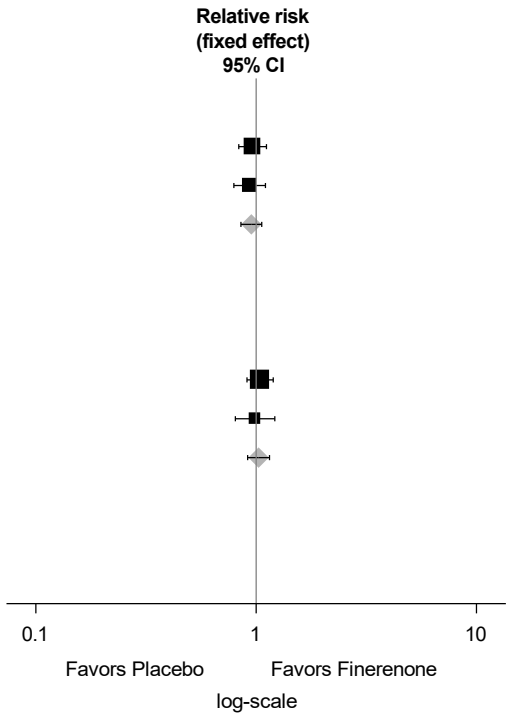
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	236 / 1078	230 / 1064	56.2	1.01 [0.86,1.19]	
FIGARO-DKD	154 / 640	190 / 639	43.8	0.81 [0.67,0.97]	
Total	390 / 1718	420 / 1703		0.92 [0.81,1.03]	Z=-1.40, p=0.1605
Heterogeneity:	Q=3.28 (df=1)	p=0.0702	I^2=69.5%		
North America					
FIDELIO-DKD	109 / 425	103 / 437	61.8	1.09 [0.86,1.37]	
FIGARO-DKD	61 / 267	71 / 271	38.2	0.87 [0.65,1.17]	
Total	170 / 692	174 / 708		1.00 [0.83,1.20]	Z=-0.00, p=0.9970
Heterogeneity:	Q=1.31 (df=1)	p=0.2515	I^2=23.9%		
Asia					
FIDELIO-DKD	164 / 751	156 / 748	71.6	1.05 [0.86,1.27]	
FIGARO-DKD	78 / 288	53 / 292	28.4	1.49 [1.10,2.03]	
Total	242 / 1039	209 / 1040		1.16 [0.99,1.37]	Z=1.78, p=0.0748
Heterogeneity:	Q=3.62 (df=1)	p=0.0570	I^2=72.4%		
Latin America					
FIDELIO-DKD	73 / 274	78 / 274	72.1	0.94 [0.71,1.23]	
FIGARO-DKD	27 / 102	31 / 101	27.9	0.86 [0.56,1.33]	
Total	100 / 376	109 / 375		0.91 [0.73,1.15]	Z=-0.76, p=0.4487
Heterogeneity:	Q=0.10 (df=1)	p=0.7553	I^2=0.0%		
Others					
FIDELIO-DKD	18 / 94	30 / 97	66.8	0.62 [0.37,1.03]	
FIGARO-DKD	17 / 62	9 / 59	33.2	1.80 [0.87,3.71]	
Total	35 / 156	39 / 156		0.89 [0.60,1.33]	Z=-0.57, p=0.5663
Heterogeneity:	Q=5.55 (df=1)	p=0.0185	I^2=82.0%		
Subgroup Heterogeneity:	Q=5.86 (df=4)	p=0.2102	I^2=31.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2.2: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

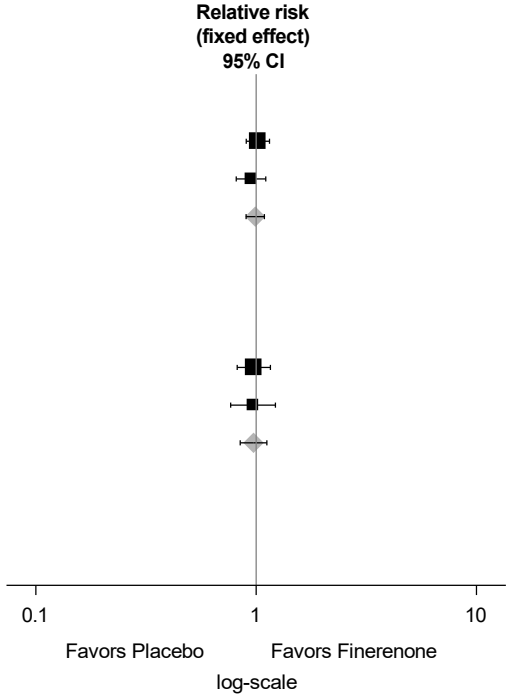
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	277 / 1215	287 / 1213	56.5	0.96 [0.83,1.11]	
FIGARO-DKD	207 / 865	218 / 851	43.5	0.93 [0.79,1.10]	
Total	484 / 2080	505 / 2064		0.95 [0.85,1.06]	Z=-0.91, p=0.3621
Heterogeneity:	Q=0.08 (df=1)	p=0.7820	I^2=0.0%		
Absent					
FIDELIO-DKD	323 / 1407	310 / 1407	69.3	1.04 [0.91,1.20]	
FIGARO-DKD	130 / 494	136 / 511	30.7	0.99 [0.80,1.22]	
Total	453 / 1901	446 / 1918		1.03 [0.91,1.15]	Z=0.43, p=0.6678
Heterogeneity:	Q=0.17 (df=1)	p=0.6785	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.88 (df=1)	p=0.3475	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2.3: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

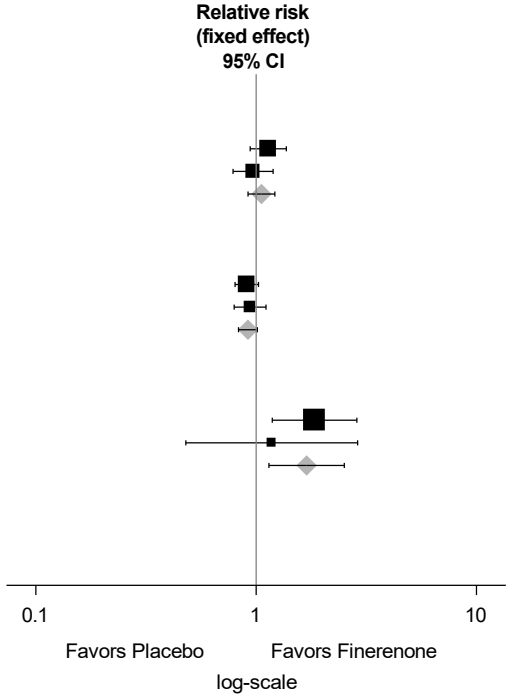
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	407 / 1737	392 / 1703	61.7	1.02 [0.90,1.15]	
FIGARO-DKD	232 / 924	247 / 932	38.3	0.95 [0.81,1.11]	
Total	639 / 2661	639 / 2635		0.99 [0.90,1.09]	Z=-0.20, p=0.8420
Heterogeneity:	Q=0.51 (df=1)	p=0.4738	I^2=0.0%		
> 4.5					
FIDELIO-DKD	193 / 884	205 / 916	64.5	0.98 [0.82,1.16]	
FIGARO-DKD	105 / 435	107 / 429	35.5	0.97 [0.77,1.22]	
Total	298 / 1319	312 / 1345		0.97 [0.85,1.12]	Z=-0.39, p=0.6979
Heterogeneity:	Q=0.00 (df=1)	p=0.9571	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8355	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2.4: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

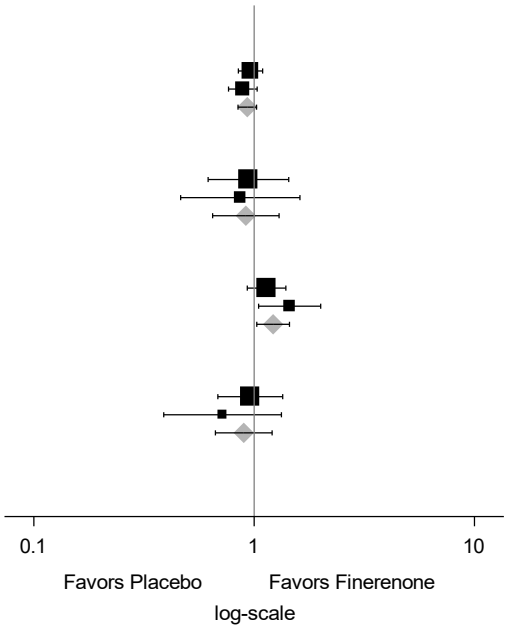
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	177 / 724	156 / 724	55.1	1.13 [0.94,1.37]	
FIGARO-DKD	127 / 494	132 / 497	44.9	0.97 [0.79,1.19]	
Total	304 / 1218	288 / 1221		1.06 [0.92,1.22]	Z=0.77, p=0.4410
Heterogeneity:	Q=1.22 (df=1)	p=0.2697	I^2=17.9%		
130 - < 160					
FIDELIO-DKD	378 / 1762	418 / 1766	64.8	0.91 [0.80,1.02]	
FIGARO-DKD	202 / 831	215 / 830	35.2	0.94 [0.79,1.11]	
Total	580 / 2593	633 / 2596		0.92 [0.83,1.01]	Z=-1.71, p=0.0869
Heterogeneity:	Q=0.11 (df=1)	p=0.7415	I^2=0.0%		
>= 160					
FIDELIO-DKD	44 / 133	23 / 128	80.5	1.84 [1.18,2.86]	
FIGARO-DKD	8 / 34	7 / 35	19.5	1.18 [0.48,2.89]	
Total	52 / 167	30 / 163		1.69 [1.14,2.51]	Z=2.62, p=0.0087
Heterogeneity:	Q=0.77 (df=1)	p=0.3803	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.24 (df=2)	p=0.0060	I^2=80.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2.5: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

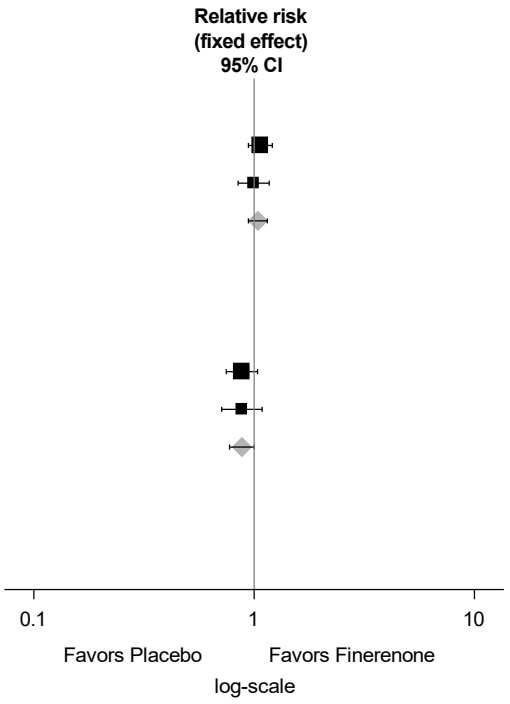
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	360 / 1637	380 / 1663	58.1	0.96 [0.85,1.09]	
FIGARO-DKD	244 / 1013	269 / 992	41.9	0.89 [0.76,1.03]	
Total	604 / 2650	649 / 2655		0.93 [0.84,1.03]	Z=-1.46, p=0.1451
Heterogeneity:	Q=0.64 (df=1)	p=0.4231	I^2=0.0%		
Black					
FIDELIO-DKD	33 / 130	31 / 115	68.7	0.94 [0.62,1.43]	
FIGARO-DKD	11 / 43	21 / 71	31.3	0.86 [0.46,1.61]	
Total	44 / 173	52 / 186		0.92 [0.65,1.30]	Z=-0.49, p=0.6233
Heterogeneity:	Q=0.05 (df=1)	p=0.8246	I^2=0.0%		
Asian					
FIDELIO-DKD	158 / 678	139 / 679	72.1	1.14 [0.93,1.39]	
FIGARO-DKD	69 / 251	48 / 253	27.9	1.45 [1.05,2.00]	
Total	227 / 929	187 / 932		1.22 [1.03,1.45]	Z=2.27, p=0.0231
Heterogeneity:	Q=1.53 (df=1)	p=0.2156	I^2=34.8%		
Others					
FIDELIO-DKD	49 / 177	47 / 163	76.7	0.96 [0.68,1.35]	
FIGARO-DKD	13 / 52	16 / 46	23.3	0.72 [0.39,1.33]	
Total	62 / 229	63 / 209		0.90 [0.67,1.21]	Z=-0.72, p=0.4717
Heterogeneity:	Q=0.65 (df=1)	p=0.4190	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.84 (df=3)	p=0.0493	I^2=61.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.2.6: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

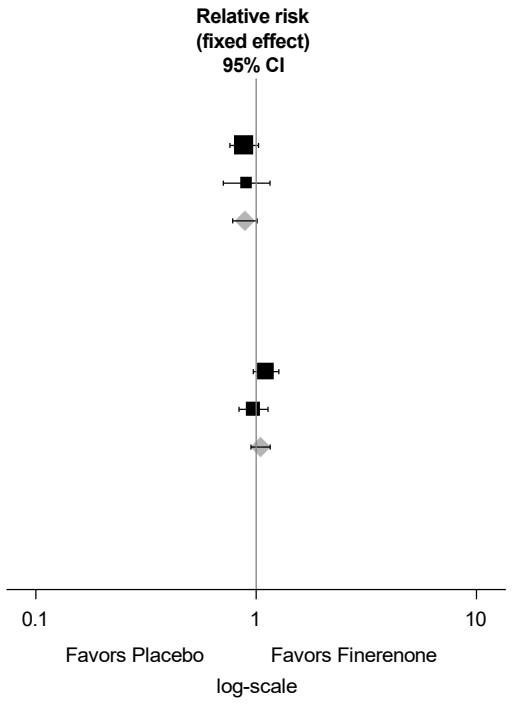
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	393 / 1800	384 / 1876	62.8	1.07 [0.94,1.21]	
FIGARO-DKD	219 / 917	225 / 937	37.2	0.99 [0.85,1.17]	
Total	612 / 2717	609 / 2813		1.04 [0.94,1.15]	Z=0.76, p=0.4459
Heterogeneity:	Q=0.45 (df=1)	p=0.5030	I^2=0.0%		
Female					
FIDELIO-DKD	207 / 822	213 / 744	62.5	0.88 [0.75,1.04]	
FIGARO-DKD	118 / 442	129 / 425	37.5	0.88 [0.71,1.09]	
Total	325 / 1264	342 / 1169		0.88 [0.77,1.00]	Z=-1.94, p=0.0518
Heterogeneity:	Q=0.00 (df=1)	p=0.9996	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.03 (df=1)	p=0.0447	I^2=75.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.2.7: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

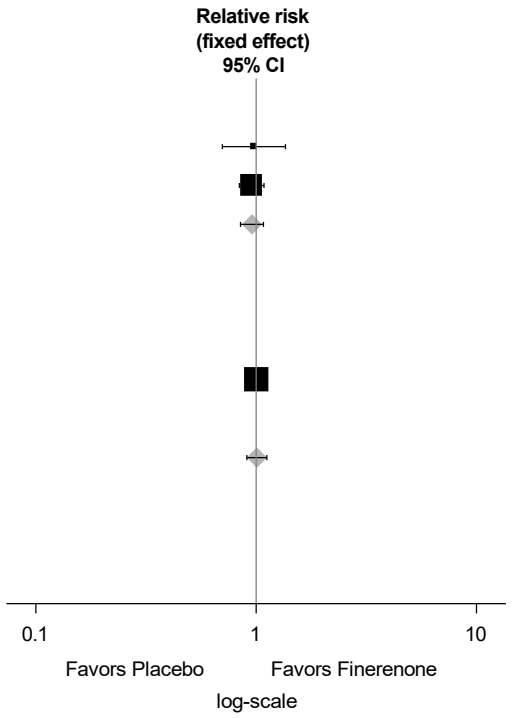
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	249 / 1106	275 / 1078	72.7	0.88 [0.76,1.02]	
FIGARO-DKD	89 / 337	98 / 336	27.3	0.91 [0.71,1.16]	
Total	338 / 1443	373 / 1414		0.89 [0.78,1.01]	Z=-1.81, p=0.0698
Heterogeneity:	Q=0.03 (df=1)	p=0.8605	I^2=0.0%		
>= 65					
FIDELIO-DKD	351 / 1516	322 / 1542	56.3	1.11 [0.97,1.27]	
FIGARO-DKD	248 / 1022	256 / 1026	43.7	0.97 [0.84,1.13]	
Total	599 / 2538	578 / 2568		1.05 [0.95,1.16]	Z=0.90, p=0.3682
Heterogeneity:	Q=1.62 (df=1)	p=0.2036	I^2=38.1%		
Subgroup Heterogeneity:	Q=3.93 (df=1)	p=0.0475	I^2=74.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.2.8: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

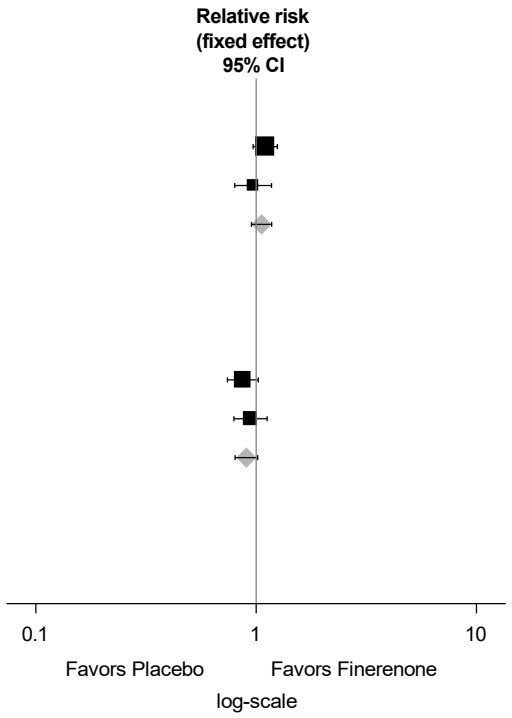
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	52 / 210	54 / 213	13.3	0.98 [0.70,1.36]	
FIGARO-DKD	337 / 1359	354 / 1362	86.7	0.95 [0.84,1.09]	
Total	389 / 1569	408 / 1575		0.96 [0.85,1.08]	Z=-0.72, p=0.4734
Heterogeneity:	Q=0.02 (df=1)	p=0.8967	I^2=0.0%		
Very High					
FIDELIO-DKD	548 / 2412	543 / 2407	100.0	1.01 [0.91,1.12]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	548 / 2412	543 / 2407		1.01 [0.91,1.12]	Z=0.13, p=0.8941
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.39 (df=1)	p=0.5298	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.2.9: EQ-5D VAS - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

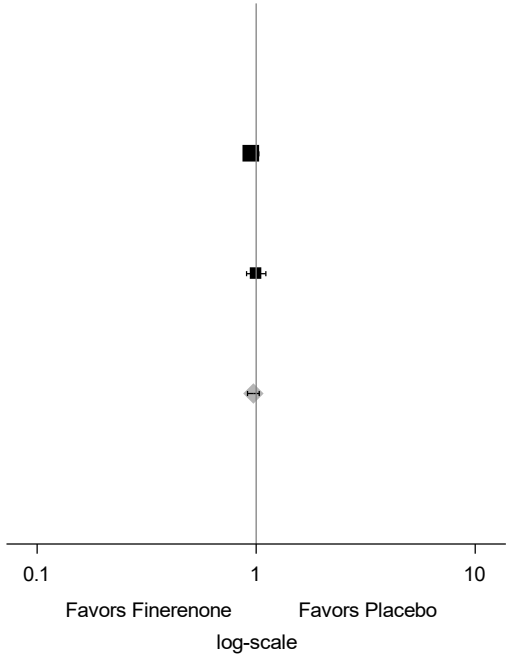
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	385 / 1559	348 / 1549	69.7	1.10 [0.97,1.25]	
FIGARO-DKD	155 / 639	158 / 631	30.3	0.97 [0.80,1.17]	
Total	540 / 2198	506 / 2180		1.06 [0.95,1.18]	Z=1.04, p=0.2962
Heterogeneity:	Q=1.16 (df=1)	p=0.2823	I^2=13.5%		
45 - < 60					
FIDELIO-DKD	215 / 1063	249 / 1071	53.6	0.87 [0.74,1.02]	
FIGARO-DKD	182 / 720	196 / 731	46.4	0.94 [0.79,1.12]	
Total	397 / 1783	445 / 1802		0.90 [0.80,1.02]	Z=-1.69, p=0.0906
Heterogeneity:	Q=0.44 (df=1)	p=0.5064	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.83 (df=1)	p=0.0503	I^2=73.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

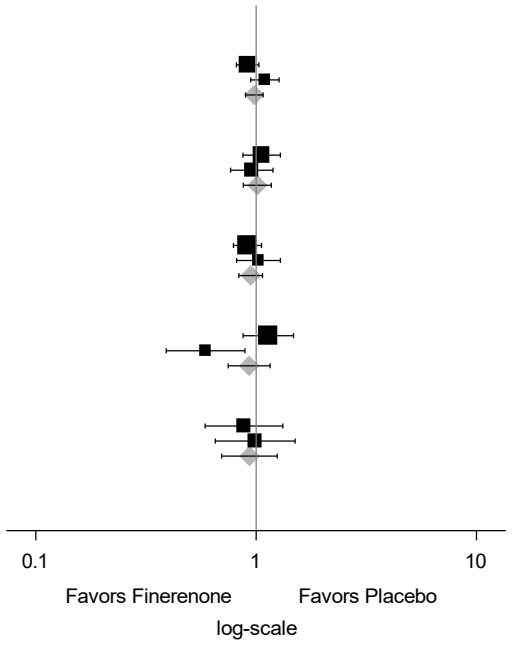
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	836 / 2622	876 / 2620	63.0	0.95 [0.88,1.03]	
FIGARO-DKD	482 / 1359	482 / 1362	37.0	1.00 [0.90,1.11]	
Total	1318 / 3981	1358 / 3982		0.97 [0.91,1.03]	Z=-0.94, p=0.3498
Heterogeneity:	Q=0.60 (df=1)	p=0.4405	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.3.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

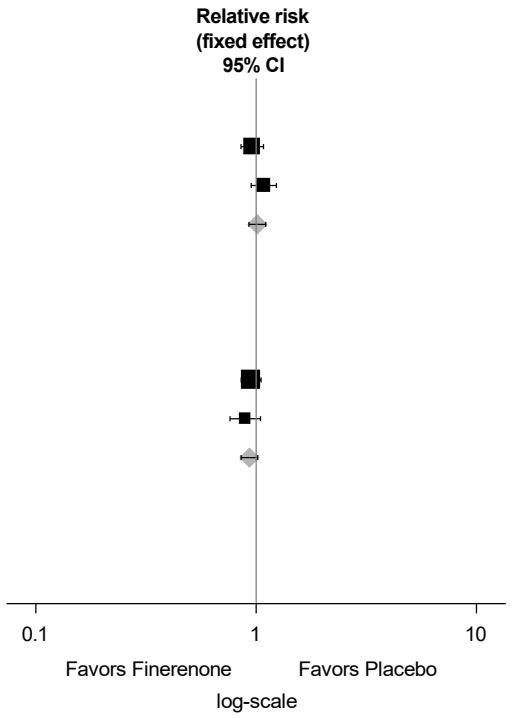
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	353 / 1078	381 / 1064	61.4	0.91 [0.81,1.03]	
FIGARO-DKD	237 / 640	216 / 639	38.6	1.10 [0.94,1.27]	
Total	590 / 1718	597 / 1703		0.98 [0.89,1.07]	Z=-0.42, p=0.6741
Heterogeneity:	Q=3.50 (df=1)	p=0.0612	I^2=71.5%		
North America					
FIDELIO-DKD	139 / 425	135 / 437	56.2	1.06 [0.87,1.29]	
FIGARO-DKD	96 / 267	102 / 271	43.8	0.96 [0.77,1.19]	
Total	235 / 692	237 / 708		1.01 [0.87,1.17]	Z=0.16, p=0.8725
Heterogeneity:	Q=0.46 (df=1)	p=0.4955	I^2=0.0%		
Asia					
FIDELIO-DKD	231 / 751	252 / 748	70.8	0.91 [0.79,1.06]	
FIGARO-DKD	98 / 288	97 / 292	29.2	1.02 [0.81,1.29]	
Total	329 / 1039	349 / 1040		0.94 [0.83,1.07]	Z=-0.91, p=0.3628
Heterogeneity:	Q=0.69 (df=1)	p=0.4069	I^2=0.0%		
Latin America					
FIDELIO-DKD	84 / 274	74 / 274	70.9	1.14 [0.87,1.48]	
FIGARO-DKD	25 / 102	42 / 101	29.1	0.59 [0.39,0.89]	
Total	109 / 376	116 / 375		0.93 [0.75,1.16]	Z=-0.66, p=0.5092
Heterogeneity:	Q=6.91 (df=1)	p=0.0086	I^2=85.5%		
Others					
FIDELIO-DKD	29 / 94	34 / 97	51.4	0.88 [0.59,1.32]	
FIGARO-DKD	26 / 62	25 / 59	48.6	0.99 [0.65,1.50]	
Total	55 / 156	59 / 156		0.93 [0.70,1.25]	Z=-0.48, p=0.6334
Heterogeneity:	Q=0.16 (df=1)	p=0.6931	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.78 (df=4)	p=0.9410	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

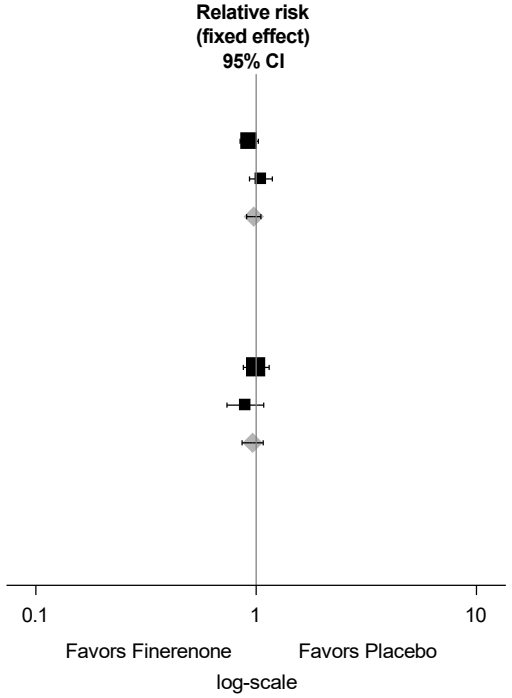
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	374 / 1215	389 / 1213	55.8	0.96 [0.85,1.08]	
FIGARO-DKD	306 / 865	278 / 851	44.2	1.08 [0.95,1.24]	
Total	680 / 2080	667 / 2064		1.01 [0.93,1.11]	Z=0.28, p=0.7809
Heterogeneity:	Q=1.79 (df=1)	p=0.1810	I^2=44.1%		
Absent					
FIDELIO-DKD	462 / 1407	487 / 1407	70.2	0.95 [0.86,1.05]	
FIGARO-DKD	176 / 494	204 / 511	29.8	0.89 [0.76,1.05]	
Total	638 / 1901	691 / 1918		0.93 [0.85,1.02]	Z=-1.60, p=0.1094
Heterogeneity:	Q=0.40 (df=1)	p=0.5285	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.75 (df=1)	p=0.1855	I^2=43.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

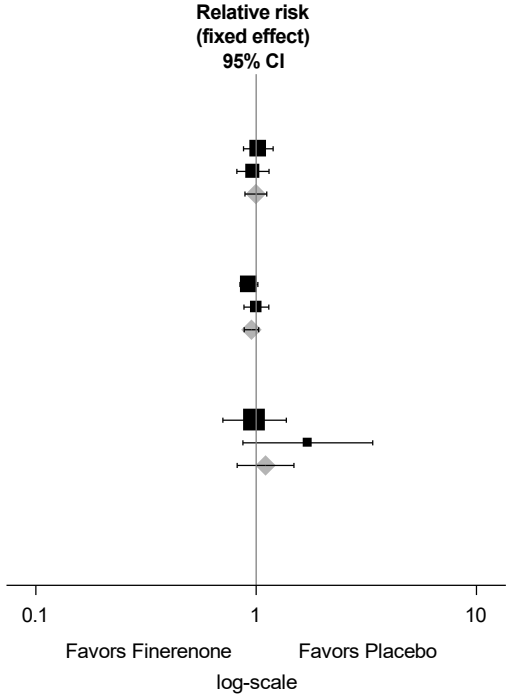
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	553 / 1737	583 / 1703	61.1	0.93 [0.85,1.02]	
FIGARO-DKD	348 / 924	334 / 932	38.9	1.05 [0.93,1.18]	
Total	901 / 2661	917 / 2635		0.98 [0.91,1.05]	Z=-0.66, p=0.5090
Heterogeneity:	Q=2.46 (df=1)	p=0.1166	I^2=59.4%		
> 4.5					
FIDELIO-DKD	283 / 884	293 / 916	67.0	1.00 [0.87,1.15]	
FIGARO-DKD	134 / 435	148 / 429	33.0	0.89 [0.74,1.08]	
Total	417 / 1319	441 / 1345		0.96 [0.86,1.08]	Z=-0.66, p=0.5118
Heterogeneity:	Q=0.91 (df=1)	p=0.3402	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8617	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

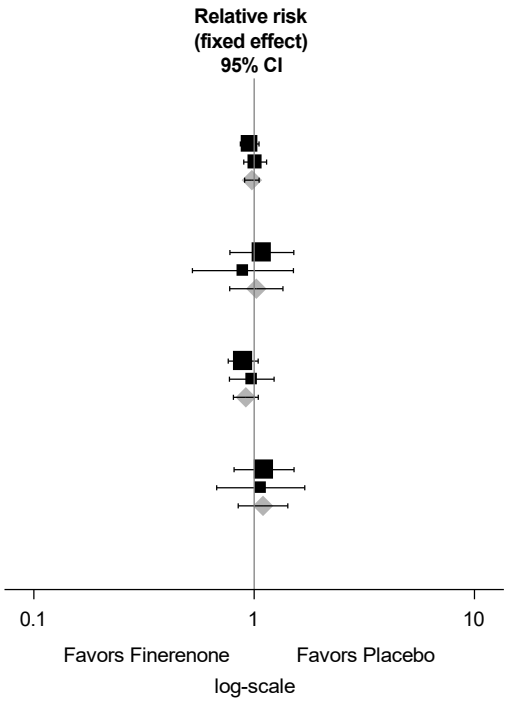
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	225 / 724	220 / 724	54.2	1.02 [0.88,1.19]	
FIGARO-DKD	172 / 494	179 / 497	45.8	0.97 [0.82,1.14]	
Total	397 / 1218	399 / 1221		1.00 [0.89,1.12]	Z=-0.06, p=0.9543
Heterogeneity:	Q=0.23 (df=1)	p=0.6291	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	565 / 1762	611 / 1766	65.9	0.93 [0.84,1.02]	
FIGARO-DKD	295 / 831	294 / 830	34.1	1.00 [0.88,1.14]	
Total	860 / 2593	905 / 2596		0.95 [0.88,1.03]	Z=-1.28, p=0.2022
Heterogeneity:	Q=0.92 (df=1)	p=0.3378	I^2=0.0%		
>= 160					
FIDELIO-DKD	46 / 133	45 / 128	80.7	0.98 [0.71,1.37]	
FIGARO-DKD	15 / 34	9 / 35	19.3	1.72 [0.87,3.38]	
Total	61 / 167	54 / 163		1.10 [0.82,1.48]	Z=0.65, p=0.5172
Heterogeneity:	Q=2.09 (df=1)	p=0.1486	I^2=52.1%		
Subgroup Heterogeneity:	Q=1.18 (df=2)	p=0.5555	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

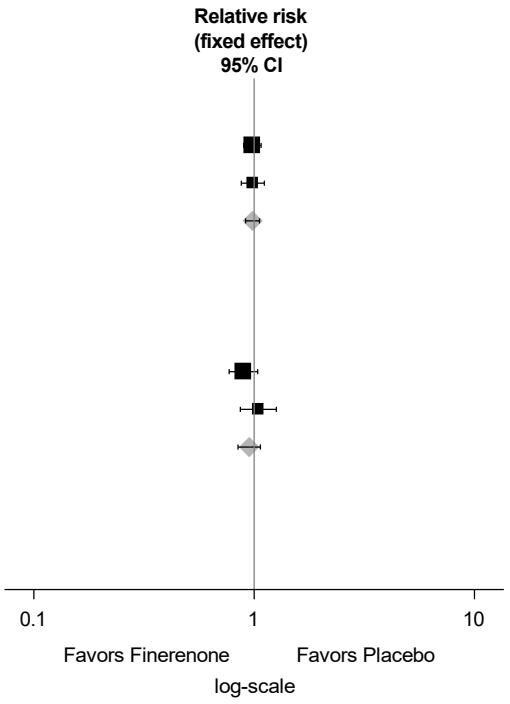
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	525 / 1637	559 / 1663	59.9	0.95 [0.87,1.05]	
FIGARO-DKD	356 / 1013	345 / 992	40.1	1.01 [0.90,1.14]	
Total	881 / 2650	904 / 2655		0.98 [0.91,1.05]	Z=-0.62, p=0.5338
Heterogeneity:	Q=0.53 (df=1)	p=0.4655	I^2=0.0%		
Black					
FIDELIO-DKD	49 / 130	40 / 115	71.4	1.08 [0.78,1.51]	
FIGARO-DKD	14 / 43	26 / 71	28.6	0.89 [0.52,1.51]	
Total	63 / 173	66 / 186		1.02 [0.77,1.35]	Z=0.16, p=0.8744
Heterogeneity:	Q=0.39 (df=1)	p=0.5346	I^2=0.0%		
Asian					
FIDELIO-DKD	203 / 678	228 / 679	69.0	0.89 [0.76,1.04]	
FIGARO-DKD	89 / 251	92 / 253	31.0	0.98 [0.77,1.23]	
Total	292 / 929	320 / 932		0.92 [0.81,1.04]	Z=-1.31, p=0.1891
Heterogeneity:	Q=0.39 (df=1)	p=0.5325	I^2=0.0%		
Others					
FIDELIO-DKD	59 / 177	49 / 163	68.3	1.11 [0.81,1.52]	
FIGARO-DKD	23 / 52	19 / 46	31.7	1.07 [0.68,1.70]	
Total	82 / 229	68 / 209		1.10 [0.85,1.42]	Z=0.70, p=0.4851
Heterogeneity:	Q=0.02 (df=1)	p=0.9023	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.76 (df=3)	p=0.6245	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.3.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

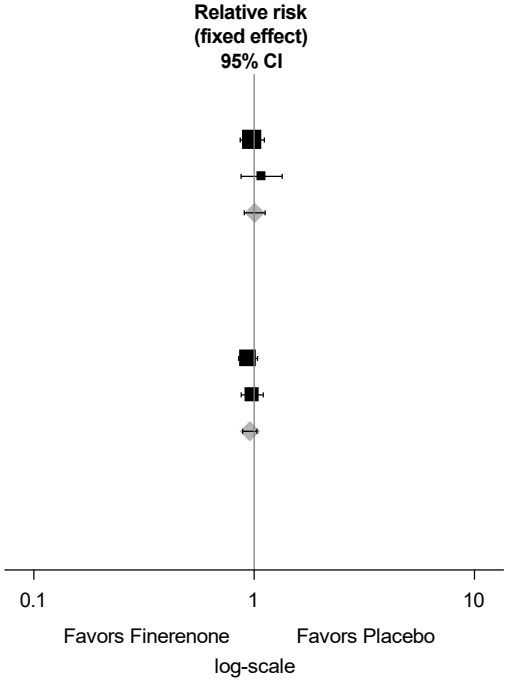
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	598 / 1800	635 / 1876	63.6	0.98 [0.90,1.08]	
FIGARO-DKD	331 / 917	343 / 937	36.4	0.99 [0.87,1.11]	
Total	929 / 2717	978 / 2813		0.98 [0.91,1.06]	Z=-0.46, p=0.6466
Heterogeneity:	Q=0.00 (df=1)	p=0.9520	I^2=0.0%		
Female					
FIDELIO-DKD	238 / 822	241 / 744	61.4	0.89 [0.77,1.04]	
FIGARO-DKD	151 / 442	139 / 425	38.6	1.04 [0.87,1.26]	
Total	389 / 1264	380 / 1169		0.95 [0.84,1.07]	Z=-0.87, p=0.3834
Heterogeneity:	Q=1.62 (df=1)	p=0.2032	I^2=38.2%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6183	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.3.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

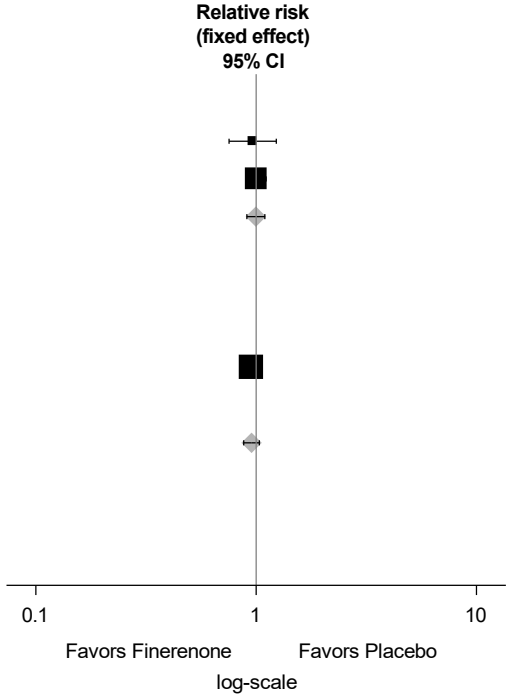
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	335 / 1106	333 / 1078	74.3	0.98 [0.86,1.11]	
FIGARO-DKD	116 / 337	107 / 336	25.7	1.08 [0.87,1.34]	
Total	451 / 1443	440 / 1414		1.01 [0.90,1.12]	Z=0.10, p=0.9224
Heterogeneity:	Q=0.59 (df=1)	p=0.4436	I^2=0.0%		
>= 65					
FIDELIO-DKD	501 / 1516	543 / 1542	57.7	0.94 [0.85,1.04]	
FIGARO-DKD	366 / 1022	375 / 1026	42.3	0.98 [0.87,1.10]	
Total	867 / 2538	918 / 2568		0.96 [0.89,1.03]	Z=-1.19, p=0.2359
Heterogeneity:	Q=0.31 (df=1)	p=0.5770	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4523	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.3.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

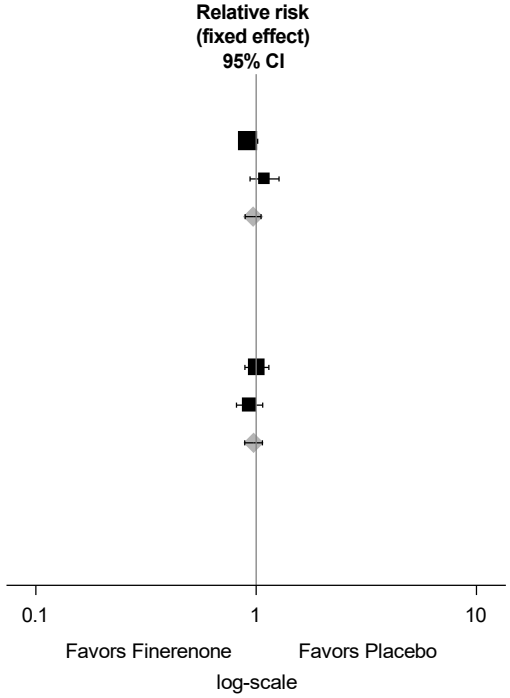
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 210	81 / 213	14.4	0.96 [0.75,1.23]	
FIGARO-DKD	482 / 1359	482 / 1362	85.6	1.00 [0.91,1.11]	
Total	559 / 1569	563 / 1575		1.00 [0.91,1.09]	Z=-0.07, p=0.9437
Heterogeneity:	Q=0.08 (df=1)	p=0.7765	I^2=0.0%		
Very High					
FIDELIO-DKD	759 / 2412	795 / 2407	100.0	0.95 [0.88,1.03]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	759 / 2412	795 / 2407		0.95 [0.88,1.03]	Z=-1.16, p=0.2465
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4785	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.3.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

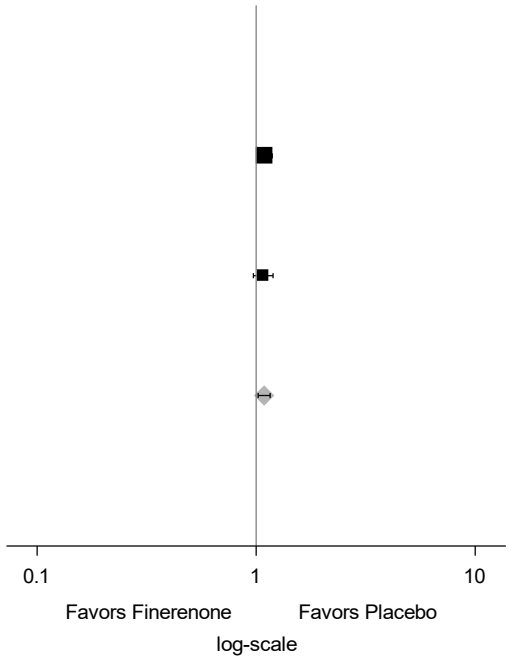
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	500 / 1559	540 / 1549	69.9	0.92 [0.83,1.02]	
FIGARO-DKD	231 / 639	209 / 631	30.1	1.09 [0.94,1.27]	
Total	731 / 2198	749 / 2180		0.97 [0.89,1.05]	Z=-0.76, p=0.4499
Heterogeneity:	Q=3.42 (df=1)	p=0.0643	I^2=70.8%		
45 - < 60					
FIDELIO-DKD	336 / 1063	336 / 1071	54.5	1.01 [0.89,1.14]	
FIGARO-DKD	251 / 720	273 / 731	45.5	0.93 [0.81,1.07]	
Total	587 / 1783	609 / 1802		0.97 [0.89,1.07]	Z=-0.58, p=0.5631
Heterogeneity:	Q=0.65 (df=1)	p=0.4201	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9408	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

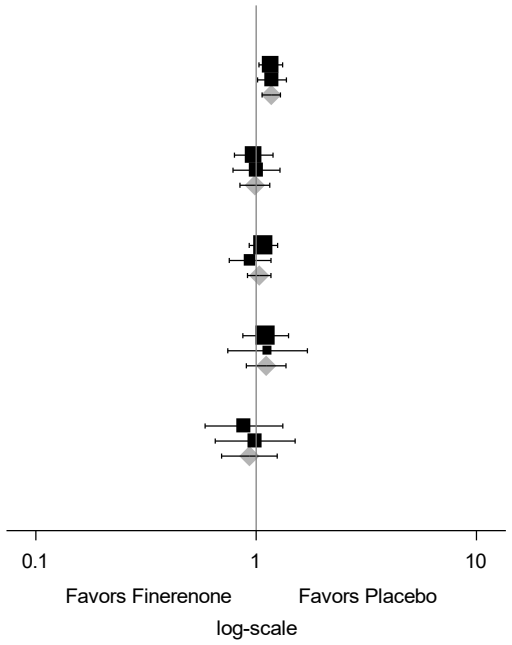
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	873 / 2622	800 / 2620	63.1	1.09 [1.01,1.18]	
FIGARO-DKD	486 / 1359	453 / 1362	36.9	1.08 [0.97,1.19]	
Total	1359 / 3981	1253 / 3982		1.09 [1.02,1.16]	Z=2.61, p=0.0090
Heterogeneity:	Q=0.06 (df=1)	p=0.8117	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.4.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

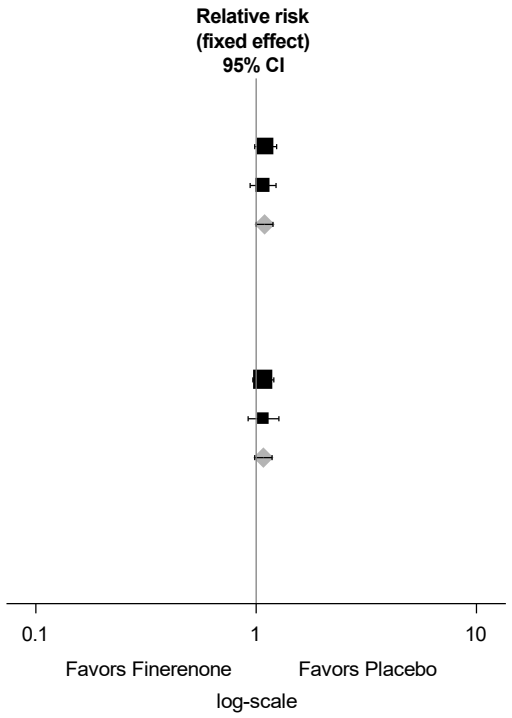
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	373 / 1078	316 / 1064	59.8	1.17 [1.03,1.32]	
FIGARO-DKD	241 / 640	204 / 639	40.2	1.18 [1.01,1.37]	
Total	614 / 1718	520 / 1703		1.17 [1.06,1.29]	Z=3.23, p=0.0012
Heterogeneity:	Q=0.02 (df=1)	p=0.9012	I^2=0.0%		
North America					
FIDELIO-DKD	128 / 425	135 / 437	59.7	0.97 [0.80,1.19]	
FIGARO-DKD	86 / 267	87 / 271	40.3	1.00 [0.78,1.28]	
Total	214 / 692	222 / 708		0.99 [0.84,1.15]	Z=-0.17, p=0.8618
Heterogeneity:	Q=0.03 (df=1)	p=0.8594	I^2=0.0%		
Asia					
FIDELIO-DKD	248 / 751	229 / 748	68.3	1.08 [0.93,1.25]	
FIGARO-DKD	100 / 288	108 / 292	31.7	0.94 [0.75,1.17]	
Total	348 / 1039	337 / 1040		1.03 [0.91,1.17]	Z=0.51, p=0.6120
Heterogeneity:	Q=1.07 (df=1)	p=0.3019	I^2=6.2%		
Latin America					
FIDELIO-DKD	95 / 274	86 / 274	75.2	1.10 [0.87,1.40]	
FIGARO-DKD	33 / 102	29 / 101	24.8	1.13 [0.74,1.71]	
Total	128 / 376	115 / 375		1.11 [0.90,1.37]	Z=0.99, p=0.3231
Heterogeneity:	Q=0.01 (df=1)	p=0.9354	I^2=0.0%		
Others					
FIDELIO-DKD	29 / 94	34 / 97	51.4	0.88 [0.59,1.32]	
FIGARO-DKD	26 / 62	25 / 59	48.6	0.99 [0.65,1.50]	
Total	55 / 156	59 / 156		0.93 [0.70,1.25]	Z=-0.48, p=0.6334
Heterogeneity:	Q=0.16 (df=1)	p=0.6931	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.62 (df=4)	p=0.2298	I^2=28.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

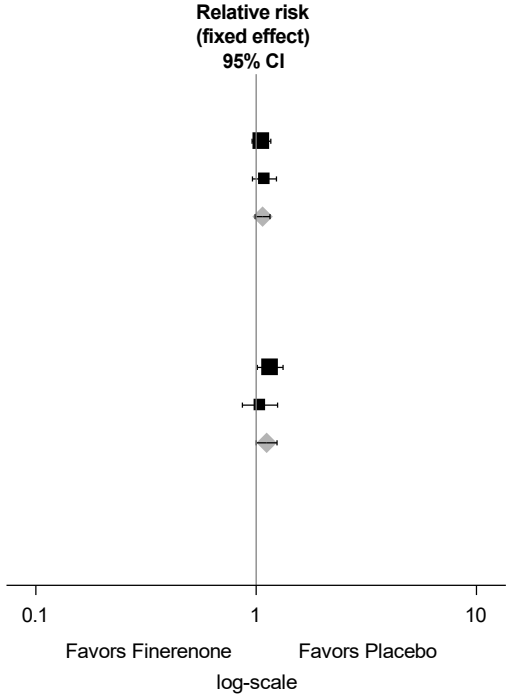
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	416 / 1215	376 / 1213	58.2	1.10 [0.99,1.24]	
FIGARO-DKD	295 / 865	270 / 851	41.8	1.07 [0.94,1.23]	
Total	711 / 2080	646 / 2064		1.09 [1.00,1.19]	Z=1.98, p=0.0483
Heterogeneity:	Q=0.09 (df=1)	p=0.7635	I^2=0.0%		
Absent					
FIDELIO-DKD	457 / 1407	424 / 1407	68.3	1.08 [0.97,1.20]	
FIGARO-DKD	191 / 494	183 / 511	31.7	1.08 [0.92,1.27]	
Total	648 / 1901	607 / 1918		1.08 [0.99,1.18]	Z=1.63, p=0.1022
Heterogeneity:	Q=0.00 (df=1)	p=0.9866	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8443	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

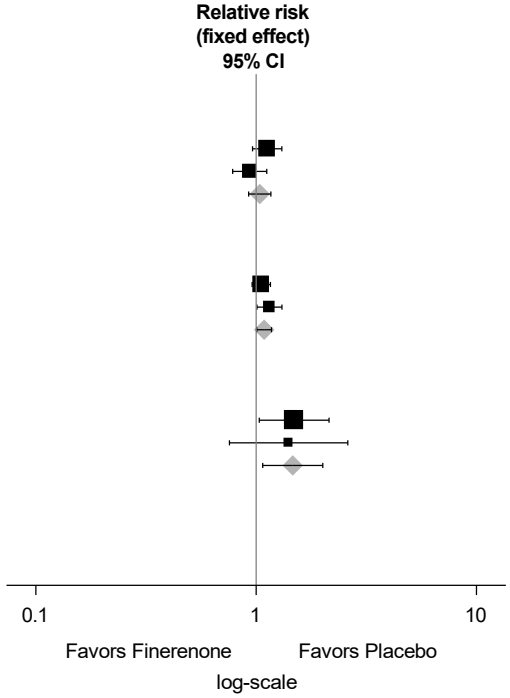
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	568 / 1737	527 / 1703	62.1	1.06 [0.96,1.17]	
FIGARO-DKD	333 / 924	308 / 932	37.9	1.09 [0.96,1.24]	
Total	901 / 2661	835 / 2635		1.07 [0.99,1.16]	Z=1.70, p=0.0884
Heterogeneity:	Q=0.15 (df=1)	p=0.6979	I^2=0.0%		
> 4.5					
FIDELIO-DKD	305 / 884	273 / 916	65.1	1.16 [1.01,1.32]	
FIGARO-DKD	153 / 435	145 / 429	34.9	1.04 [0.87,1.25]	
Total	458 / 1319	418 / 1345		1.12 [1.00,1.24]	Z=1.97, p=0.0486
Heterogeneity:	Q=0.84 (df=1)	p=0.3593	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.39 (df=1)	p=0.5345	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

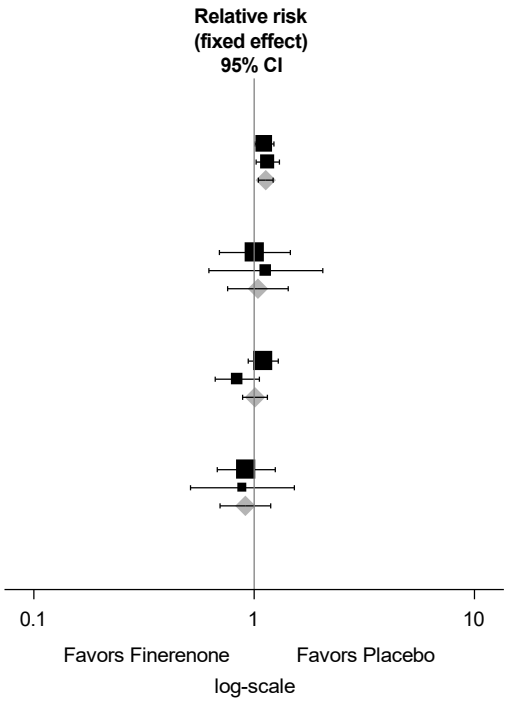
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	239 / 724	213 / 724	57.4	1.12 [0.96,1.31]	
FIGARO-DKD	157 / 494	169 / 497	42.6	0.93 [0.78,1.12]	
Total	396 / 1218	382 / 1221		1.04 [0.92,1.17]	Z=0.63, p=0.5270
Heterogeneity:	Q=2.33 (df=1)	p=0.1273	I^2=57.0%		
130 - < 160					
FIDELIO-DKD	583 / 1762	554 / 1766	65.0	1.05 [0.96,1.16]	
FIGARO-DKD	314 / 831	273 / 830	35.0	1.15 [1.01,1.31]	
Total	897 / 2593	827 / 2596		1.09 [1.01,1.17]	Z=2.11, p=0.0345
Heterogeneity:	Q=1.07 (df=1)	p=0.3011	I^2=6.5%		
>= 160					
FIDELIO-DKD	51 / 133	33 / 128	74.2	1.49 [1.03,2.14]	
FIGARO-DKD	15 / 34	11 / 35	25.8	1.40 [0.76,2.61]	
Total	66 / 167	44 / 163		1.47 [1.07,2.01]	Z=2.39, p=0.0170
Heterogeneity:	Q=0.02 (df=1)	p=0.8745	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.08 (df=2)	p=0.1301	I^2=51.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

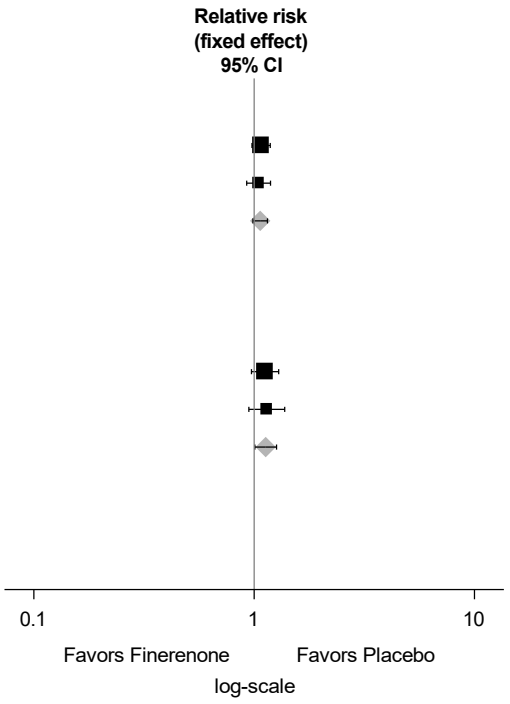
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	552 / 1637	504 / 1663	59.9	1.11 [1.01,1.23]	
FIGARO-DKD	372 / 1013	316 / 992	40.1	1.15 [1.02,1.30]	
Total	924 / 2650	820 / 2655		1.13 [1.04,1.22]	Z=3.08, p=0.0021
Heterogeneity:	Q=0.20 (df=1)	p=0.6585	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 130	36 / 115	72.0	1.01 [0.70,1.46]	
FIGARO-DKD	13 / 43	19 / 71	28.0	1.13 [0.62,2.05]	
Total	54 / 173	55 / 186		1.04 [0.76,1.43]	Z=0.24, p=0.8084
Heterogeneity:	Q=0.10 (df=1)	p=0.7488	I^2=0.0%		
Asian					
FIDELIO-DKD	224 / 678	204 / 679	68.4	1.10 [0.94,1.29]	
FIGARO-DKD	84 / 251	101 / 253	31.6	0.84 [0.67,1.06]	
Total	308 / 929	305 / 932		1.01 [0.89,1.15]	Z=0.13, p=0.8955
Heterogeneity:	Q=3.63 (df=1)	p=0.0568	I^2=72.5%		
Others					
FIDELIO-DKD	56 / 177	56 / 163	76.2	0.92 [0.68,1.25]	
FIGARO-DKD	17 / 52	17 / 46	23.8	0.88 [0.51,1.52]	
Total	73 / 229	73 / 209		0.91 [0.70,1.19]	Z=-0.68, p=0.4959
Heterogeneity:	Q=0.02 (df=1)	p=0.8991	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.94 (df=3)	p=0.2685	I^2=23.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.4.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

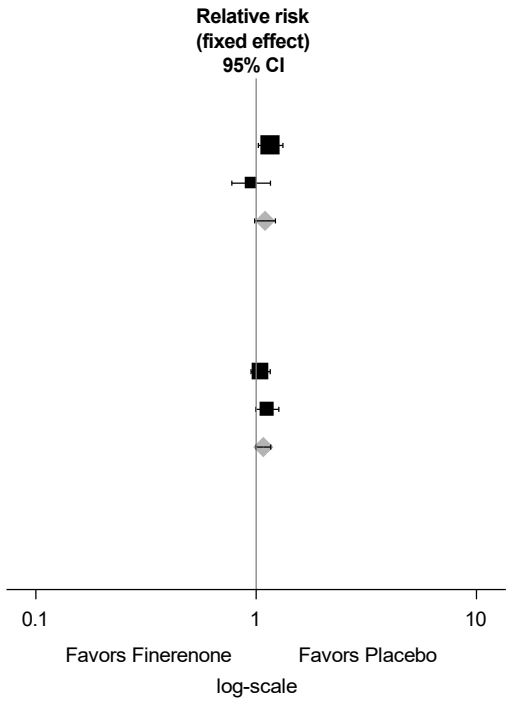
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	587 / 1800	569 / 1876	63.0	1.08 [0.98,1.18]	
FIGARO-DKD	327 / 917	319 / 937	37.0	1.05 [0.92,1.19]	
Total	914 / 2717	888 / 2813		1.06 [0.99,1.15]	Z=1.63, p=0.1041
Heterogeneity:	Q=0.11 (df=1)	p=0.7439	I^2=0.0%		
Female					
FIDELIO-DKD	286 / 822	231 / 744	63.4	1.12 [0.97,1.29]	
FIGARO-DKD	159 / 442	134 / 425	36.6	1.14 [0.95,1.38]	
Total	445 / 1264	365 / 1169		1.13 [1.01,1.26]	Z=2.08, p=0.0372
Heterogeneity:	Q=0.02 (df=1)	p=0.8810	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.69 (df=1)	p=0.4072	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.4.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

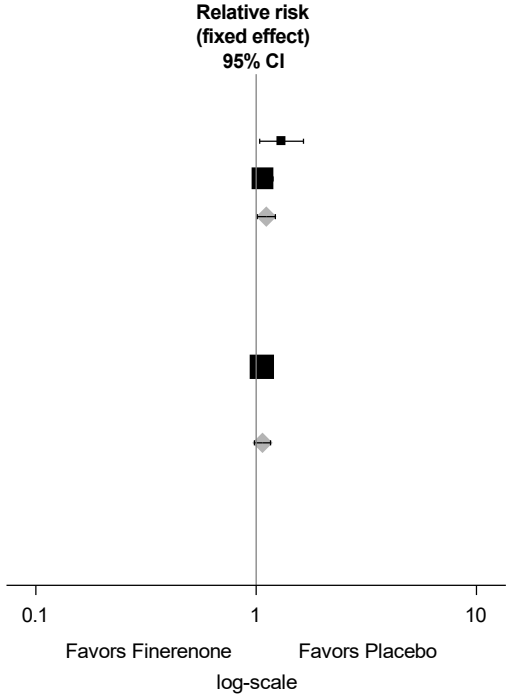
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	358 / 1106	300 / 1078	71.2	1.16 [1.02,1.32]	
FIGARO-DKD	118 / 337	124 / 336	28.8	0.95 [0.78,1.16]	
Total	476 / 1443	424 / 1414		1.10 [0.98,1.22]	Z=1.68, p=0.0934
Heterogeneity:	Q=2.79 (df=1)	p=0.0951	I^2=64.1%		
>= 65					
FIDELIO-DKD	515 / 1516	500 / 1542	59.1	1.05 [0.95,1.16]	
FIGARO-DKD	368 / 1022	329 / 1026	40.9	1.12 [1.00,1.27]	
Total	883 / 2538	829 / 2568		1.08 [1.00,1.16]	Z=1.90, p=0.0572
Heterogeneity:	Q=0.75 (df=1)	p=0.3873	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7949	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.4.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

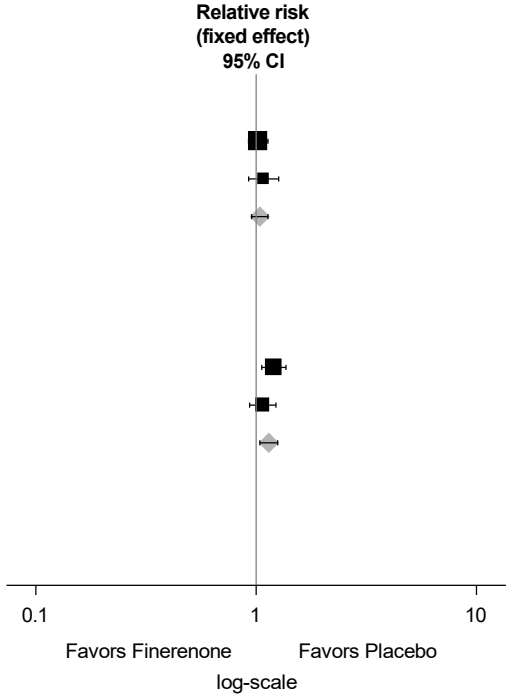
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	99 / 210	77 / 213	17.0	1.30 [1.04,1.64]	
FIGARO-DKD	486 / 1359	453 / 1362	83.0	1.08 [0.97,1.19]	
Total	585 / 1569	530 / 1575		1.11 [1.01,1.22]	Z=2.20, p=0.0277
Heterogeneity:	Q=2.27 (df=1)	p=0.1321	I^2=55.9%		
Very High					
FIDELIO-DKD	774 / 2412	723 / 2407	100.0	1.07 [0.98,1.16]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	774 / 2412	723 / 2407		1.07 [0.98,1.16]	Z=1.54, p=0.1239
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.38 (df=1)	p=0.5366	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.4.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

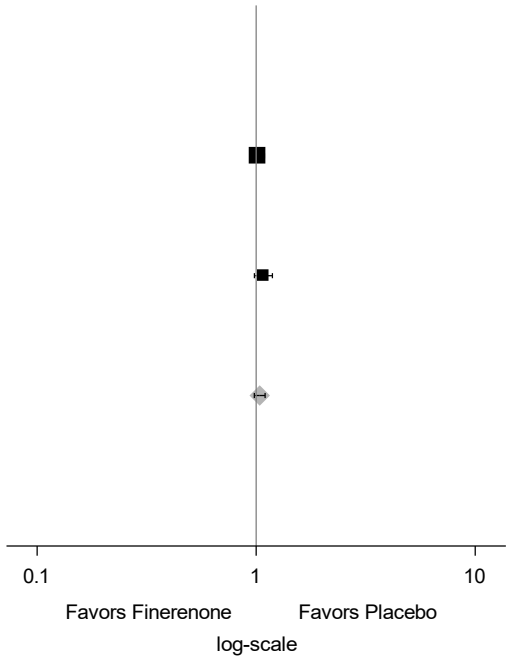
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	510 / 1559	496 / 1549	70.5	1.02 [0.92,1.13]	
FIGARO-DKD	219 / 639	200 / 631	29.5	1.08 [0.92,1.27]	
Total	729 / 2198	696 / 2180		1.04 [0.95,1.13]	Z=0.88, p=0.3803
Heterogeneity:	Q=0.35 (df=1)	p=0.5520	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	363 / 1063	304 / 1071	54.2	1.20 [1.06,1.37]	
FIGARO-DKD	267 / 720	253 / 731	45.8	1.07 [0.93,1.23]	
Total	630 / 1783	557 / 1802		1.14 [1.04,1.25]	Z=2.78, p=0.0055
Heterogeneity:	Q=1.47 (df=1)	p=0.2248	I^2=32.1%		
Subgroup Heterogeneity:	Q=2.12 (df=1)	p=0.1453	I^2=52.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

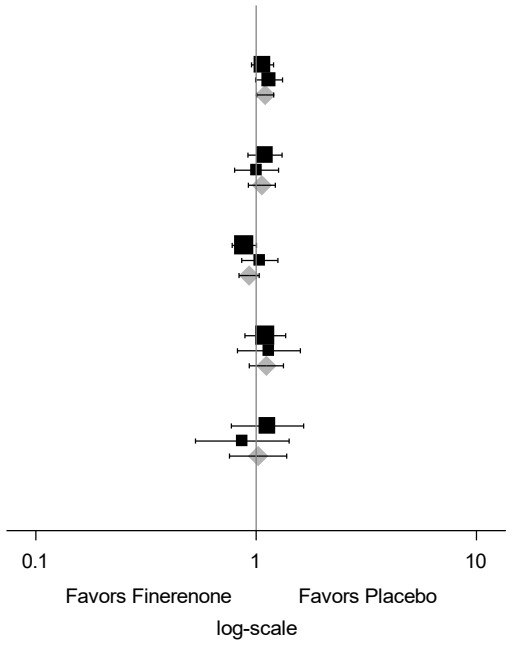
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	973 / 2622	955 / 2620	64.0	1.02 [0.95,1.09]	
FIGARO-DKD	543 / 1359	504 / 1362	36.0	1.08 [0.98,1.19]	
Total	1516 / 3981	1459 / 3982		1.04 [0.98,1.10]	Z=1.28, p=0.1990
Heterogeneity:	Q=0.99 (df=1)	p=0.3187	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.5.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

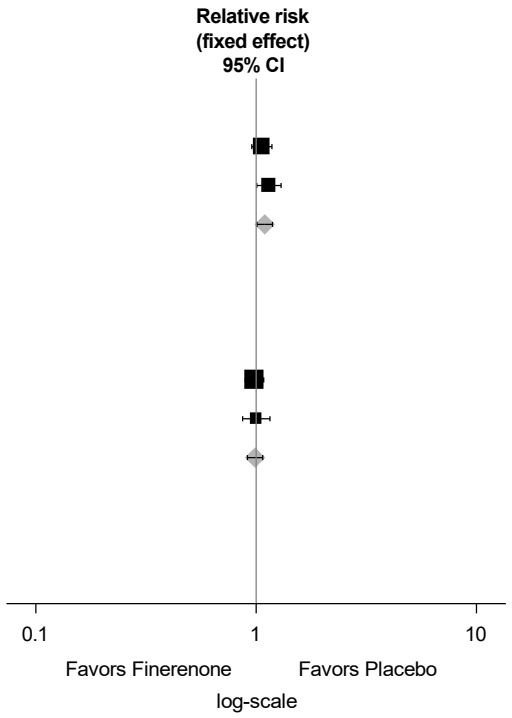
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	392 / 1078	362 / 1064	60.0	1.07 [0.95,1.20]	
FIGARO-DKD	259 / 640	226 / 639	40.0	1.14 [0.99,1.32]	
Total	651 / 1718	588 / 1703		1.10 [1.00,1.20]	Z=2.07, p=0.0387
Heterogeneity:	Q=0.54 (df=1)	p=0.4623	I^2=0.0%		
North America					
FIDELIO-DKD	160 / 425	150 / 437	62.4	1.10 [0.92,1.31]	
FIGARO-DKD	94 / 267	95 / 271	37.6	1.00 [0.80,1.26]	
Total	254 / 692	245 / 708		1.06 [0.92,1.22]	Z=0.83, p=0.4093
Heterogeneity:	Q=0.35 (df=1)	p=0.5526	I^2=0.0%		
Asia					
FIDELIO-DKD	275 / 751	310 / 748	68.9	0.88 [0.78,1.00]	
FIGARO-DKD	125 / 288	122 / 292	31.1	1.04 [0.86,1.25]	
Total	400 / 1039	432 / 1040		0.93 [0.84,1.03]	Z=-1.37, p=0.1703
Heterogeneity:	Q=1.94 (df=1)	p=0.1634	I^2=48.5%		
Latin America					
FIDELIO-DKD	110 / 274	100 / 274	70.5	1.10 [0.89,1.36]	
FIGARO-DKD	45 / 102	39 / 101	29.5	1.14 [0.82,1.59]	
Total	155 / 376	139 / 375		1.11 [0.93,1.33]	Z=1.17, p=0.2425
Heterogeneity:	Q=0.04 (df=1)	p=0.8495	I^2=0.0%		
Others					
FIDELIO-DKD	36 / 94	33 / 97	62.7	1.13 [0.77,1.64]	
FIGARO-DKD	20 / 62	22 / 59	37.3	0.87 [0.53,1.41]	
Total	56 / 156	55 / 156		1.02 [0.76,1.38]	Z=0.13, p=0.8947
Heterogeneity:	Q=0.70 (df=1)	p=0.4038	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.50 (df=4)	p=0.1648	I^2=38.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

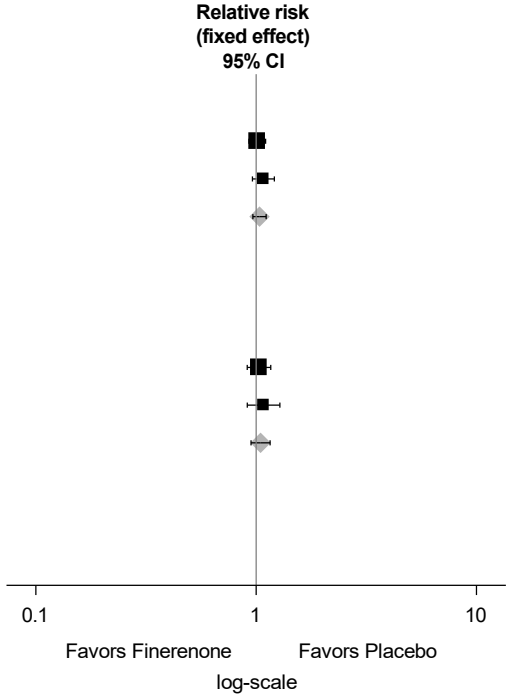
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	456 / 1215	429 / 1213	59.3	1.06 [0.96,1.18]	
FIGARO-DKD	331 / 865	285 / 851	40.7	1.14 [1.01,1.30]	
Total	787 / 2080	714 / 2064		1.09 [1.01,1.19]	Z=2.17, p=0.0302
Heterogeneity:	Q=0.77 (df=1)	p=0.3795	I^2=0.0%		
Absent					
FIDELIO-DKD	517 / 1407	526 / 1407	68.7	0.98 [0.89,1.08]	
FIGARO-DKD	212 / 494	219 / 511	31.3	1.00 [0.87,1.15]	
Total	729 / 1901	745 / 1918		0.99 [0.91,1.07]	Z=-0.28, p=0.7788
Heterogeneity:	Q=0.04 (df=1)	p=0.8322	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.03 (df=1)	p=0.0818	I^2=67.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

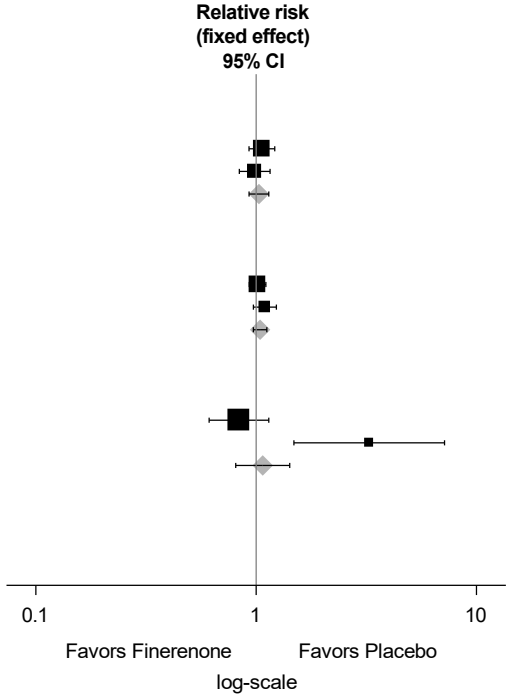
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	649 / 1737	629 / 1703	63.5	1.01 [0.93,1.10]	
FIGARO-DKD	371 / 924	347 / 932	36.5	1.08 [0.96,1.21]	
Total	1020 / 2661	976 / 2635		1.04 [0.97,1.11]	Z=0.99, p=0.3233
Heterogeneity:	Q=0.76 (df=1)	p=0.3836	I^2=0.0%		
> 4.5					
FIDELIO-DKD	324 / 884	326 / 916	65.8	1.03 [0.91,1.16]	
FIGARO-DKD	172 / 435	157 / 429	34.2	1.08 [0.91,1.28]	
Total	496 / 1319	483 / 1345		1.05 [0.95,1.16]	Z=0.90, p=0.3672
Heterogeneity:	Q=0.20 (df=1)	p=0.6545	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8600	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

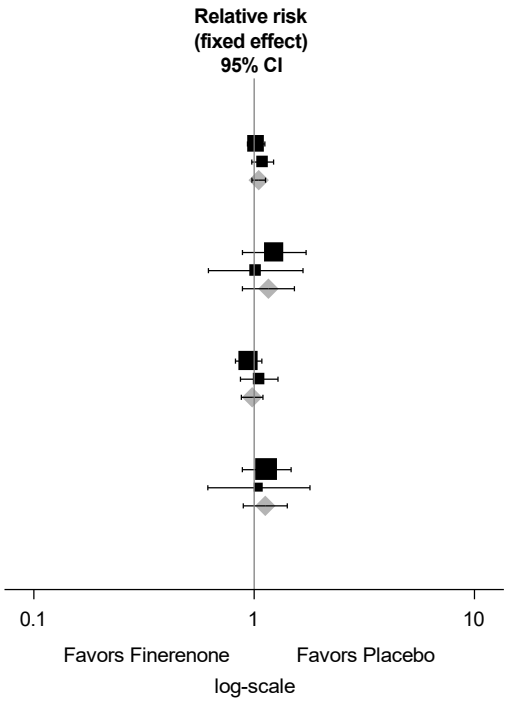
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	276 / 724	260 / 724	58.8	1.06 [0.93,1.21]	
FIGARO-DKD	184 / 494	188 / 497	41.2	0.98 [0.84,1.16]	
Total	460 / 1218	448 / 1221		1.03 [0.93,1.14]	Z=0.55, p=0.5844
Heterogeneity:	Q=0.49 (df=1)	p=0.4819	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	650 / 1762	642 / 1766	65.7	1.01 [0.93,1.11]	
FIGARO-DKD	340 / 831	310 / 830	34.3	1.10 [0.97,1.24]	
Total	990 / 2593	952 / 2596		1.04 [0.97,1.12]	Z=1.14, p=0.2540
Heterogeneity:	Q=1.02 (df=1)	p=0.3117	I^2=2.3%		
>= 160					
FIDELIO-DKD	46 / 133	53 / 128	86.5	0.84 [0.61,1.14]	
FIGARO-DKD	19 / 34	6 / 35	13.5	3.26 [1.48,7.16]	
Total	65 / 167	59 / 163		1.07 [0.81,1.42]	Z=0.48, p=0.6346
Heterogeneity:	Q=10.12 (df=1)	p=0.0015	I^2=90.1%		
Subgroup Heterogeneity:	Q=0.08 (df=2)	p=0.9598	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

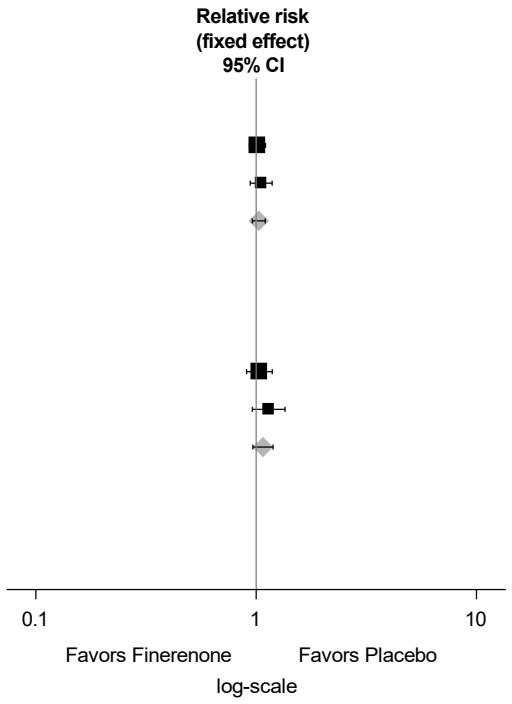
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	596 / 1637	593 / 1663	61.1	1.02 [0.93,1.12]	
FIGARO-DKD	394 / 1013	353 / 992	38.9	1.09 [0.98,1.22]	
Total	990 / 2650	946 / 2655		1.05 [0.98,1.13]	Z=1.31, p=0.1911
Heterogeneity:	Q=0.84 (df=1)	p=0.3595	I^2=0.0%		
Black					
FIDELIO-DKD	53 / 130	38 / 115	68.8	1.23 [0.88,1.72]	
FIGARO-DKD	16 / 43	26 / 71	31.2	1.02 [0.62,1.67]	
Total	69 / 173	64 / 186		1.16 [0.88,1.52]	Z=1.07, p=0.2831
Heterogeneity:	Q=0.41 (df=1)	p=0.5231	I^2=0.0%		
Asian					
FIDELIO-DKD	246 / 678	261 / 679	66.9	0.94 [0.82,1.08]	
FIGARO-DKD	114 / 251	109 / 253	33.1	1.05 [0.87,1.28]	
Total	360 / 929	370 / 932		0.98 [0.87,1.10]	Z=-0.37, p=0.7129
Heterogeneity:	Q=0.82 (df=1)	p=0.3663	I^2=0.0%		
Others					
FIDELIO-DKD	78 / 177	63 / 163	81.4	1.14 [0.88,1.47]	
FIGARO-DKD	19 / 52	16 / 46	18.6	1.05 [0.62,1.79]	
Total	97 / 229	79 / 209		1.12 [0.89,1.41]	Z=0.99, p=0.3225
Heterogeneity:	Q=0.07 (df=1)	p=0.7860	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.21 (df=3)	p=0.5307	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.5.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

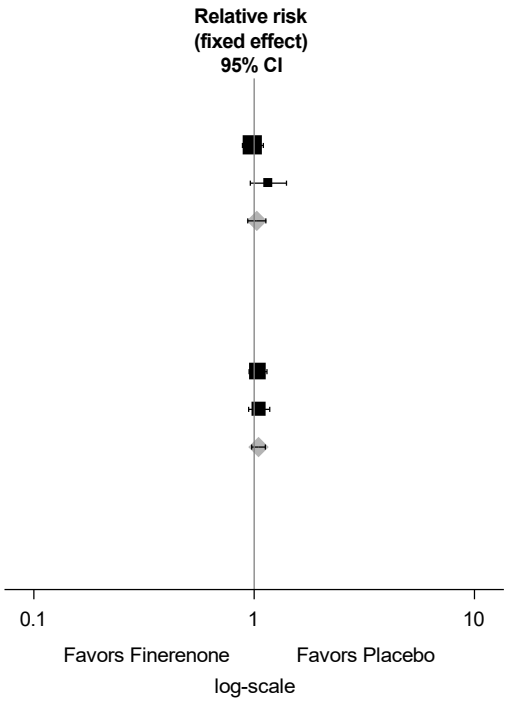
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	677 / 1800	696 / 1876	65.2	1.01 [0.93,1.10]	
FIGARO-DKD	364 / 917	353 / 937	34.8	1.05 [0.94,1.18]	
Total	1041 / 2717	1049 / 2813		1.03 [0.96,1.10]	Z=0.79, p=0.4321
Heterogeneity:	Q=0.28 (df=1)	p=0.5943	I^2=0.0%		
Female					
FIDELIO-DKD	296 / 822	259 / 744	61.9	1.03 [0.90,1.18]	
FIGARO-DKD	179 / 442	151 / 425	38.1	1.14 [0.96,1.35]	
Total	475 / 1264	410 / 1169		1.07 [0.97,1.19]	Z=1.32, p=0.1870
Heterogeneity:	Q=0.77 (df=1)	p=0.3810	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4920	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.5.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

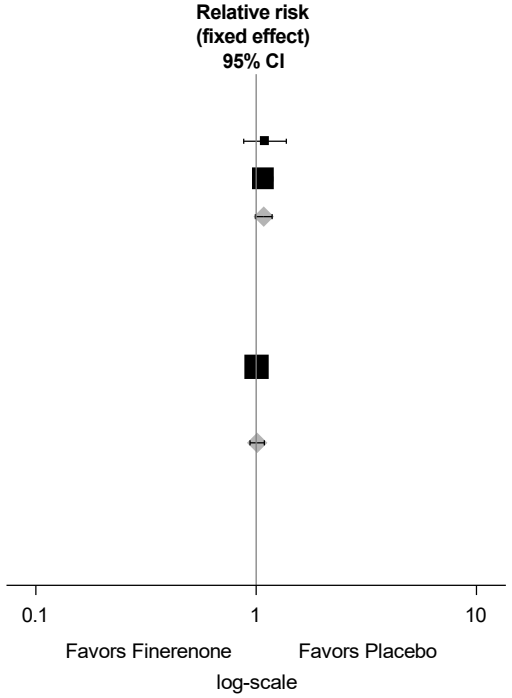
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	408 / 1106	403 / 1078	75.0	0.99 [0.88,1.10]	
FIGARO-DKD	142 / 337	122 / 336	25.0	1.16 [0.96,1.40]	
Total	550 / 1443	525 / 1414		1.03 [0.94,1.13]	Z=0.57, p=0.5684
Heterogeneity:	Q=2.12 (df=1)	p=0.1453	I^2=52.9%		
>= 65					
FIDELIO-DKD	565 / 1516	552 / 1542	58.1	1.04 [0.95,1.14]	
FIGARO-DKD	401 / 1022	382 / 1026	41.9	1.05 [0.94,1.18]	
Total	966 / 2538	934 / 2568		1.05 [0.97,1.12]	Z=1.25, p=0.2120
Heterogeneity:	Q=0.03 (df=1)	p=0.8689	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7670	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.5.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

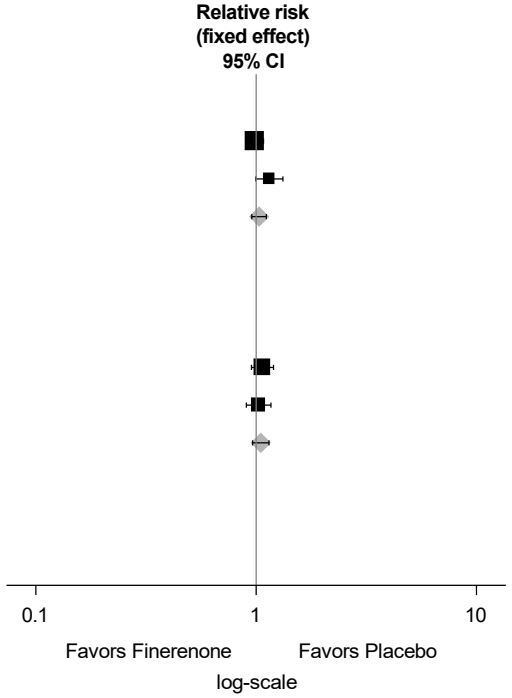
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	93 / 210	86 / 213	15.4	1.10 [0.88,1.37]	
FIGARO-DKD	543 / 1359	504 / 1362	84.6	1.08 [0.98,1.19]	
Total	636 / 1569	590 / 1575		1.08 [0.99,1.18]	Z=1.77, p=0.0762
Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		
Very High					
FIDELIO-DKD	880 / 2412	869 / 2407	100.0	1.01 [0.94,1.09]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	880 / 2412	869 / 2407		1.01 [0.94,1.09]	Z=0.28, p=0.7832
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2424	I^2=26.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.5.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

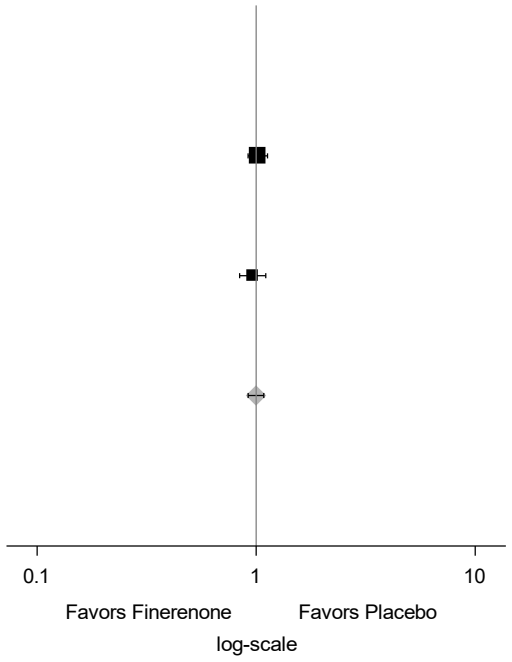
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	586 / 1559	590 / 1549	71.2	0.99 [0.90,1.08]	
FIGARO-DKD	258 / 639	222 / 631	28.8	1.15 [1.00,1.32]	
Total	844 / 2198	812 / 2180		1.03 [0.96,1.11]	Z=0.78, p=0.4327
Heterogeneity:	Q=3.10 (df=1)	p=0.0782	I^2=67.8%		
45 - < 60					
FIDELIO-DKD	387 / 1063	365 / 1071	55.5	1.07 [0.95,1.20]	
FIGARO-DKD	285 / 720	282 / 731	44.5	1.03 [0.90,1.17]	
Total	672 / 1783	647 / 1802		1.05 [0.96,1.14]	Z=1.10, p=0.2715
Heterogeneity:	Q=0.21 (df=1)	p=0.6472	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7623	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

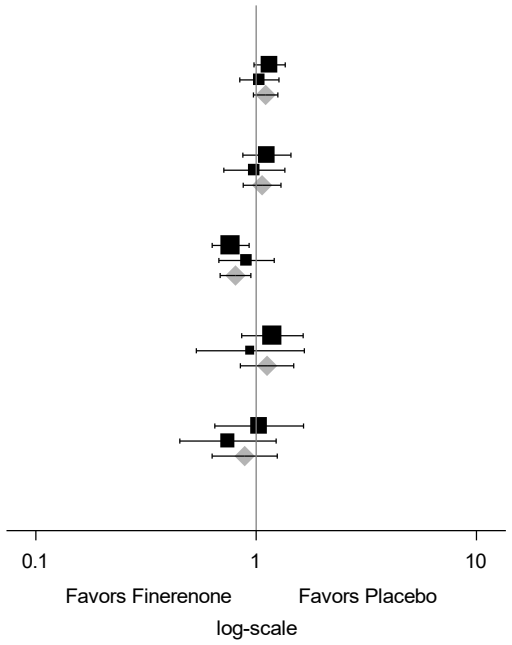
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	578 / 2622	568 / 2620	64.4	1.02 [0.92,1.13]	
FIGARO-DKD	306 / 1359	317 / 1362	35.6	0.96 [0.84,1.11]	
Total	884 / 3981	885 / 3982		1.00 [0.92,1.08]	Z=-0.05, p=0.9589
Heterogeneity:	Q=0.38 (df=1)	p=0.5390	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.6.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

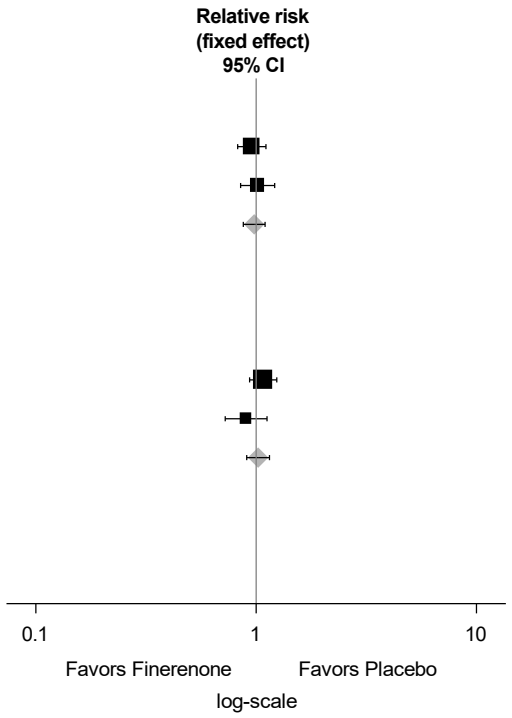
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	246 / 1078	211 / 1064	61.1	1.15 [0.98,1.35]	
FIGARO-DKD	145 / 640	140 / 639	38.9	1.03 [0.84,1.27]	
Total	391 / 1718	351 / 1703		1.10 [0.97,1.25]	Z=1.52, p=0.1284
Heterogeneity:	Q=0.64 (df=1)	p=0.4237	I^2=0.0%		
North America					
FIDELIO-DKD	99 / 425	91 / 437	61.7	1.12 [0.87,1.44]	
FIGARO-DKD	58 / 267	60 / 271	38.3	0.98 [0.71,1.35]	
Total	157 / 692	151 / 708		1.06 [0.87,1.30]	Z=0.61, p=0.5387
Heterogeneity:	Q=0.40 (df=1)	p=0.5268	I^2=0.0%		
Asia					
FIDELIO-DKD	143 / 751	186 / 748	69.2	0.77 [0.63,0.93]	
FIGARO-DKD	66 / 288	74 / 292	30.8	0.90 [0.68,1.21]	
Total	209 / 1039	260 / 1040		0.81 [0.69,0.95]	Z=-2.64, p=0.0083
Heterogeneity:	Q=0.88 (df=1)	p=0.3486	I^2=0.0%		
Latin America					
FIDELIO-DKD	64 / 274	54 / 274	75.5	1.19 [0.86,1.63]	
FIGARO-DKD	19 / 102	20 / 101	24.5	0.94 [0.53,1.65]	
Total	83 / 376	74 / 375		1.12 [0.85,1.48]	Z=0.80, p=0.4244
Heterogeneity:	Q=0.49 (df=1)	p=0.4856	I^2=0.0%		
Others					
FIDELIO-DKD	26 / 94	26 / 97	54.1	1.03 [0.65,1.64]	
FIGARO-DKD	18 / 62	23 / 59	45.9	0.74 [0.45,1.23]	
Total	44 / 156	49 / 156		0.89 [0.63,1.25]	Z=-0.69, p=0.4895
Heterogeneity:	Q=0.87 (df=1)	p=0.3503	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.77 (df=4)	p=0.0293	I^2=62.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

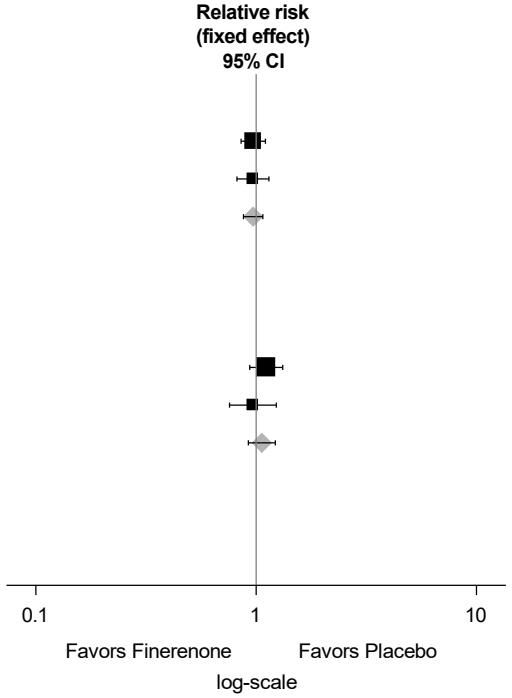
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	267 / 1215	279 / 1213	59.2	0.96 [0.82,1.11]	
FIGARO-DKD	192 / 865	186 / 851	40.8	1.02 [0.85,1.21]	
Total	459 / 2080	465 / 2064		0.98 [0.87,1.10]	Z=-0.36, p=0.7209
Heterogeneity:	Q=0.27 (df=1)	p=0.6051	I^2=0.0%		
Absent					
FIDELIO-DKD	311 / 1407	289 / 1407	70.3	1.08 [0.93,1.24]	
FIGARO-DKD	114 / 494	131 / 511	29.7	0.90 [0.72,1.12]	
Total	425 / 1901	420 / 1918		1.02 [0.91,1.15]	Z=0.33, p=0.7395
Heterogeneity:	Q=1.80 (df=1)	p=0.1794	I^2=44.5%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6261	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

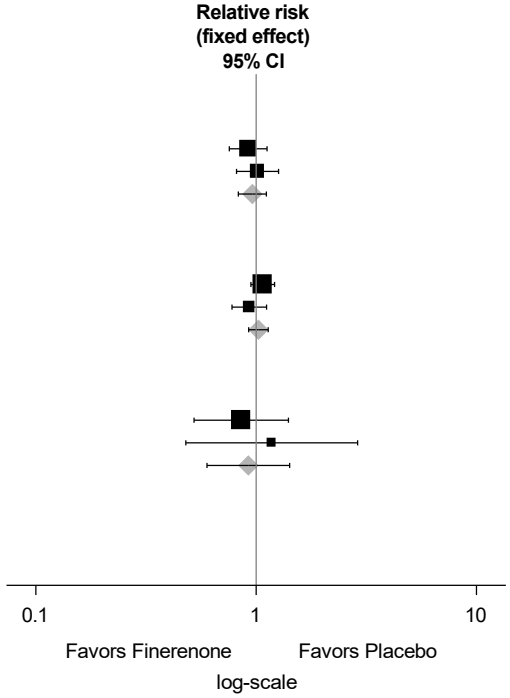
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	370 / 1737	374 / 1703	63.3	0.97 [0.85,1.10]	
FIGARO-DKD	208 / 924	217 / 932	36.7	0.97 [0.82,1.14]	
Total	578 / 2661	591 / 2635		0.97 [0.88,1.07]	Z=-0.61, p=0.5392
Heterogeneity:	Q=0.00 (df=1)	p=0.9760	I^2=0.0%		
> 4.5					
FIDELIO-DKD	208 / 884	194 / 916	66.8	1.11 [0.94,1.32]	
FIGARO-DKD	98 / 435	100 / 429	33.2	0.97 [0.76,1.23]	
Total	306 / 1319	294 / 1345		1.06 [0.92,1.22]	Z=0.82, p=0.4116
Heterogeneity:	Q=0.83 (df=1)	p=0.3615	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3053	I^2=4.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

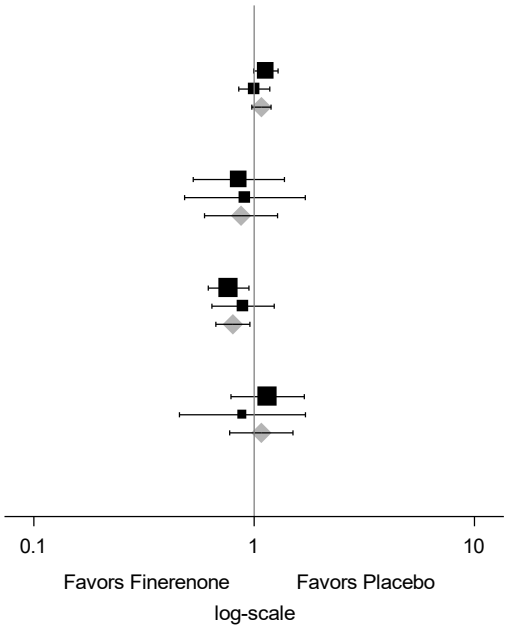
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	149 / 724	162 / 724	55.4	0.92 [0.76,1.12]	
FIGARO-DKD	121 / 494	120 / 497	44.6	1.01 [0.81,1.26]	
Total	270 / 1218	282 / 1221		0.96 [0.83,1.11]	Z=-0.53, p=0.5935
Heterogeneity:	Q=0.42 (df=1)	p=0.5152	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	405 / 1762	379 / 1766	68.2	1.07 [0.95,1.21]	
FIGARO-DKD	177 / 831	190 / 830	31.8	0.93 [0.78,1.11]	
Total	582 / 2593	569 / 2596		1.02 [0.92,1.13]	Z=0.46, p=0.6472
Heterogeneity:	Q=1.59 (df=1)	p=0.2078	I^2=37.0%		
>= 160					
FIDELIO-DKD	24 / 133	27 / 128	76.8	0.86 [0.52,1.40]	
FIGARO-DKD	8 / 34	7 / 35	23.2	1.18 [0.48,2.89]	
Total	32 / 167	34 / 163		0.92 [0.60,1.42]	Z=-0.37, p=0.7092
Heterogeneity:	Q=0.37 (df=1)	p=0.5422	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=2)	p=0.7285	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

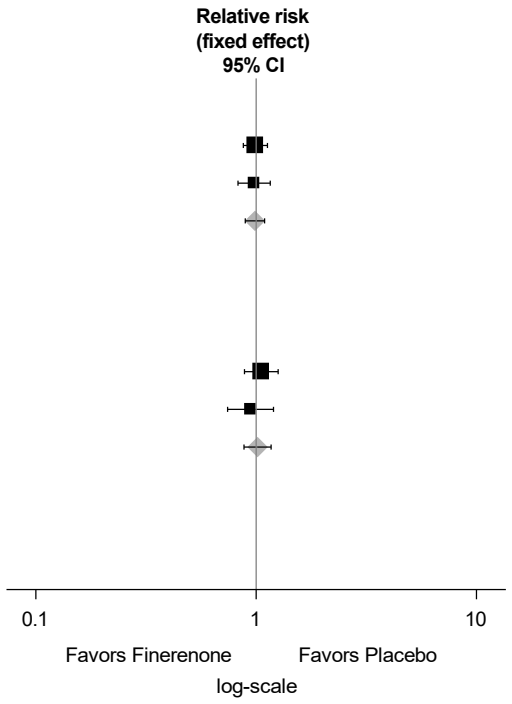
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	387 / 1637	348 / 1663	61.7	1.13 [0.99,1.28]	
FIGARO-DKD	229 / 1013	224 / 992	38.3	1.00 [0.85,1.18]	
Total	616 / 2650	572 / 2655		1.08 [0.98,1.19]	Z=1.48, p=0.1387
Heterogeneity:	Q=1.32 (df=1)	p=0.2509	I^2=24.1%		
Black					
FIDELIO-DKD	26 / 130	27 / 115	63.7	0.85 [0.53,1.37]	
FIGARO-DKD	11 / 43	20 / 71	36.3	0.91 [0.48,1.71]	
Total	37 / 173	47 / 186		0.87 [0.60,1.28]	Z=-0.70, p=0.4809
Heterogeneity:	Q=0.03 (df=1)	p=0.8740	I^2=0.0%		
Asian					
FIDELIO-DKD	120 / 678	157 / 679	70.1	0.77 [0.62,0.95]	
FIGARO-DKD	53 / 251	60 / 253	29.9	0.89 [0.64,1.23]	
Total	173 / 929	217 / 932		0.80 [0.67,0.96]	Z=-2.45, p=0.0142
Heterogeneity:	Q=0.58 (df=1)	p=0.4460	I^2=0.0%		
Others					
FIDELIO-DKD	45 / 177	36 / 163	74.7	1.15 [0.78,1.69]	
FIGARO-DKD	13 / 52	13 / 46	25.3	0.88 [0.46,1.71]	
Total	58 / 229	49 / 209		1.08 [0.77,1.50]	Z=0.44, p=0.6579
Heterogeneity:	Q=0.46 (df=1)	p=0.4981	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.90 (df=3)	p=0.0307	I^2=66.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.6.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

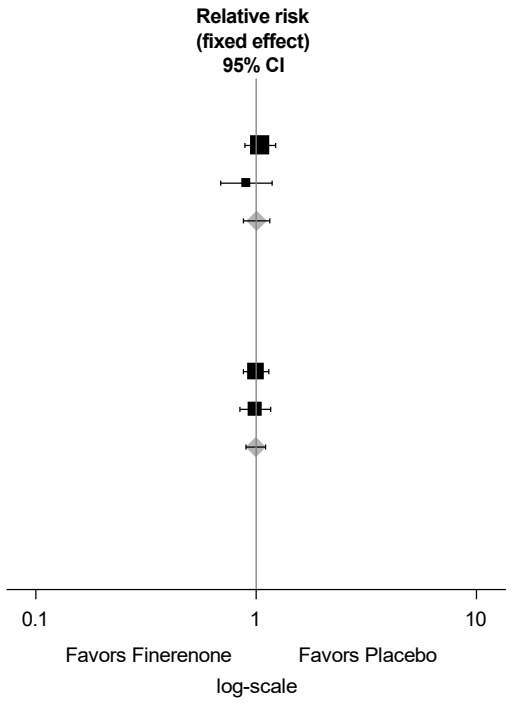
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	374 / 1800	393 / 1876	64.2	0.99 [0.87,1.12]	
FIGARO-DKD	205 / 917	214 / 937	35.8	0.98 [0.83,1.16]	
Total	579 / 2717	607 / 2813		0.99 [0.89,1.09]	Z=-0.25, p=0.8017
Heterogeneity:	Q=0.02 (df=1)	p=0.9022	I^2=0.0%		
Female					
FIDELIO-DKD	204 / 822	175 / 744	65.1	1.06 [0.88,1.26]	
FIGARO-DKD	101 / 442	103 / 425	34.9	0.94 [0.74,1.20]	
Total	305 / 1264	278 / 1169		1.01 [0.88,1.17]	Z=0.20, p=0.8422
Heterogeneity:	Q=0.55 (df=1)	p=0.4588	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7582	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.6.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

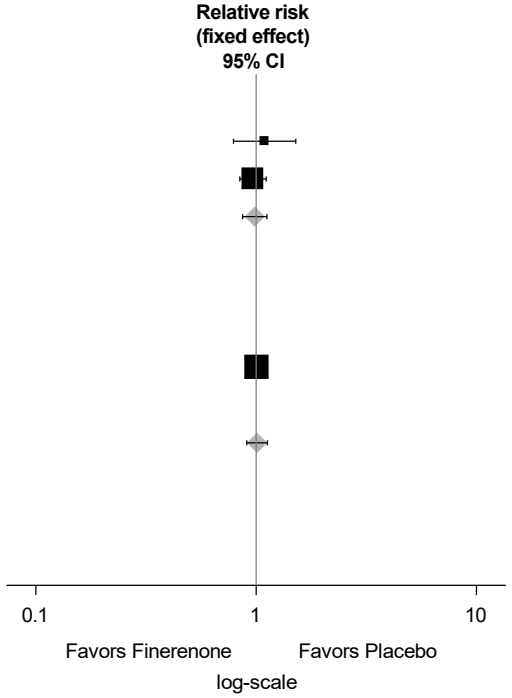
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	242 / 1106	226 / 1078	73.7	1.04 [0.89,1.23]	
FIGARO-DKD	77 / 337	85 / 336	26.3	0.90 [0.69,1.18]	
Total	319 / 1443	311 / 1414		1.00 [0.88,1.15]	Z=0.07, p=0.9475
Heterogeneity:	Q=0.82 (df=1)	p=0.3656	I^2=0.0%		
>= 65					
FIDELIO-DKD	336 / 1516	342 / 1542	59.4	1.00 [0.88,1.14]	
FIGARO-DKD	229 / 1022	232 / 1026	40.6	0.99 [0.84,1.16]	
Total	565 / 2538	574 / 2568		1.00 [0.90,1.10]	Z=-0.08, p=0.9373
Heterogeneity:	Q=0.01 (df=1)	p=0.9370	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9205	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.6.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

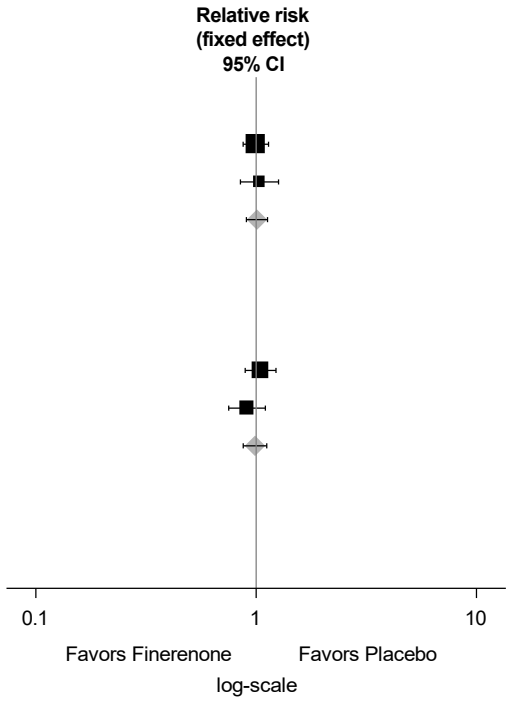
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	56 / 210	52 / 213	15.2	1.09 [0.79,1.51]	
FIGARO-DKD	306 / 1359	317 / 1362	84.8	0.97 [0.84,1.11]	
Total	362 / 1569	369 / 1575		0.99 [0.87,1.12]	Z=-0.23, p=0.8212
Heterogeneity:	Q=0.45 (df=1)	p=0.5012	I^2=0.0%		
Very High					
FIDELIO-DKD	522 / 2412	516 / 2407	100.0	1.01 [0.91,1.12]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	522 / 2412	516 / 2407		1.01 [0.91,1.12]	Z=0.17, p=0.8630
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7765	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.6.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

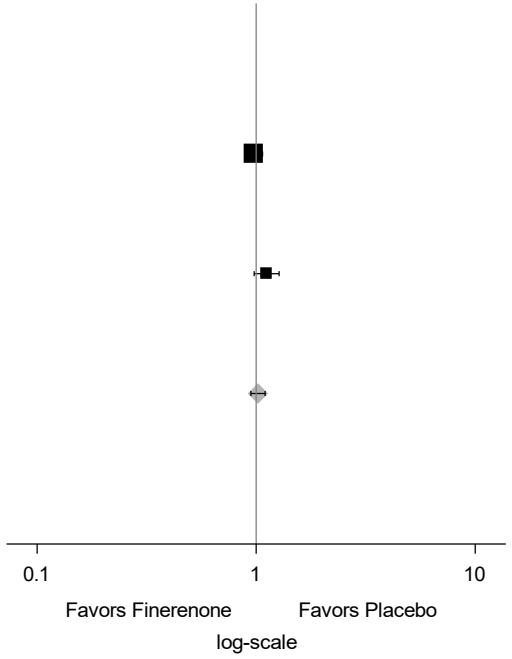
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	341 / 1559	340 / 1549	69.2	1.00 [0.87,1.14]	
FIGARO-DKD	152 / 639	145 / 631	30.8	1.04 [0.85,1.26]	
Total	493 / 2198	485 / 2180		1.01 [0.90,1.13]	Z=0.15, p=0.8842
Heterogeneity:	Q=0.10 (df=1)	p=0.7554	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	237 / 1063	228 / 1071	58.7	1.05 [0.89,1.23]	
FIGARO-DKD	154 / 720	172 / 731	41.3	0.91 [0.75,1.10]	
Total	391 / 1783	400 / 1802		0.99 [0.87,1.12]	Z=-0.20, p=0.8434
Heterogeneity:	Q=1.23 (df=1)	p=0.2671	I^2=18.8%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8070	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

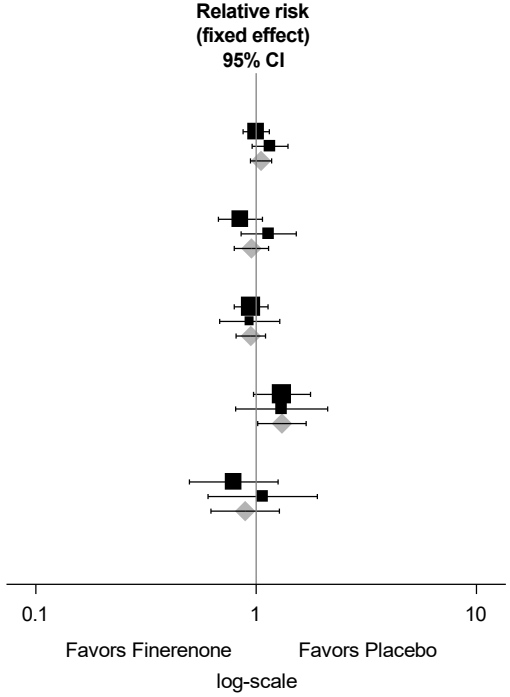
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	677 / 2622	692 / 2620	67.5	0.98 [0.89,1.07]	
FIGARO-DKD	355 / 1359	319 / 1362	32.5	1.12 [0.98,1.27]	
Total	1032 / 3981	1011 / 3982		1.02 [0.95,1.10]	Z=0.50, p=0.6178
Heterogeneity:	Q=2.70 (df=1)	p=0.1002	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.7.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

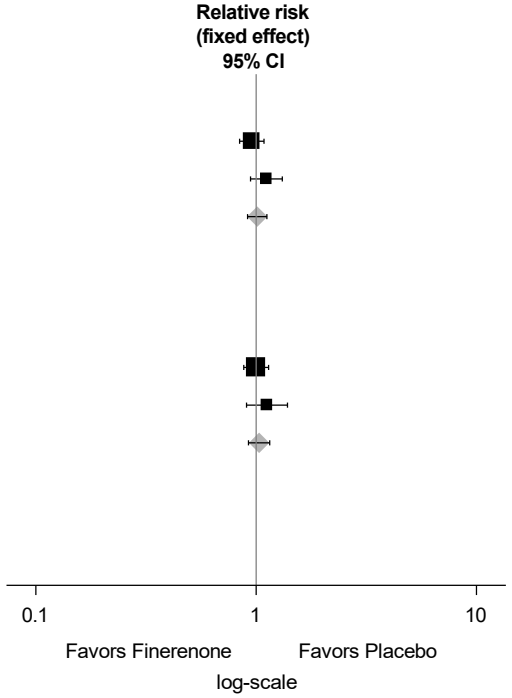
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	298 / 1078	294 / 1064	65.1	1.00 [0.87,1.15]	
FIGARO-DKD	176 / 640	152 / 639	34.9	1.16 [0.96,1.39]	
Total	474 / 1718	446 / 1703		1.05 [0.94,1.18]	Z=0.90, p=0.3656
Heterogeneity:	Q=1.49 (df=1)	p=0.2221	I^2=32.9%		
North America					
FIDELIO-DKD	99 / 425	120 / 437	61.1	0.85 [0.67,1.07]	
FIGARO-DKD	73 / 267	65 / 271	38.9	1.14 [0.85,1.52]	
Total	172 / 692	185 / 708		0.95 [0.80,1.14]	Z=-0.54, p=0.5859
Heterogeneity:	Q=2.46 (df=1)	p=0.1165	I^2=59.4%		
Asia					
FIDELIO-DKD	181 / 751	190 / 748	76.0	0.95 [0.80,1.13]	
FIGARO-DKD	59 / 288	64 / 292	24.0	0.93 [0.68,1.28]	
Total	240 / 1039	254 / 1040		0.95 [0.81,1.10]	Z=-0.71, p=0.4747
Heterogeneity:	Q=0.01 (df=1)	p=0.9349	I^2=0.0%		
Latin America					
FIDELIO-DKD	76 / 274	58 / 274	72.3	1.31 [0.97,1.77]	
FIGARO-DKD	29 / 102	22 / 101	27.7	1.31 [0.81,2.11]	
Total	105 / 376	80 / 375		1.31 [1.02,1.69]	Z=2.08, p=0.0372
Heterogeneity:	Q=0.00 (df=1)	p=0.9893	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 94	30 / 97	60.3	0.79 [0.50,1.26]	
FIGARO-DKD	18 / 62	16 / 59	39.7	1.07 [0.60,1.90]	
Total	41 / 156	46 / 156		0.89 [0.62,1.27]	Z=-0.63, p=0.5287
Heterogeneity:	Q=0.65 (df=1)	p=0.4203	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.09 (df=4)	p=0.1924	I^2=34.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

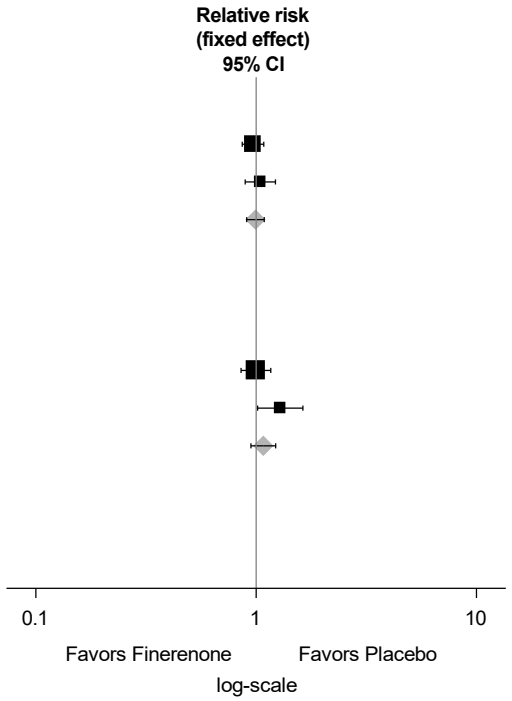
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	333 / 1215	348 / 1213	62.9	0.96 [0.84,1.09]	
FIGARO-DKD	224 / 865	198 / 851	37.1	1.11 [0.94,1.31]	
Total	557 / 2080	546 / 2064		1.01 [0.91,1.12]	Z=0.21, p=0.8309
Heterogeneity:	Q=2.04 (df=1)	p=0.1527	I^2=51.1%		
Absent					
FIDELIO-DKD	344 / 1407	344 / 1407	73.1	1.00 [0.88,1.14]	
FIGARO-DKD	131 / 494	121 / 511	26.9	1.12 [0.90,1.39]	
Total	475 / 1901	465 / 1918		1.03 [0.92,1.15]	Z=0.54, p=0.5898
Heterogeneity:	Q=0.79 (df=1)	p=0.3752	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7987	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

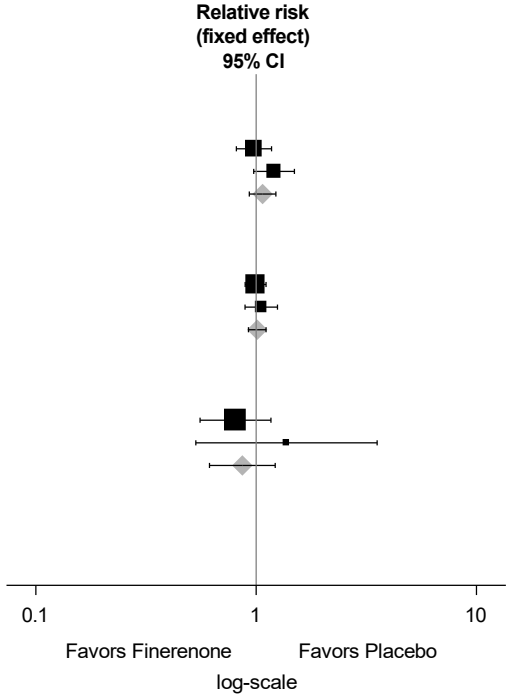
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	446 / 1737	452 / 1703	66.4	0.97 [0.86,1.08]	
FIGARO-DKD	235 / 924	227 / 932	33.6	1.04 [0.89,1.22]	
Total	681 / 2661	679 / 2635		0.99 [0.91,1.09]	Z=-0.16, p=0.8732
Heterogeneity:	Q=0.60 (df=1)	p=0.4403	I^2=0.0%		
> 4.5					
FIDELIO-DKD	231 / 884	240 / 916	69.9	1.00 [0.85,1.16]	
FIGARO-DKD	120 / 435	92 / 429	30.1	1.29 [1.02,1.63]	
Total	351 / 1319	332 / 1345		1.08 [0.95,1.23]	Z=1.13, p=0.2579
Heterogeneity:	Q=3.11 (df=1)	p=0.0780	I^2=67.8%		
Subgroup Heterogeneity:	Q=1.03 (df=1)	p=0.3098	I^2=3.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

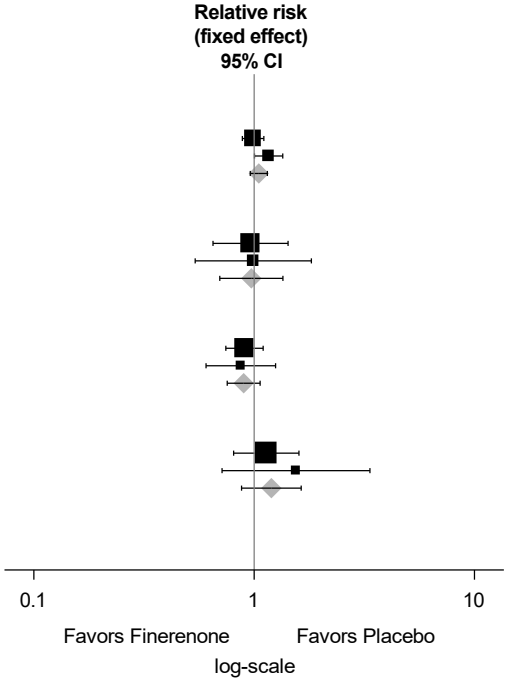
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	171 / 724	175 / 724	57.2	0.98 [0.81,1.17]	
FIGARO-DKD	139 / 494	116 / 497	42.8	1.21 [0.97,1.49]	
Total	310 / 1218	291 / 1221		1.07 [0.93,1.23]	Z=0.95, p=0.3437
Heterogeneity:	Q=2.14 (df=1)	p=0.1431	I^2=53.4%		
130 - < 160					
FIDELIO-DKD	470 / 1762	474 / 1766	70.7	0.99 [0.89,1.11]	
FIGARO-DKD	208 / 831	197 / 830	29.3	1.05 [0.89,1.25]	
Total	678 / 2593	671 / 2596		1.01 [0.92,1.11]	Z=0.24, p=0.8108
Heterogeneity:	Q=0.33 (df=1)	p=0.5640	I^2=0.0%		
>= 160					
FIDELIO-DKD	36 / 133	43 / 128	86.7	0.81 [0.56,1.17]	
FIGARO-DKD	8 / 34	6 / 35	13.3	1.37 [0.53,3.54]	
Total	44 / 167	49 / 163		0.87 [0.61,1.22]	Z=-0.83, p=0.4091
Heterogeneity:	Q=1.05 (df=1)	p=0.3048	I^2=5.1%		
Subgroup Heterogeneity:	Q=1.36 (df=2)	p=0.5067	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

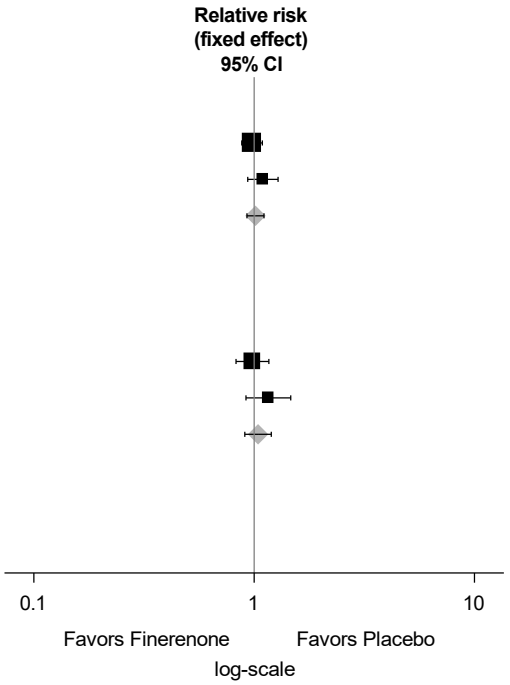
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	439 / 1637	451 / 1663	63.4	0.99 [0.88,1.11]	
FIGARO-DKD	285 / 1013	240 / 992	36.6	1.16 [1.00,1.35]	
Total	724 / 2650	691 / 2655		1.05 [0.96,1.15]	Z=1.06, p=0.2880
Heterogeneity:	Q=2.93 (df=1)	p=0.0868	I^2=65.9%		
Black					
FIDELIO-DKD	37 / 130	34 / 115	70.6	0.96 [0.65,1.43]	
FIGARO-DKD	12 / 43	20 / 71	29.4	0.99 [0.54,1.82]	
Total	49 / 173	54 / 186		0.97 [0.70,1.35]	Z=-0.18, p=0.8604
Heterogeneity:	Q=0.01 (df=1)	p=0.9380	I^2=0.0%		
Asian					
FIDELIO-DKD	148 / 678	164 / 679	77.6	0.90 [0.74,1.10]	
FIGARO-DKD	44 / 251	51 / 253	22.4	0.87 [0.60,1.25]	
Total	192 / 929	215 / 932		0.90 [0.75,1.06]	Z=-1.25, p=0.2105
Heterogeneity:	Q=0.03 (df=1)	p=0.8548	I^2=0.0%		
Others					
FIDELIO-DKD	53 / 177	43 / 163	83.7	1.14 [0.81,1.60]	
FIGARO-DKD	14 / 52	8 / 46	16.3	1.55 [0.71,3.35]	
Total	67 / 229	51 / 209		1.20 [0.88,1.63]	Z=1.13, p=0.2588
Heterogeneity:	Q=0.52 (df=1)	p=0.4715	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.67 (df=3)	p=0.2993	I^2=18.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.7.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

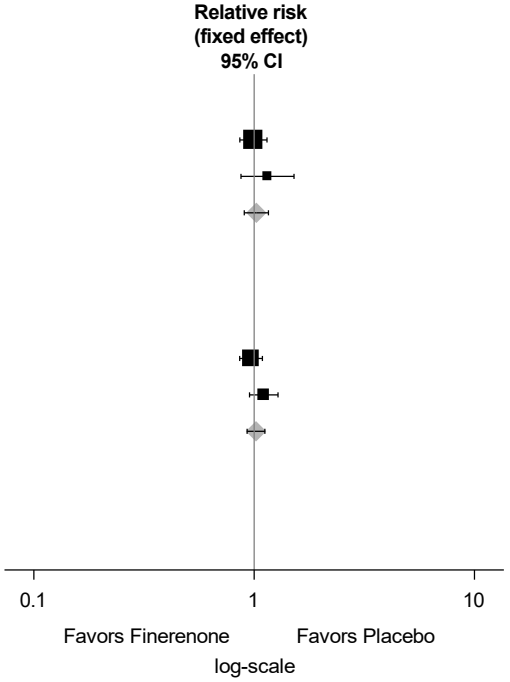
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	473 / 1800	504 / 1876	68.5	0.98 [0.88,1.09]	
FIGARO-DKD	238 / 917	222 / 937	31.5	1.10 [0.93,1.28]	
Total	711 / 2717	726 / 2813		1.01 [0.93,1.11]	Z=0.30, p=0.7651
Heterogeneity:	Q=1.34 (df=1)	p=0.2465	I^2=25.5%		
Female					
FIDELIO-DKD	204 / 822	188 / 744	65.0	0.98 [0.83,1.17]	
FIGARO-DKD	117 / 442	97 / 425	35.0	1.16 [0.92,1.47]	
Total	321 / 1264	285 / 1169		1.04 [0.91,1.20]	Z=0.57, p=0.5663
Heterogeneity:	Q=1.26 (df=1)	p=0.2612	I^2=20.8%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7484	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.7.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

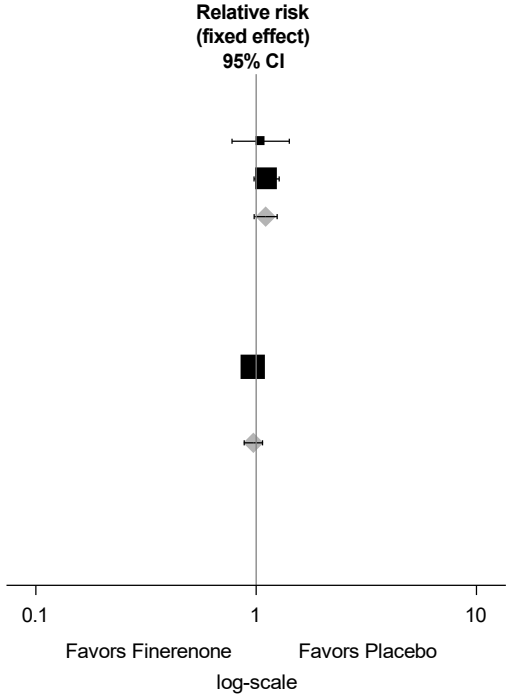
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	285 / 1106	280 / 1078	79.2	0.99 [0.86,1.14]	
FIGARO-DKD	83 / 337	72 / 336	20.8	1.15 [0.87,1.52]	
Total	368 / 1443	352 / 1414		1.02 [0.90,1.16]	Z=0.35, p=0.7239
Heterogeneity:	Q=0.86 (df=1)	p=0.3544	I^2=0.0%		
>= 65					
FIDELIO-DKD	392 / 1516	412 / 1542	61.1	0.97 [0.86,1.09]	
FIGARO-DKD	272 / 1022	247 / 1026	38.9	1.11 [0.95,1.28]	
Total	664 / 2538	659 / 2568		1.02 [0.93,1.12]	Z=0.40, p=0.6878
Heterogeneity:	Q=1.88 (df=1)	p=0.1708	I^2=46.7%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9626	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.7.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

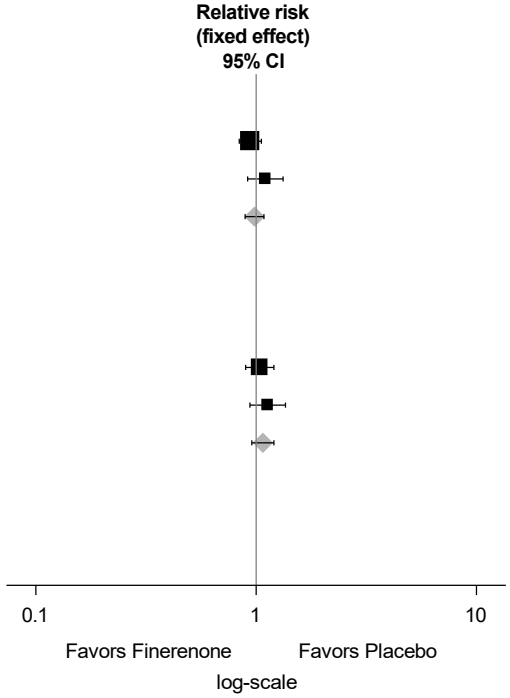
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	60 / 213	16.1	1.05 [0.78,1.41]	
FIGARO-DKD	355 / 1359	319 / 1362	83.9	1.12 [0.98,1.27]	
Total	417 / 1569	379 / 1575		1.10 [0.98,1.25]	Z=1.62, p=0.1059
Heterogeneity:	Q=0.14 (df=1)	p=0.7094	I^2=0.0%		
Very High					
FIDELIO-DKD	615 / 2412	632 / 2407	100.0	0.97 [0.88,1.07]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	615 / 2412	632 / 2407		0.97 [0.88,1.07]	Z=-0.60, p=0.5474
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.69 (df=1)	p=0.1010	I^2=62.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.7.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

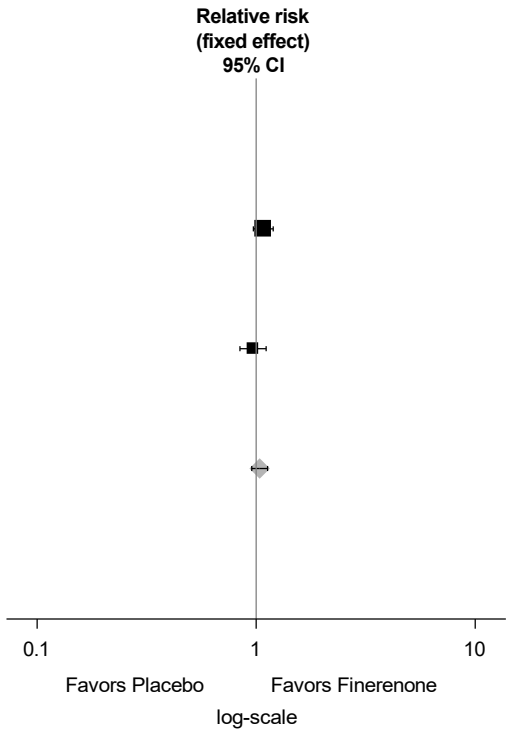
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	408 / 1559	431 / 1549	71.9	0.94 [0.84,1.06]	
FIGARO-DKD	175 / 639	157 / 631	28.1	1.10 [0.91,1.32]	
Total	583 / 2198	588 / 2180		0.98 [0.89,1.08]	Z=-0.34, p=0.7326
Heterogeneity:	Q=1.99 (df=1)	p=0.1583	I^2=49.8%		
45 - < 60					
FIDELIO-DKD	269 / 1063	261 / 1071	61.3	1.04 [0.90,1.20]	
FIGARO-DKD	180 / 720	162 / 731	38.7	1.13 [0.94,1.36]	
Total	449 / 1783	423 / 1802		1.07 [0.96,1.20]	Z=1.18, p=0.2362
Heterogeneity:	Q=0.47 (df=1)	p=0.4937	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.26 (df=1)	p=0.2609	I^2=20.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

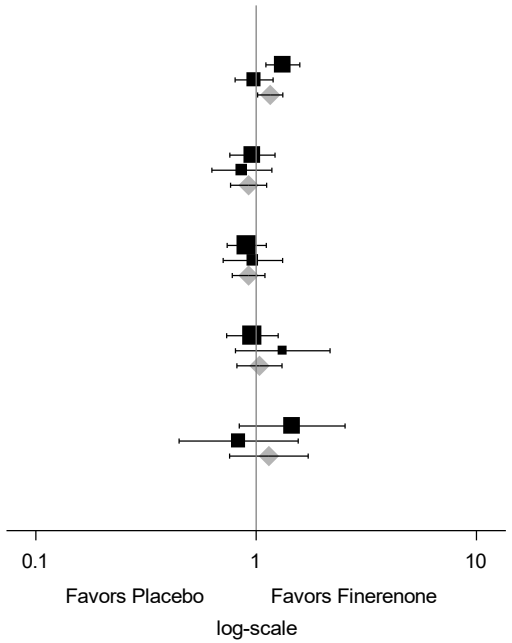
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	574 / 2622	532 / 2620	63.5	1.08 [0.97,1.20]	
FIGARO-DKD	307 / 1359	318 / 1362	36.5	0.97 [0.84,1.11]	
Total	881 / 3981	850 / 3982		1.04 [0.95,1.13]	Z=0.87, p=0.3867
Heterogeneity:	Q=1.50 (df=1)	p=0.2213	I^2=33.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.8.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

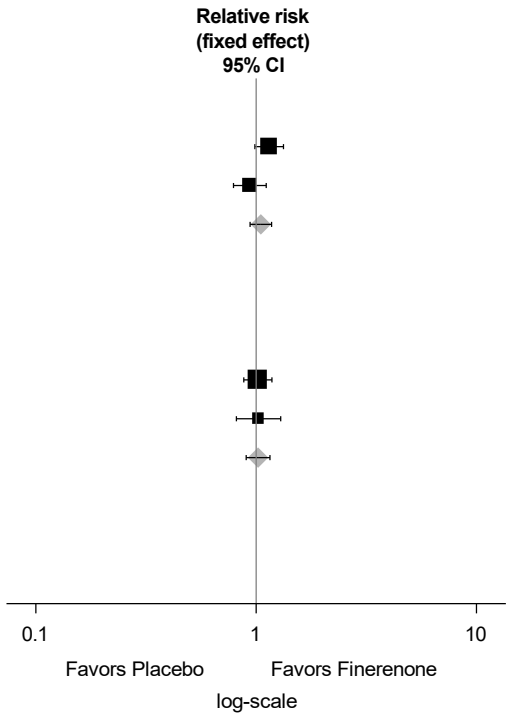
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	233 / 1078	174 / 1064	55.6	1.32 [1.11,1.58]	
FIGARO-DKD	148 / 640	151 / 639	44.4	0.98 [0.80,1.19]	
Total	381 / 1718	325 / 1703		1.16 [1.02,1.32]	Z=2.18, p=0.0290
Heterogeneity:	Q=4.90 (df=1)	p=0.0268	I^2=79.6%		
North America					
FIDELIO-DKD	101 / 425	108 / 437	63.8	0.96 [0.76,1.22]	
FIGARO-DKD	56 / 267	66 / 271	36.2	0.86 [0.63,1.18]	
Total	157 / 692	174 / 708		0.92 [0.77,1.12]	Z=-0.82, p=0.4102
Heterogeneity:	Q=0.30 (df=1)	p=0.5818	I^2=0.0%		
Asia					
FIDELIO-DKD	141 / 751	155 / 748	69.8	0.91 [0.74,1.11]	
FIGARO-DKD	61 / 288	64 / 292	30.2	0.97 [0.71,1.32]	
Total	202 / 1039	219 / 1040		0.92 [0.78,1.10]	Z=-0.91, p=0.3632
Heterogeneity:	Q=0.12 (df=1)	p=0.7341	I^2=0.0%		
Latin America					
FIDELIO-DKD	75 / 274	78 / 274	77.1	0.96 [0.73,1.26]	
FIGARO-DKD	28 / 102	21 / 101	22.9	1.32 [0.81,2.16]	
Total	103 / 376	99 / 375		1.03 [0.82,1.31]	Z=0.29, p=0.7754
Heterogeneity:	Q=1.22 (df=1)	p=0.2696	I^2=17.9%		
Others					
FIDELIO-DKD	24 / 94	17 / 97	55.9	1.46 [0.84,2.53]	
FIGARO-DKD	14 / 62	16 / 59	44.1	0.83 [0.45,1.55]	
Total	38 / 156	33 / 156		1.14 [0.76,1.72]	Z=0.63, p=0.5259
Heterogeneity:	Q=1.73 (df=1)	p=0.1878	I^2=42.4%		
Subgroup Heterogeneity:	Q=6.11 (df=4)	p=0.1910	I^2=34.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

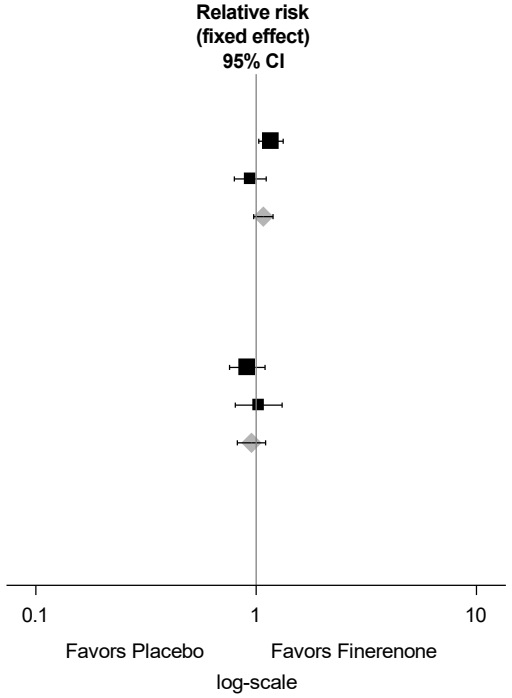
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	288 / 1215	251 / 1213	56.8	1.15 [0.99,1.33]	
FIGARO-DKD	196 / 865	206 / 851	43.2	0.94 [0.79,1.11]	
Total	484 / 2080	457 / 2064		1.05 [0.94,1.17]	Z=0.85, p=0.3956
Heterogeneity:	Q=3.04 (df=1)	p=0.0815	I^2=67.1%		
Absent					
FIDELIO-DKD	286 / 1407	281 / 1407	71.2	1.02 [0.88,1.18]	
FIGARO-DKD	111 / 494	112 / 511	28.8	1.03 [0.81,1.29]	
Total	397 / 1901	393 / 1918		1.02 [0.90,1.15]	Z=0.31, p=0.7556
Heterogeneity:	Q=0.00 (df=1)	p=0.9588	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7343	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

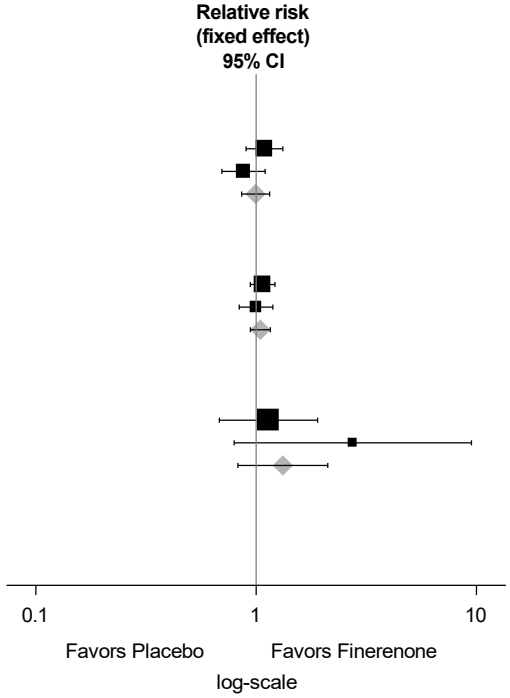
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	406 / 1737	341 / 1703	63.1	1.17 [1.03,1.33]	
FIGARO-DKD	206 / 924	221 / 932	36.9	0.94 [0.80,1.11]	
Total	612 / 2661	562 / 2635		1.08 [0.97,1.19]	Z=1.45, p=0.1459
Heterogeneity:	Q=4.09 (df=1)	p=0.0432	I^2=75.5%		
> 4.5					
FIDELIO-DKD	168 / 884	191 / 916	63.5	0.91 [0.76,1.10]	
FIGARO-DKD	101 / 435	97 / 429	36.5	1.03 [0.80,1.31]	
Total	269 / 1319	288 / 1345		0.95 [0.82,1.10]	Z=-0.65, p=0.5136
Heterogeneity:	Q=0.58 (df=1)	p=0.4465	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.85 (df=1)	p=0.1738	I^2=45.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

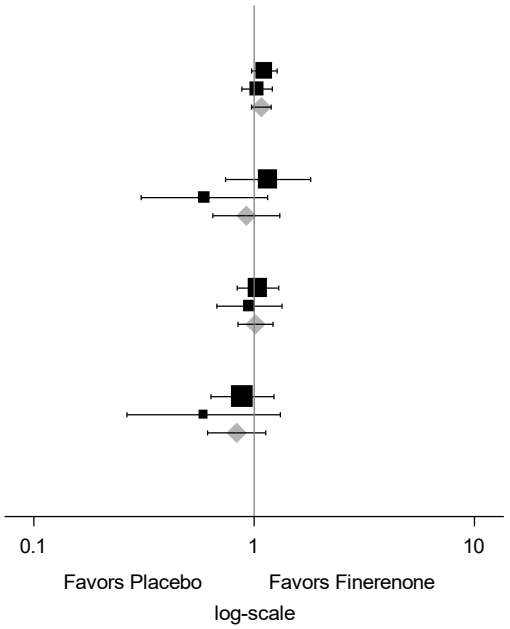
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	169 / 724	155 / 724	58.0	1.09 [0.90,1.32]	
FIGARO-DKD	108 / 494	124 / 497	42.0	0.88 [0.70,1.10]	
Total	277 / 1218	279 / 1221		0.99 [0.86,1.15]	Z=-0.07, p=0.9424
Heterogeneity:	Q=2.09 (df=1)	p=0.1486	I^2=52.1%		
130 - < 160					
FIDELIO-DKD	379 / 1762	355 / 1766	65.1	1.07 [0.94,1.22]	
FIGARO-DKD	191 / 831	191 / 830	34.9	1.00 [0.84,1.19]	
Total	570 / 2593	546 / 2596		1.04 [0.94,1.16]	Z=0.82, p=0.4104
Heterogeneity:	Q=0.38 (df=1)	p=0.5359	I^2=0.0%		
>= 160					
FIDELIO-DKD	26 / 133	22 / 128	85.4	1.14 [0.68,1.90]	
FIGARO-DKD	8 / 34	3 / 35	14.6	2.75 [0.79,9.49]	
Total	34 / 167	25 / 163		1.32 [0.83,2.11]	Z=1.16, p=0.2446
Heterogeneity:	Q=1.66 (df=1)	p=0.1972	I^2=39.9%		
Subgroup Heterogeneity:	Q=1.36 (df=2)	p=0.5078	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

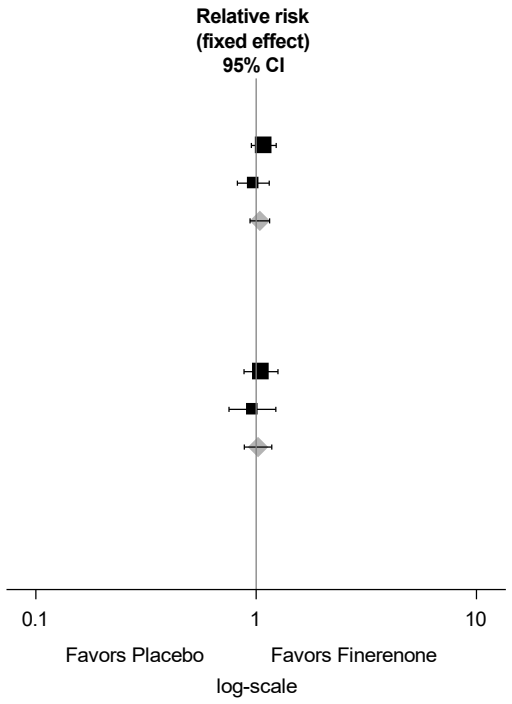
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	357 / 1637	326 / 1663	58.6	1.11 [0.97,1.27]	
FIGARO-DKD	239 / 1013	227 / 992	41.4	1.03 [0.88,1.21]	
Total	596 / 2650	553 / 2655		1.08 [0.97,1.19]	Z=1.44, p=0.1502
Heterogeneity:	Q=0.51 (df=1)	p=0.4735	I^2=0.0%		
Black					
FIDELIO-DKD	34 / 130	26 / 115	68.8	1.16 [0.74,1.80]	
FIGARO-DKD	9 / 43	25 / 71	31.2	0.59 [0.31,1.15]	
Total	43 / 173	51 / 186		0.92 [0.65,1.31]	Z=-0.46, p=0.6462
Heterogeneity:	Q=2.69 (df=1)	p=0.1007	I^2=62.9%		
Asian					
FIDELIO-DKD	134 / 678	129 / 679	71.1	1.04 [0.84,1.29]	
FIGARO-DKD	51 / 251	54 / 253	28.9	0.95 [0.68,1.34]	
Total	185 / 929	183 / 932		1.01 [0.84,1.22]	Z=0.15, p=0.8820
Heterogeneity:	Q=0.19 (df=1)	p=0.6668	I^2=0.0%		
Others					
FIDELIO-DKD	49 / 177	51 / 163	85.6	0.88 [0.64,1.23]	
FIGARO-DKD	8 / 52	12 / 46	14.4	0.59 [0.26,1.31]	
Total	57 / 229	63 / 209		0.83 [0.61,1.13]	Z=-1.18, p=0.2385
Heterogeneity:	Q=0.84 (df=1)	p=0.3590	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.04 (df=3)	p=0.3850	I^2=1.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.8.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

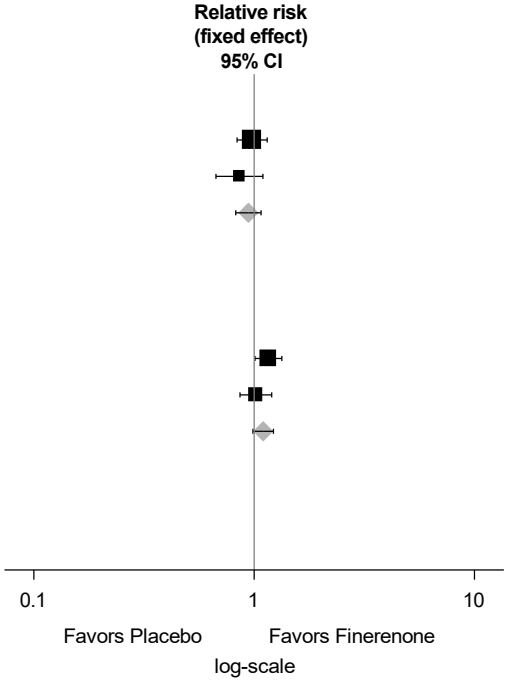
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	373 / 1800	359 / 1876	62.2	1.08 [0.95,1.23]	
FIGARO-DKD	208 / 917	219 / 937	37.8	0.97 [0.82,1.15]	
Total	581 / 2717	578 / 2813		1.04 [0.94,1.15]	Z=0.73, p=0.4638
Heterogeneity:	Q=1.04 (df=1)	p=0.3089	I^2=3.4%		
Female					
FIDELIO-DKD	201 / 822	173 / 744	65.5	1.05 [0.88,1.26]	
FIGARO-DKD	99 / 442	99 / 425	34.5	0.96 [0.75,1.23]	
Total	300 / 1264	272 / 1169		1.02 [0.88,1.18]	Z=0.27, p=0.7899
Heterogeneity:	Q=0.34 (df=1)	p=0.5615	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8351	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.8.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

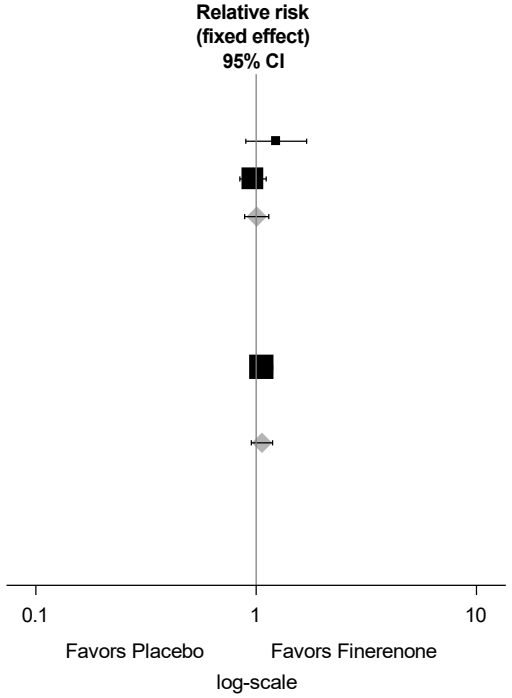
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	242 / 1106	241 / 1078	70.9	0.98 [0.84,1.15]	
FIGARO-DKD	86 / 337	100 / 336	29.1	0.86 [0.67,1.10]	
Total	328 / 1443	341 / 1414		0.94 [0.82,1.07]	Z=-0.89, p=0.3729
Heterogeneity:	Q=0.79 (df=1)	p=0.3739	I^2=0.0%		
>= 65					
FIDELIO-DKD	332 / 1516	291 / 1542	58.2	1.16 [1.01,1.34]	
FIGARO-DKD	221 / 1022	218 / 1026	41.8	1.02 [0.86,1.20]	
Total	553 / 2538	509 / 2568		1.10 [0.99,1.22]	Z=1.72, p=0.0853
Heterogeneity:	Q=1.40 (df=1)	p=0.2366	I^2=28.6%		
Subgroup Heterogeneity:	Q=3.15 (df=1)	p=0.0758	I^2=68.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.8.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

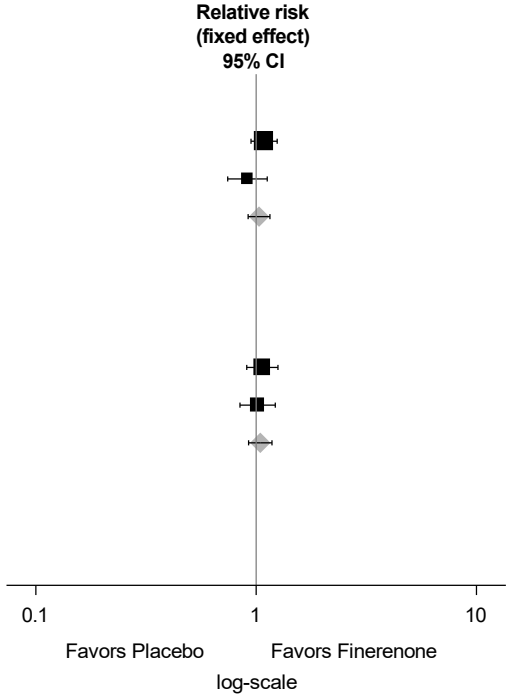
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	51 / 213	15.8	1.23 [0.90,1.69]	
FIGARO-DKD	307 / 1359	318 / 1362	84.2	0.97 [0.84,1.11]	
Total	369 / 1569	369 / 1575		1.01 [0.89,1.14]	Z=0.09, p=0.9303
Heterogeneity:	Q=1.88 (df=1)	p=0.1699	I^2=46.9%		
Very High					
FIDELIO-DKD	512 / 2412	481 / 2407	100.0	1.06 [0.95,1.19]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	512 / 2412	481 / 2407		1.06 [0.95,1.19]	Z=1.07, p=0.2859
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5230	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.8.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

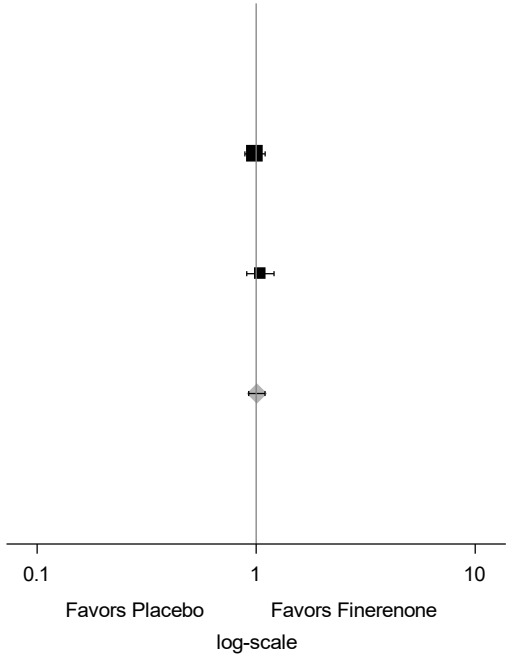
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	340 / 1559	311 / 1549	69.5	1.09 [0.95,1.25]	
FIGARO-DKD	135 / 639	146 / 631	30.5	0.91 [0.74,1.12]	
Total	475 / 2198	457 / 2180		1.03 [0.92,1.15]	Z=0.51, p=0.6083
Heterogeneity:	Q=1.89 (df=1)	p=0.1695	I^2=47.0%		
45 - < 60					
FIDELIO-DKD	234 / 1063	221 / 1071	56.2	1.07 [0.91,1.26]	
FIGARO-DKD	172 / 720	172 / 731	43.8	1.02 [0.84,1.22]	
Total	406 / 1783	393 / 1802		1.04 [0.92,1.18]	Z=0.69, p=0.4908
Heterogeneity:	Q=0.16 (df=1)	p=0.6937	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8772	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

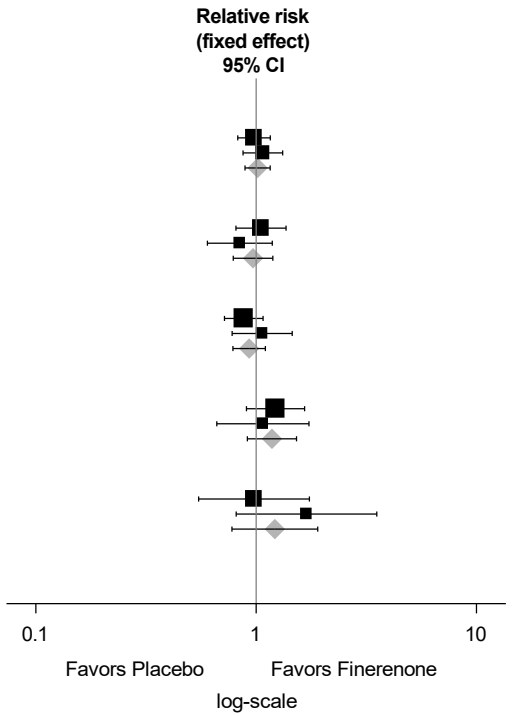
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	533 / 2622	540 / 2620	64.4	0.99 [0.89,1.10]	
FIGARO-DKD	299 / 1359	287 / 1362	35.6	1.05 [0.91,1.21]	
Total	832 / 3981	827 / 3982		1.01 [0.92,1.10]	Z=0.17, p=0.8682
Heterogeneity:	Q=0.39 (df=1)	p=0.5348	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.9.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

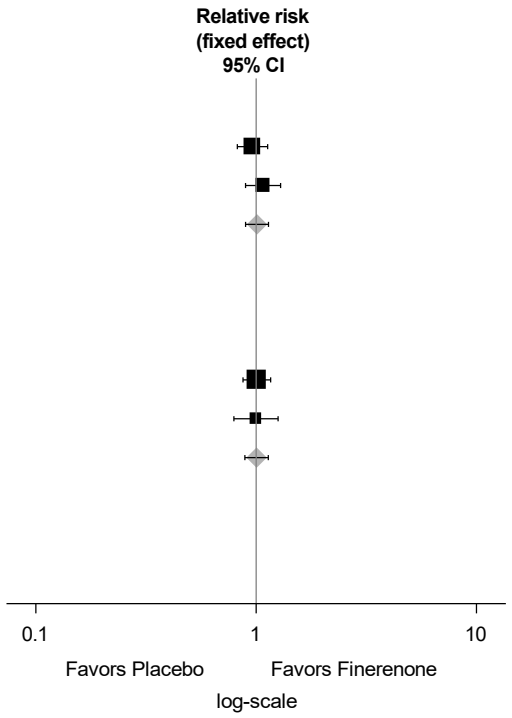
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	212 / 1078	214 / 1064	59.8	0.98 [0.82,1.16]	
FIGARO-DKD	145 / 640	135 / 639	40.2	1.07 [0.87,1.32]	
Total	357 / 1718	349 / 1703		1.01 [0.89,1.16]	Z=0.22, p=0.8262
Heterogeneity:	Q=0.46 (df=1)	p=0.4994	I^2=0.0%		
North America					
FIDELIO-DKD	90 / 425	88 / 437	62.7	1.05 [0.81,1.37]	
FIGARO-DKD	49 / 267	59 / 271	37.3	0.84 [0.60,1.18]	
Total	139 / 692	147 / 708		0.97 [0.79,1.19]	Z=-0.31, p=0.7571
Heterogeneity:	Q=1.02 (df=1)	p=0.3115	I^2=2.4%		
Asia					
FIDELIO-DKD	142 / 751	161 / 748	70.8	0.88 [0.72,1.07]	
FIGARO-DKD	63 / 288	60 / 292	29.2	1.06 [0.78,1.46]	
Total	205 / 1039	221 / 1040		0.93 [0.78,1.10]	Z=-0.85, p=0.3951
Heterogeneity:	Q=1.02 (df=1)	p=0.3127	I^2=1.9%		
Latin America					
FIDELIO-DKD	71 / 274	58 / 274	71.5	1.22 [0.90,1.66]	
FIGARO-DKD	26 / 102	24 / 101	28.5	1.07 [0.66,1.74]	
Total	97 / 376	82 / 375		1.18 [0.91,1.52]	Z=1.26, p=0.2084
Heterogeneity:	Q=0.21 (df=1)	p=0.6495	I^2=0.0%		
Others					
FIDELIO-DKD	18 / 94	19 / 97	61.7	0.98 [0.55,1.74]	
FIGARO-DKD	16 / 62	9 / 59	38.3	1.69 [0.81,3.53]	
Total	34 / 156	28 / 156		1.22 [0.78,1.90]	Z=0.85, p=0.3938
Heterogeneity:	Q=1.32 (df=1)	p=0.2503	I^2=24.3%		
Subgroup Heterogeneity:	Q=3.15 (df=4)	p=0.5333	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

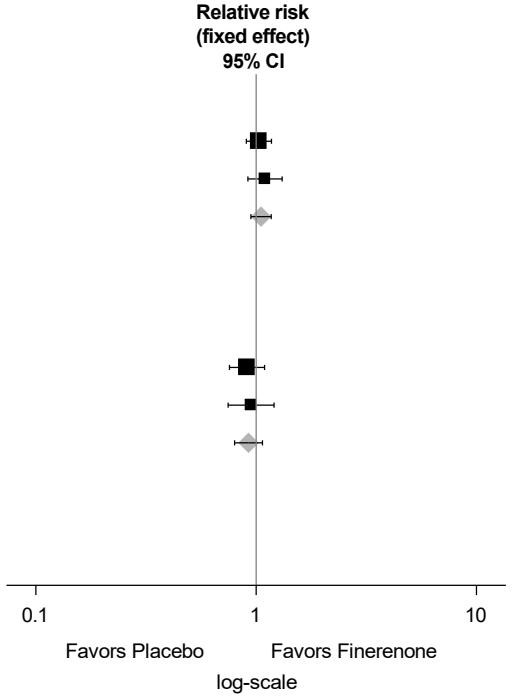
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	240 / 1215	249 / 1213	57.2	0.96 [0.82,1.13]	
FIGARO-DKD	189 / 865	173 / 851	42.8	1.07 [0.89,1.29]	
Total	429 / 2080	422 / 2064		1.01 [0.90,1.14]	Z=0.15, p=0.8843
Heterogeneity:	Q=0.80 (df=1)	p=0.3709	I^2=0.0%		
Absent					
FIDELIO-DKD	293 / 1407	291 / 1407	71.9	1.01 [0.87,1.16]	
FIGARO-DKD	110 / 494	114 / 511	28.1	1.00 [0.79,1.26]	
Total	403 / 1901	405 / 1918		1.00 [0.89,1.14]	Z=0.07, p=0.9439
Heterogeneity:	Q=0.00 (df=1)	p=0.9499	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9590	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

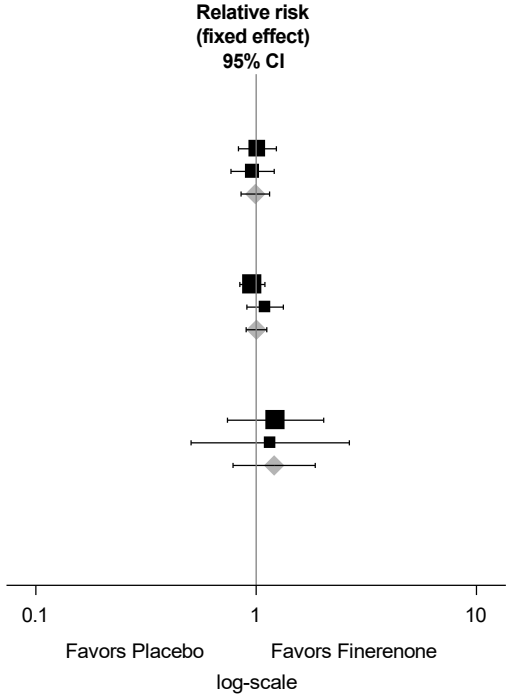
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	362 / 1737	345 / 1703	64.9	1.03 [0.90,1.17]	
FIGARO-DKD	199 / 924	183 / 932	35.1	1.10 [0.92,1.31]	
Total	561 / 2661	528 / 2635		1.05 [0.95,1.17]	Z=0.94, p=0.3470
Heterogeneity:	Q=0.32 (df=1)	p=0.5714	I^2=0.0%		
> 4.5					
FIDELIO-DKD	171 / 884	195 / 916	63.1	0.91 [0.76,1.09]	
FIGARO-DKD	100 / 435	104 / 429	36.9	0.95 [0.75,1.21]	
Total	271 / 1319	299 / 1345		0.92 [0.80,1.07]	Z=-1.08, p=0.2814
Heterogeneity:	Q=0.08 (df=1)	p=0.7818	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.03 (df=1)	p=0.1544	I^2=50.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

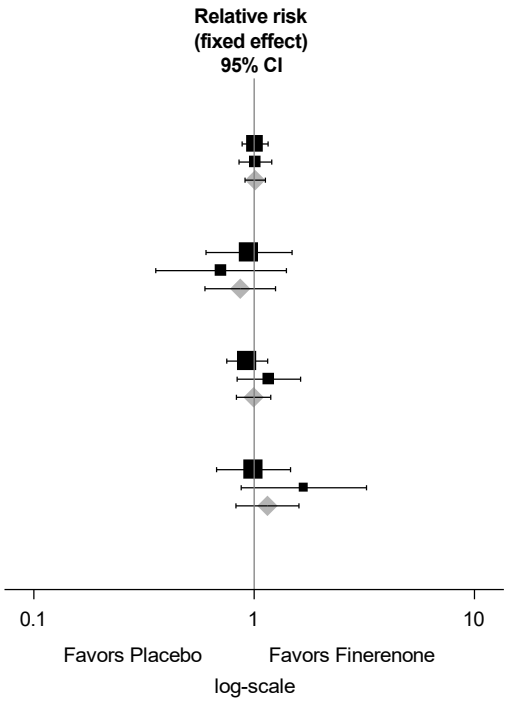
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	155 / 724	153 / 724	56.5	1.01 [0.83,1.24]	
FIGARO-DKD	113 / 494	118 / 497	43.5	0.96 [0.77,1.21]	
Total	268 / 1218	271 / 1221		0.99 [0.85,1.15]	Z=-0.12, p=0.9072
Heterogeneity:	Q=0.11 (df=1)	p=0.7432	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	350 / 1762	365 / 1766	67.9	0.96 [0.84,1.10]	
FIGARO-DKD	177 / 831	161 / 830	32.1	1.10 [0.91,1.33]	
Total	527 / 2593	526 / 2596		1.00 [0.90,1.12]	Z=0.06, p=0.9553
Heterogeneity:	Q=1.28 (df=1)	p=0.2587	I^2=21.6%		
>= 160					
FIDELIO-DKD	28 / 133	22 / 128	73.0	1.22 [0.74,2.03]	
FIGARO-DKD	9 / 34	8 / 35	27.0	1.16 [0.51,2.65]	
Total	37 / 167	30 / 163		1.21 [0.79,1.85]	Z=0.86, p=0.3917
Heterogeneity:	Q=0.01 (df=1)	p=0.9096	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=2)	p=0.6947	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

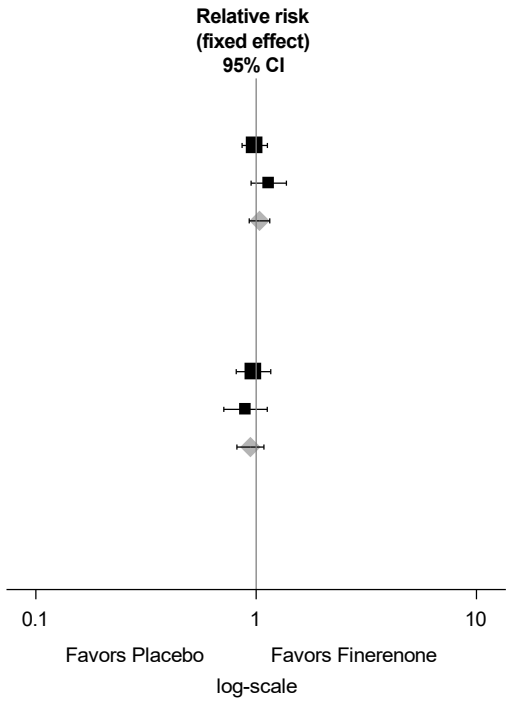
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	332 / 1637	334 / 1663	61.3	1.01 [0.88,1.16]	
FIGARO-DKD	212 / 1013	205 / 992	38.7	1.01 [0.85,1.20]	
Total	544 / 2650	539 / 2655		1.01 [0.91,1.12]	Z=0.20, p=0.8412
Heterogeneity:	Q=0.00 (df=1)	p=0.9794	I^2=0.0%		
Black					
FIDELIO-DKD	30 / 130	28 / 115	69.7	0.95 [0.60,1.49]	
FIGARO-DKD	9 / 43	21 / 71	30.3	0.71 [0.36,1.40]	
Total	39 / 173	49 / 186		0.86 [0.60,1.25]	Z=-0.77, p=0.4385
Heterogeneity:	Q=0.49 (df=1)	p=0.4835	I^2=0.0%		
Asian					
FIDELIO-DKD	130 / 678	140 / 679	70.7	0.93 [0.75,1.15]	
FIGARO-DKD	59 / 251	51 / 253	29.3	1.17 [0.84,1.62]	
Total	189 / 929	191 / 932		0.99 [0.83,1.19]	Z=-0.07, p=0.9473
Heterogeneity:	Q=1.26 (df=1)	p=0.2609	I^2=20.9%		
Others					
FIDELIO-DKD	41 / 177	38 / 163	74.2	0.99 [0.67,1.46]	
FIGARO-DKD	19 / 52	10 / 46	25.8	1.68 [0.87,3.24]	
Total	60 / 229	48 / 209		1.15 [0.83,1.60]	Z=0.83, p=0.4085
Heterogeneity:	Q=1.84 (df=1)	p=0.1752	I^2=45.6%		
Subgroup Heterogeneity:	Q=1.30 (df=3)	p=0.7290	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.9.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

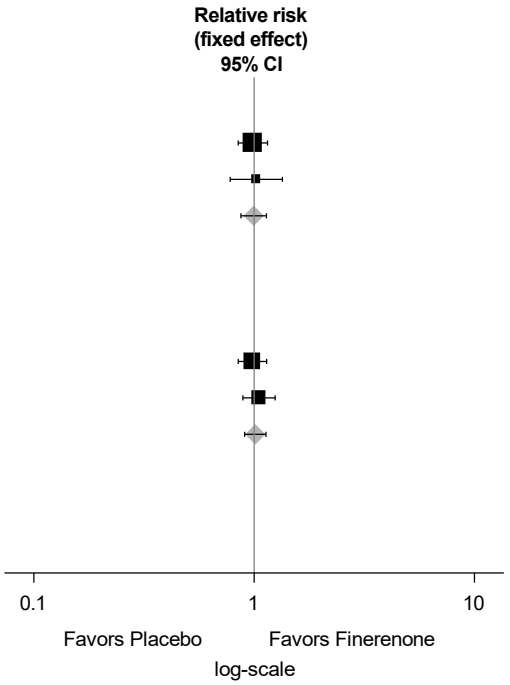
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	345 / 1800	365 / 1876	66.1	0.99 [0.86,1.12]	
FIGARO-DKD	192 / 917	172 / 937	33.9	1.14 [0.95,1.37]	
Total	537 / 2717	537 / 2813		1.04 [0.93,1.15]	Z=0.63, p=0.5255
Heterogeneity:	Q=1.60 (df=1)	p=0.2057	I^2=37.6%		
Female					
FIDELIO-DKD	188 / 822	175 / 744	61.3	0.97 [0.81,1.16]	
FIGARO-DKD	107 / 442	115 / 425	38.7	0.89 [0.71,1.12]	
Total	295 / 1264	290 / 1169		0.94 [0.82,1.08]	Z=-0.84, p=0.4026
Heterogeneity:	Q=0.32 (df=1)	p=0.5736	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.10 (df=1)	p=0.2935	I^2=9.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.9.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

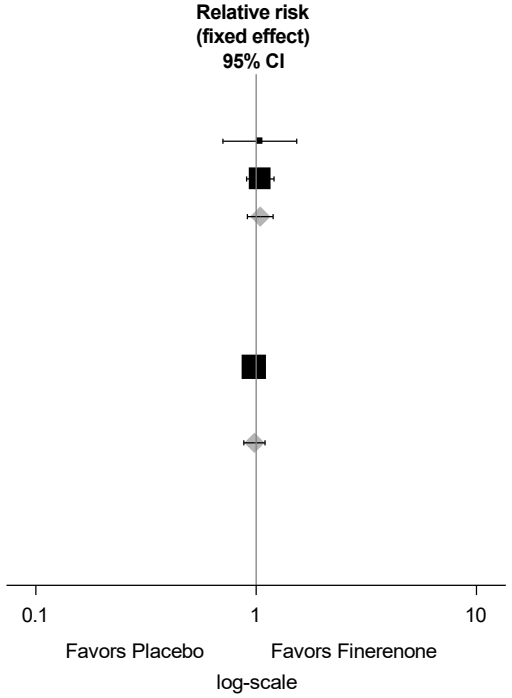
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	254 / 1106	251 / 1078	76.1	0.99 [0.85,1.15]	
FIGARO-DKD	80 / 337	78 / 336	23.9	1.02 [0.78,1.34]	
Total	334 / 1443	329 / 1414		0.99 [0.87,1.14]	Z=-0.08, p=0.9400
Heterogeneity:	Q=0.05 (df=1)	p=0.8210	I^2=0.0%		
>= 65					
FIDELIO-DKD	279 / 1516	289 / 1542	56.3	0.98 [0.85,1.14]	
FIGARO-DKD	219 / 1022	209 / 1026	43.7	1.05 [0.89,1.25]	
Total	498 / 2538	498 / 2568		1.01 [0.91,1.13]	Z=0.21, p=0.8346
Heterogeneity:	Q=0.36 (df=1)	p=0.5480	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8480	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.9.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

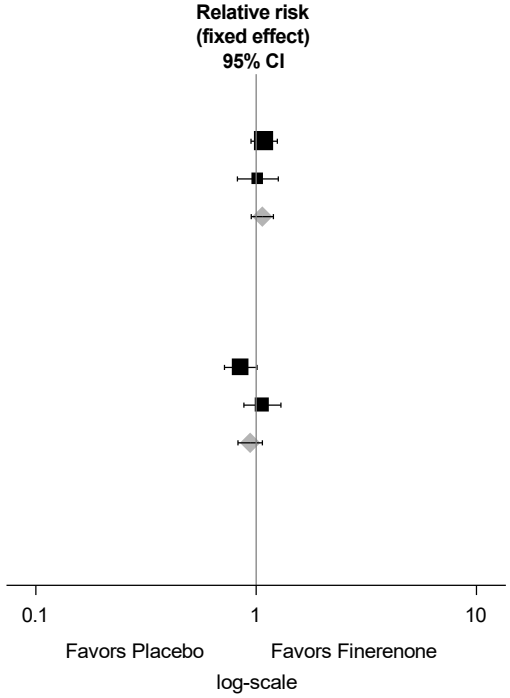
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 210	41 / 213	12.2	1.04 [0.71,1.53]	
FIGARO-DKD	299 / 1359	287 / 1362	87.8	1.04 [0.90,1.21]	
Total	341 / 1569	328 / 1575		1.04 [0.91,1.19]	Z=0.62, p=0.5349
Heterogeneity:	Q=0.00 (df=1)	p=0.9814	I^2=0.0%		
Very High					
FIDELIO-DKD	491 / 2412	499 / 2407	100.0	0.98 [0.88,1.10]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	491 / 2412	499 / 2407		0.98 [0.88,1.10]	Z=-0.32, p=0.7476
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4944	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.9.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

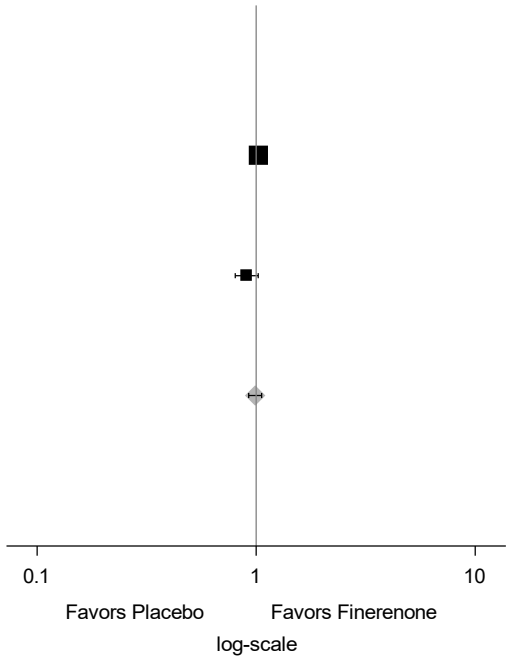
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	337 / 1559	308 / 1549	70.7	1.09 [0.95,1.25]	
FIGARO-DKD	135 / 639	131 / 631	29.3	1.02 [0.82,1.26]	
Total	472 / 2198	439 / 2180		1.07 [0.95,1.20]	Z=1.09, p=0.2766
Heterogeneity:	Q=0.26 (df=1)	p=0.6104	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	196 / 1063	232 / 1071	56.4	0.85 [0.72,1.01]	
FIGARO-DKD	164 / 720	156 / 731	43.6	1.07 [0.88,1.30]	
Total	360 / 1783	388 / 1802		0.94 [0.83,1.07]	Z=-0.96, p=0.3351
Heterogeneity:	Q=2.96 (df=1)	p=0.0852	I^2=66.2%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1485	I^2=52.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

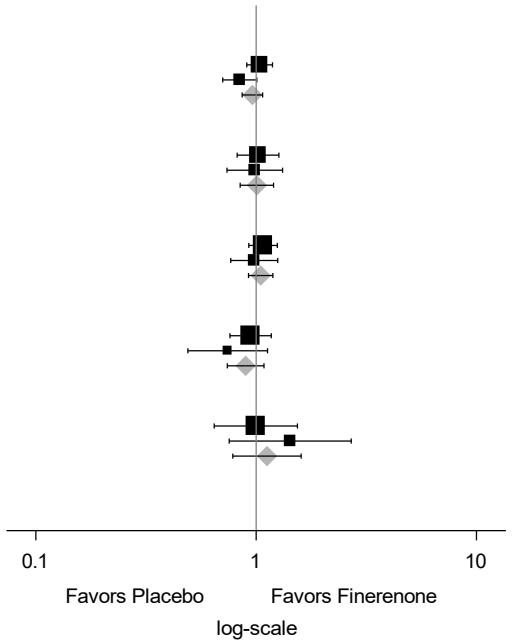
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	803 / 2622	778 / 2620	68.4	1.03 [0.95,1.12]	
FIGARO-DKD	361 / 1359	399 / 1362	31.6	0.91 [0.80,1.02]	
Total	1164 / 3981	1177 / 3982		0.99 [0.92,1.06]	Z=-0.31, p=0.7584
Heterogeneity:	Q=3.01 (df=1)	p=0.0828	I^2=66.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.10.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

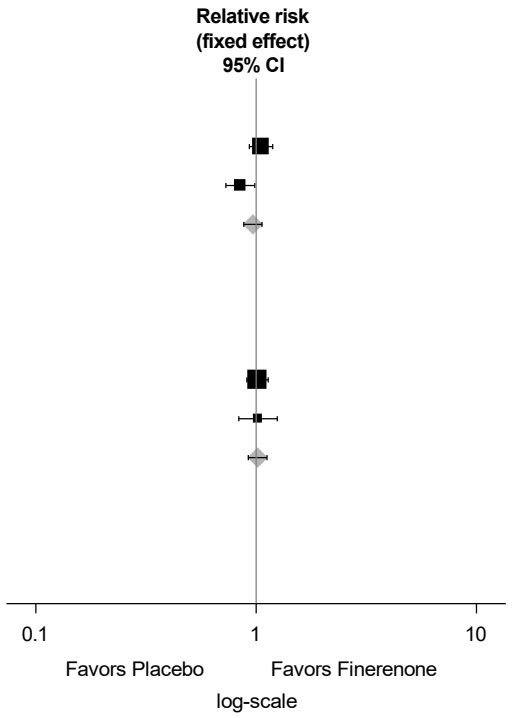
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	312 / 1078	297 / 1064	63.7	1.04 [0.91,1.19]	
FIGARO-DKD	162 / 640	192 / 639	36.3	0.84 [0.71,1.01]	
Total	474 / 1718	489 / 1703		0.96 [0.86,1.07]	Z=-0.72, p=0.4697
Heterogeneity:	Q=3.33 (df=1)	p=0.0681	I^2=70.0%		
North America					
FIDELIO-DKD	117 / 425	118 / 437	64.0	1.02 [0.82,1.27]	
FIGARO-DKD	67 / 267	69 / 271	36.0	0.99 [0.74,1.32]	
Total	184 / 692	187 / 708		1.01 [0.85,1.20]	Z=0.08, p=0.9362
Heterogeneity:	Q=0.03 (df=1)	p=0.8550	I^2=0.0%		
Asia					
FIDELIO-DKD	246 / 751	228 / 748	73.1	1.07 [0.93,1.25]	
FIGARO-DKD	87 / 288	90 / 292	26.9	0.98 [0.77,1.25]	
Total	333 / 1039	318 / 1040		1.05 [0.92,1.19]	Z=0.73, p=0.4675
Heterogeneity:	Q=0.39 (df=1)	p=0.5299	I^2=0.0%		
Latin America					
FIDELIO-DKD	100 / 274	106 / 274	78.8	0.94 [0.76,1.17]	
FIGARO-DKD	27 / 102	36 / 101	21.2	0.74 [0.49,1.13]	
Total	127 / 376	142 / 375		0.90 [0.74,1.09]	Z=-1.12, p=0.2608
Heterogeneity:	Q=1.00 (df=1)	p=0.3173	I^2=0.0%		
Others					
FIDELIO-DKD	28 / 94	29 / 97	68.2	1.00 [0.64,1.54]	
FIGARO-DKD	18 / 62	12 / 59	31.8	1.43 [0.75,2.70]	
Total	46 / 156	41 / 156		1.12 [0.78,1.60]	Z=0.62, p=0.5348
Heterogeneity:	Q=0.83 (df=1)	p=0.3612	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.60 (df=4)	p=0.6261	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

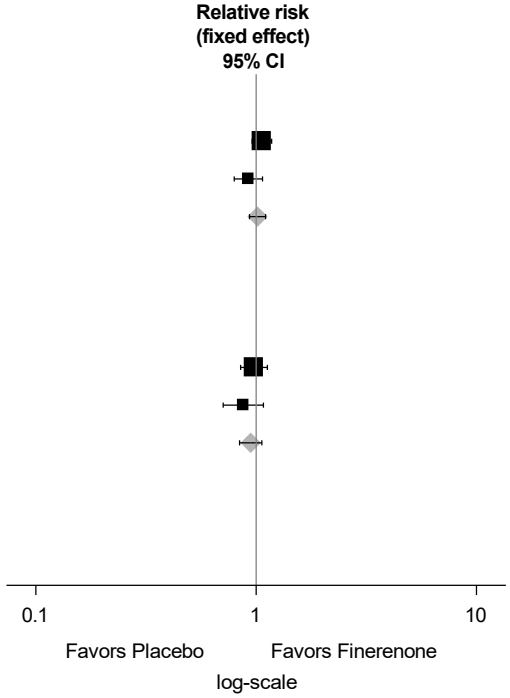
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	372 / 1215	353 / 1213	60.7	1.05 [0.93,1.19]	
FIGARO-DKD	224 / 865	260 / 851	39.3	0.85 [0.73,0.99]	
Total	596 / 2080	613 / 2064		0.97 [0.88,1.06]	Z=-0.71, p=0.4766
Heterogeneity:	Q=4.74 (df=1)	p=0.0295	I^2=78.9%		
Absent					
FIDELIO-DKD	431 / 1407	425 / 1407	76.4	1.01 [0.91,1.13]	
FIGARO-DKD	137 / 494	139 / 511	23.6	1.02 [0.83,1.25]	
Total	568 / 1901	564 / 1918		1.02 [0.92,1.12]	Z=0.31, p=0.7592
Heterogeneity:	Q=0.00 (df=1)	p=0.9638	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4741	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

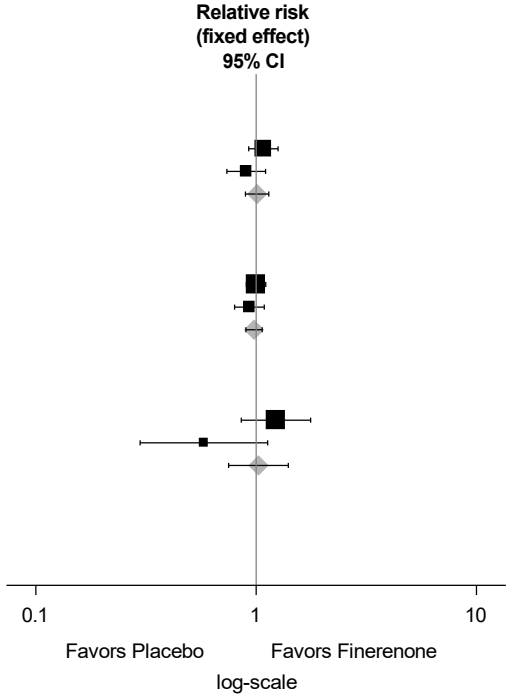
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	537 / 1737	496 / 1703	67.7	1.06 [0.96,1.18]	
FIGARO-DKD	244 / 924	267 / 932	32.3	0.92 [0.80,1.07]	
Total	781 / 2661	763 / 2635		1.01 [0.93,1.10]	Z=0.33, p=0.7431
Heterogeneity:	Q=2.37 (df=1)	p=0.1237	I^2=57.8%		
> 4.5					
FIDELIO-DKD	266 / 884	282 / 916	69.3	0.98 [0.85,1.12]	
FIGARO-DKD	117 / 435	132 / 429	30.7	0.87 [0.71,1.08]	
Total	383 / 1319	414 / 1345		0.94 [0.84,1.06]	Z=-0.96, p=0.3354
Heterogeneity:	Q=0.75 (df=1)	p=0.3858	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.95 (df=1)	p=0.3305	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

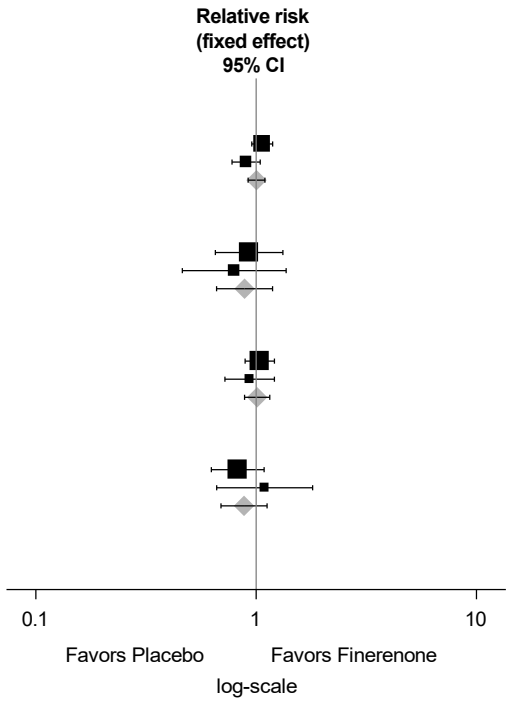
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	234 / 724	217 / 724	63.5	1.08 [0.93,1.26]	
FIGARO-DKD	129 / 494	144 / 497	36.5	0.90 [0.74,1.10]	
Total	363 / 1218	361 / 1221		1.01 [0.89,1.14]	Z=0.16, p=0.8732
Heterogeneity:	Q=1.92 (df=1)	p=0.1661	I^2=47.8%		
130 - < 160					
FIDELIO-DKD	523 / 1762	525 / 1766	70.0	1.00 [0.90,1.11]	
FIGARO-DKD	223 / 831	239 / 830	30.0	0.93 [0.80,1.09]	
Total	746 / 2593	764 / 2596		0.98 [0.90,1.06]	Z=-0.51, p=0.6076
Heterogeneity:	Q=0.53 (df=1)	p=0.4660	I^2=0.0%		
>= 160					
FIDELIO-DKD	46 / 133	36 / 128	77.2	1.23 [0.86,1.77]	
FIGARO-DKD	9 / 34	16 / 35	22.8	0.58 [0.30,1.13]	
Total	55 / 167	52 / 163		1.02 [0.75,1.40]	Z=0.15, p=0.8810
Heterogeneity:	Q=3.79 (df=1)	p=0.0515	I^2=73.6%		
Subgroup Heterogeneity:	Q=0.23 (df=2)	p=0.8924	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

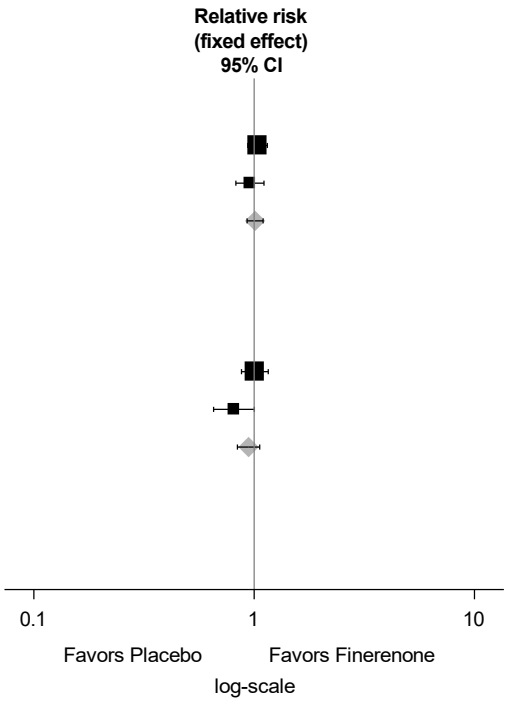
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	476 / 1637	454 / 1663	64.6	1.07 [0.96,1.19]	
FIGARO-DKD	251 / 1013	273 / 992	35.4	0.90 [0.78,1.04]	
Total	727 / 2650	727 / 2655		1.00 [0.92,1.10]	Z=0.08, p=0.9355
Heterogeneity:	Q=3.23 (df=1)	p=0.0723	I^2=69.0%		
Black					
FIDELIO-DKD	42 / 130	40 / 115	70.3	0.93 [0.65,1.32]	
FIGARO-DKD	13 / 43	27 / 71	29.7	0.80 [0.46,1.37]	
Total	55 / 173	67 / 186		0.89 [0.66,1.19]	Z=-0.81, p=0.4168
Heterogeneity:	Q=0.22 (df=1)	p=0.6375	I^2=0.0%		
Asian					
FIDELIO-DKD	225 / 678	217 / 679	74.0	1.04 [0.89,1.21]	
FIGARO-DKD	76 / 251	82 / 253	26.0	0.93 [0.72,1.21]	
Total	301 / 929	299 / 932		1.01 [0.89,1.15]	Z=0.15, p=0.8793
Heterogeneity:	Q=0.48 (df=1)	p=0.4906	I^2=0.0%		
Others					
FIDELIO-DKD	60 / 177	67 / 163	76.8	0.82 [0.63,1.09]	
FIGARO-DKD	21 / 52	17 / 46	23.2	1.09 [0.66,1.80]	
Total	81 / 229	84 / 209		0.88 [0.69,1.12]	Z=-1.03, p=0.3016
Heterogeneity:	Q=0.93 (df=1)	p=0.3351	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.64 (df=3)	p=0.6500	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.10.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

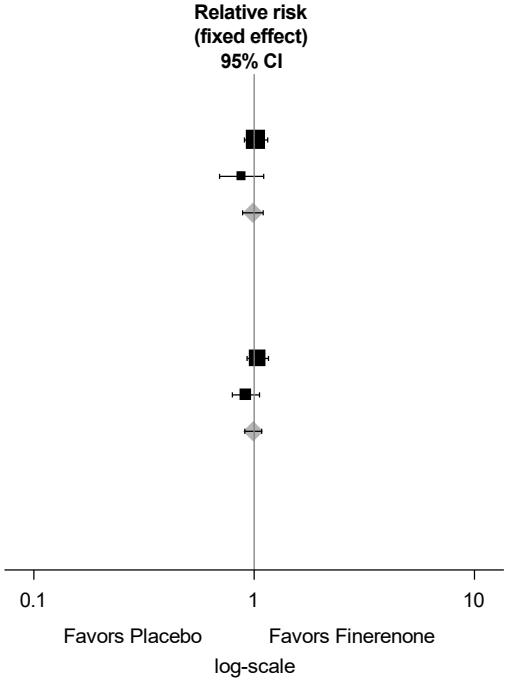
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	527 / 1800	530 / 1876	67.6	1.04 [0.94,1.15]	
FIGARO-DKD	249 / 917	266 / 937	32.4	0.96 [0.83,1.11]	
Total	776 / 2717	796 / 2813		1.01 [0.93,1.10]	Z=0.23, p=0.8208
Heterogeneity:	Q=0.77 (df=1)	p=0.3794	I^2=0.0%		
Female					
FIDELIO-DKD	276 / 822	248 / 744	69.9	1.01 [0.88,1.16]	
FIGARO-DKD	112 / 442	133 / 425	30.1	0.81 [0.65,1.00]	
Total	388 / 1264	381 / 1169		0.94 [0.84,1.06]	Z=-0.99, p=0.3240
Heterogeneity:	Q=2.82 (df=1)	p=0.0933	I^2=64.5%		
Subgroup Heterogeneity:	Q=0.87 (df=1)	p=0.3505	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.10.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

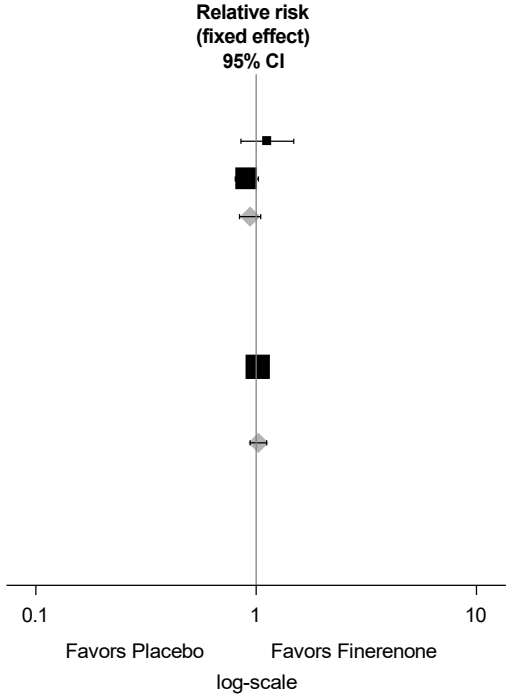
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	361 / 1106	345 / 1078	78.3	1.02 [0.90,1.15]	
FIGARO-DKD	95 / 337	108 / 336	21.7	0.88 [0.70,1.10]	
Total	456 / 1443	453 / 1414		0.99 [0.89,1.10]	Z=-0.24, p=0.8100
Heterogeneity:	Q=1.29 (df=1)	p=0.2564	I^2=22.4%		
>= 65					
FIDELIO-DKD	442 / 1516	433 / 1542	61.6	1.04 [0.93,1.16]	
FIGARO-DKD	266 / 1022	291 / 1026	38.4	0.92 [0.80,1.06]	
Total	708 / 2538	724 / 2568		0.99 [0.91,1.08]	Z=-0.22, p=0.8259
Heterogeneity:	Q=1.79 (df=1)	p=0.1806	I^2=44.2%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9628	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.10.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

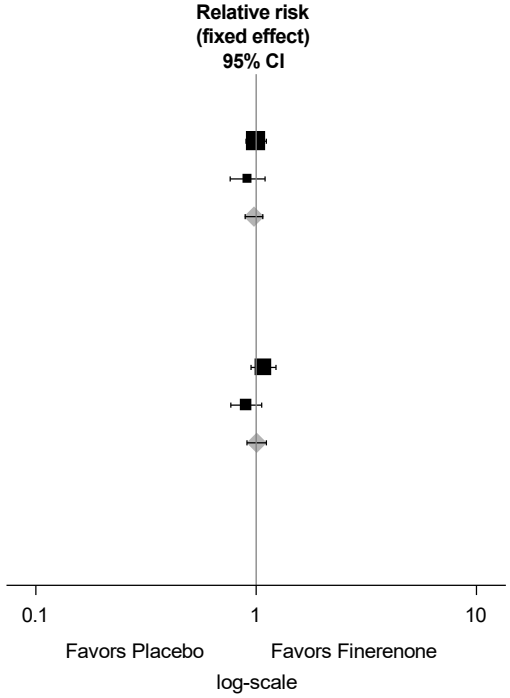
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	72 / 210	65 / 213	16.1	1.12 [0.85,1.48]	
FIGARO-DKD	361 / 1359	399 / 1362	83.9	0.91 [0.80,1.02]	
Total	433 / 1569	464 / 1575		0.94 [0.84,1.05]	Z=-1.12, p=0.2621
Heterogeneity:	Q=1.94 (df=1)	p=0.1631	I^2=48.6%		
Very High					
FIDELIO-DKD	731 / 2412	713 / 2407	100.0	1.02 [0.94,1.12]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	731 / 2412	713 / 2407		1.02 [0.94,1.12]	Z=0.52, p=0.6038
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.45 (df=1)	p=0.2288	I^2=31.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.10.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

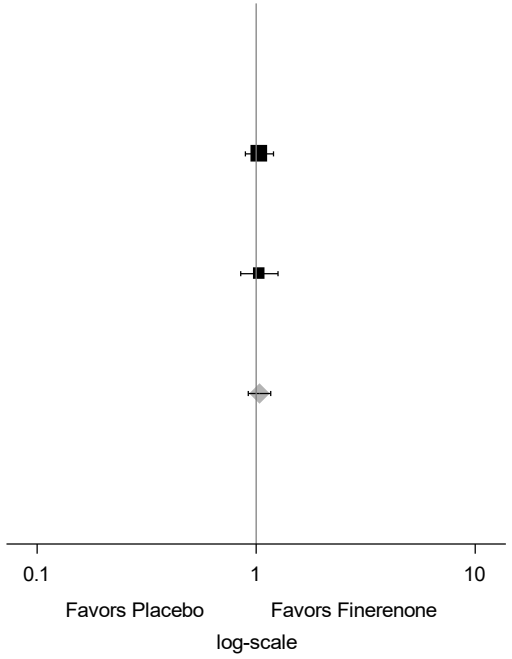
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	474 / 1559	471 / 1549	74.6	1.00 [0.90,1.11]	
FIGARO-DKD	163 / 639	176 / 631	25.4	0.91 [0.76,1.10]	
Total	637 / 2198	647 / 2180		0.98 [0.89,1.07]	Z=-0.49, p=0.6275
Heterogeneity:	Q=0.69 (df=1)	p=0.4076	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	329 / 1063	307 / 1071	60.5	1.08 [0.95,1.23]	
FIGARO-DKD	198 / 720	223 / 731	39.5	0.90 [0.77,1.06]	
Total	527 / 1783	530 / 1802		1.01 [0.91,1.11]	Z=0.10, p=0.9174
Heterogeneity:	Q=2.91 (df=1)	p=0.0882	I^2=65.6%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6870	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

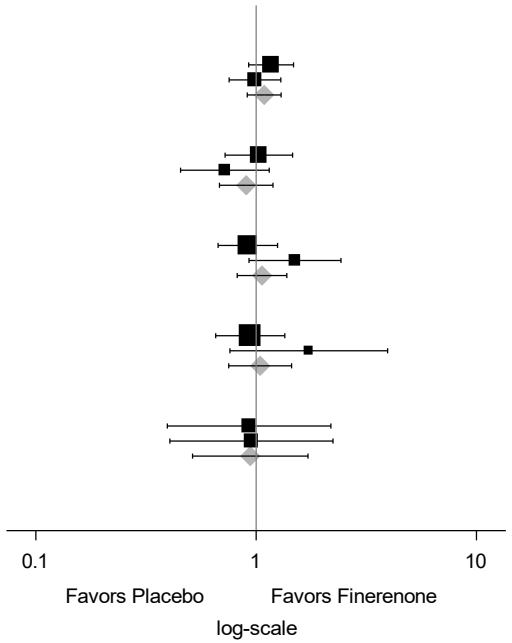
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	314 / 2622	303 / 2620	63.8	1.03 [0.89,1.20]	
FIGARO-DKD	177 / 1359	171 / 1362	36.2	1.03 [0.85,1.26]	
Total	491 / 3981	474 / 3982		1.04 [0.92,1.17]	Z=0.58, p=0.5630
Heterogeneity:	Q=0.00 (df=1)	p=0.9877	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.11.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

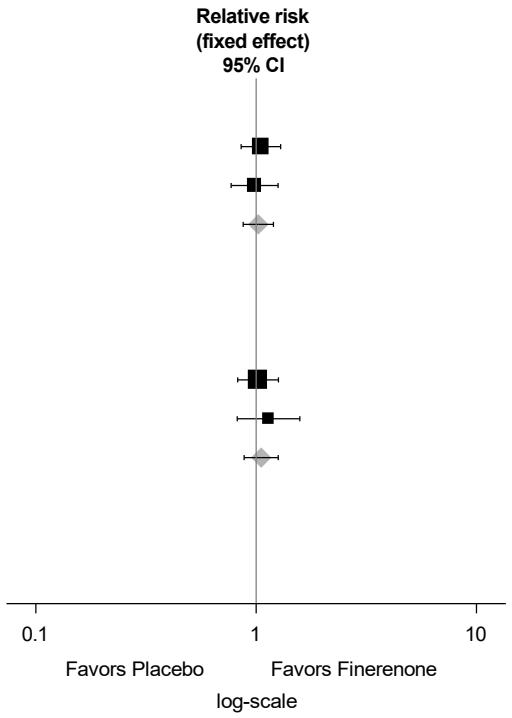
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	135 / 1078	114 / 1064	57.0	1.17 [0.92,1.48]	
FIGARO-DKD	90 / 640	91 / 639	43.0	0.99 [0.75,1.29]	
Total	225 / 1718	205 / 1703		1.09 [0.91,1.30]	Z=0.93, p=0.3537
Heterogeneity:	Q=0.85 (df=1)	p=0.3554	I^2=0.0%		
North America					
FIDELIO-DKD	54 / 425	54 / 437	63.3	1.03 [0.72,1.46]	
FIGARO-DKD	27 / 267	38 / 271	36.7	0.72 [0.45,1.15]	
Total	81 / 692	92 / 708		0.90 [0.68,1.19]	Z=-0.73, p=0.4662
Heterogeneity:	Q=1.42 (df=1)	p=0.2326	I^2=29.8%		
Asia					
FIDELIO-DKD	69 / 751	75 / 748	70.5	0.92 [0.67,1.25]	
FIGARO-DKD	37 / 288	25 / 292	29.5	1.50 [0.93,2.43]	
Total	106 / 1039	100 / 1040		1.06 [0.82,1.38]	Z=0.46, p=0.6455
Heterogeneity:	Q=2.85 (df=1)	p=0.0912	I^2=64.9%		
Latin America					
FIDELIO-DKD	47 / 274	50 / 274	83.9	0.94 [0.65,1.35]	
FIGARO-DKD	14 / 102	8 / 101	16.1	1.73 [0.76,3.95]	
Total	61 / 376	58 / 375		1.04 [0.75,1.45]	Z=0.25, p=0.8040
Heterogeneity:	Q=1.78 (df=1)	p=0.1826	I^2=43.7%		
Others					
FIDELIO-DKD	9 / 94	10 / 97	49.9	0.93 [0.40,2.18]	
FIGARO-DKD	9 / 62	9 / 59	50.1	0.95 [0.41,2.23]	
Total	18 / 156	19 / 156		0.94 [0.51,1.72]	Z=-0.20, p=0.8411
Heterogeneity:	Q=0.00 (df=1)	p=0.9685	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.38 (df=4)	p=0.8480	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

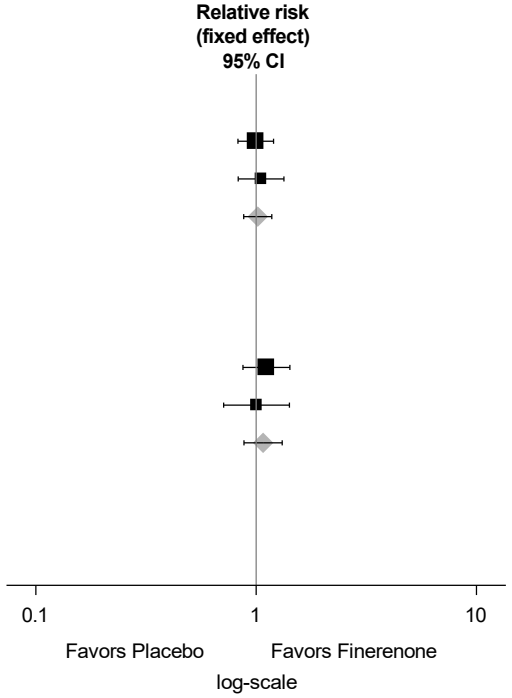
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	161 / 1215	153 / 1213	58.6	1.05 [0.85,1.29]	
FIGARO-DKD	111 / 865	111 / 851	41.4	0.98 [0.77,1.26]	
Total	272 / 2080	264 / 2064		1.02 [0.87,1.20]	Z=0.27, p=0.7837
Heterogeneity:	Q=0.16 (df=1)	p=0.6884	I^2=0.0%		
Absent					
FIDELIO-DKD	153 / 1407	150 / 1407	70.3	1.02 [0.82,1.26]	
FIGARO-DKD	66 / 494	60 / 511	29.7	1.14 [0.82,1.58]	
Total	219 / 1901	210 / 1918		1.05 [0.88,1.26]	Z=0.58, p=0.5649
Heterogeneity:	Q=0.30 (df=1)	p=0.5828	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8036	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

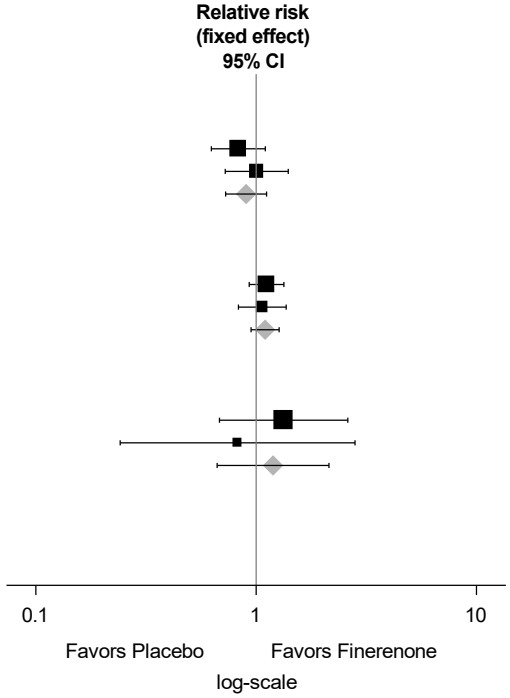
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	198 / 1737	195 / 1703	62.3	1.00 [0.83,1.20]	
FIGARO-DKD	120 / 924	115 / 932	37.7	1.05 [0.83,1.34]	
Total	318 / 2661	310 / 2635		1.02 [0.88,1.18]	Z=0.22, p=0.8255
Heterogeneity:	Q=0.13 (df=1)	p=0.7187	I^2=0.0%		
> 4.5					
FIDELIO-DKD	116 / 884	108 / 916	66.3	1.11 [0.87,1.42]	
FIGARO-DKD	57 / 435	56 / 429	33.7	1.00 [0.71,1.42]	
Total	173 / 1319	164 / 1345		1.07 [0.88,1.31]	Z=0.71, p=0.4782
Heterogeneity:	Q=0.23 (df=1)	p=0.6319	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6594	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

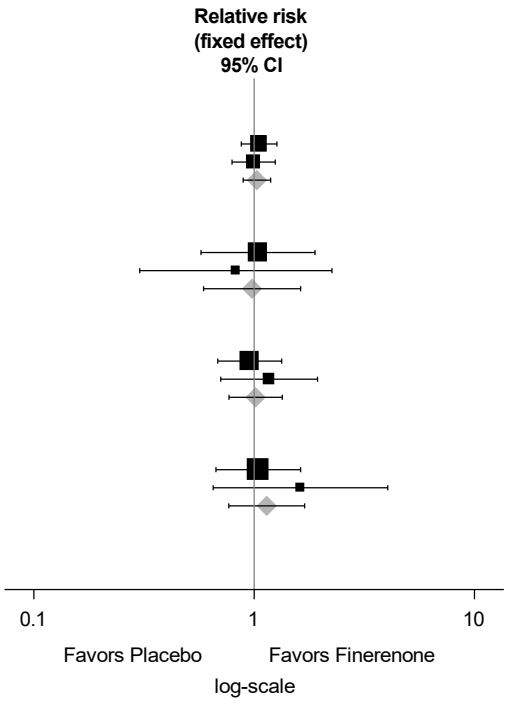
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	78 / 724	94 / 724	57.7	0.83 [0.63,1.10]	
FIGARO-DKD	62 / 494	62 / 497	42.3	1.01 [0.72,1.40]	
Total	140 / 1218	156 / 1221		0.90 [0.73,1.11]	Z=-0.97, p=0.3344
Heterogeneity:	Q=0.76 (df=1)	p=0.3838	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	218 / 1762	196 / 1766	65.5	1.11 [0.93,1.34]	
FIGARO-DKD	111 / 831	104 / 830	34.5	1.07 [0.83,1.37]	
Total	329 / 2593	300 / 2596		1.10 [0.95,1.27]	Z=1.25, p=0.2129
Heterogeneity:	Q=0.08 (df=1)	p=0.7763	I^2=0.0%		
>= 160					
FIDELIO-DKD	18 / 133	13 / 128	77.0	1.33 [0.68,2.61]	
FIGARO-DKD	4 / 34	5 / 35	23.0	0.82 [0.24,2.81]	
Total	22 / 167	18 / 163		1.19 [0.67,2.14]	Z=0.59, p=0.5541
Heterogeneity:	Q=0.45 (df=1)	p=0.5000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.48 (df=2)	p=0.2889	I^2=19.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

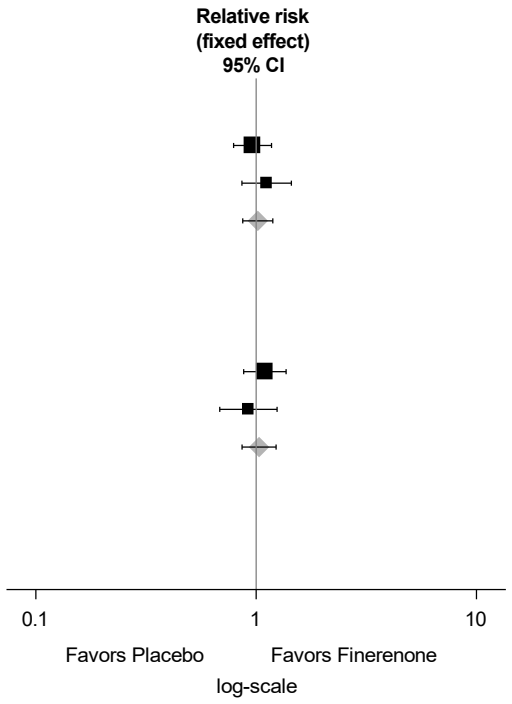
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	199 / 1637	192 / 1663	59.5	1.05 [0.87,1.27]	
FIGARO-DKD	132 / 1013	130 / 992	40.5	0.99 [0.79,1.25]	
Total	331 / 2650	322 / 2655		1.03 [0.89,1.19]	Z=0.39, p=0.6983
Heterogeneity:	Q=0.15 (df=1)	p=0.7014	I^2=0.0%		
Black					
FIDELIO-DKD	20 / 130	17 / 115	74.0	1.04 [0.57,1.89]	
FIGARO-DKD	5 / 43	10 / 71	26.0	0.83 [0.30,2.25]	
Total	25 / 173	27 / 186		0.98 [0.59,1.62]	Z=-0.08, p=0.9330
Heterogeneity:	Q=0.15 (df=1)	p=0.6975	I^2=0.0%		
Asian					
FIDELIO-DKD	61 / 678	64 / 679	69.6	0.95 [0.68,1.33]	
FIGARO-DKD	29 / 251	25 / 253	30.4	1.17 [0.71,1.94]	
Total	90 / 929	89 / 932		1.02 [0.77,1.34]	Z=0.11, p=0.9142
Heterogeneity:	Q=0.43 (df=1)	p=0.5117	I^2=0.0%		
Others					
FIDELIO-DKD	34 / 177	30 / 163	81.0	1.04 [0.67,1.62]	
FIGARO-DKD	11 / 52	6 / 46	19.0	1.62 [0.65,4.04]	
Total	45 / 229	36 / 209		1.14 [0.77,1.69]	Z=0.65, p=0.5166
Heterogeneity:	Q=0.73 (df=1)	p=0.3940	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=3)	p=0.9601	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.11.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

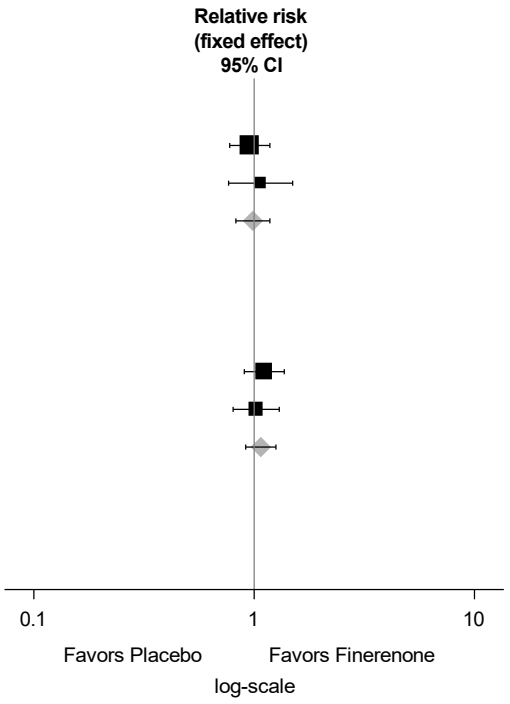
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	170 / 1800	184 / 1876	63.0	0.96 [0.79,1.17]	
FIGARO-DKD	107 / 917	98 / 937	37.0	1.12 [0.86,1.44]	
Total	277 / 2717	282 / 2813		1.02 [0.87,1.19]	Z=0.21, p=0.8345
Heterogeneity:	Q=0.78 (df=1)	p=0.3757	I^2=0.0%		
Female					
FIDELIO-DKD	144 / 822	119 / 744	64.6	1.10 [0.88,1.37]	
FIGARO-DKD	70 / 442	73 / 425	35.4	0.92 [0.68,1.24]	
Total	214 / 1264	192 / 1169		1.03 [0.86,1.23]	Z=0.33, p=0.7390
Heterogeneity:	Q=0.82 (df=1)	p=0.3652	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9113	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.11.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

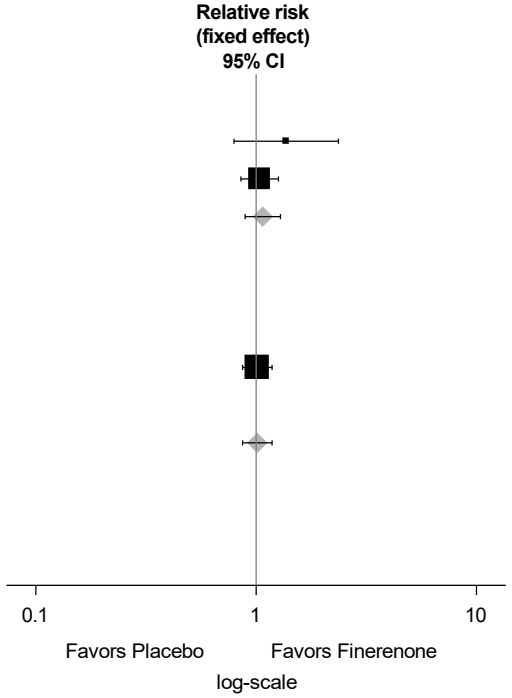
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	149 / 1106	152 / 1078	71.8	0.96 [0.77,1.18]	
FIGARO-DKD	59 / 337	55 / 336	28.2	1.07 [0.77,1.49]	
Total	208 / 1443	207 / 1414		0.99 [0.83,1.18]	Z=-0.15, p=0.8795
Heterogeneity:	Q=0.31 (df=1)	p=0.5758	I^2=0.0%		
>= 65					
FIDELIO-DKD	165 / 1516	151 / 1542	57.1	1.11 [0.90,1.37]	
FIGARO-DKD	118 / 1022	116 / 1026	42.9	1.02 [0.80,1.30]	
Total	283 / 2538	267 / 2568		1.07 [0.92,1.26]	Z=0.86, p=0.3893
Heterogeneity:	Q=0.27 (df=1)	p=0.6031	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4932	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.11.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

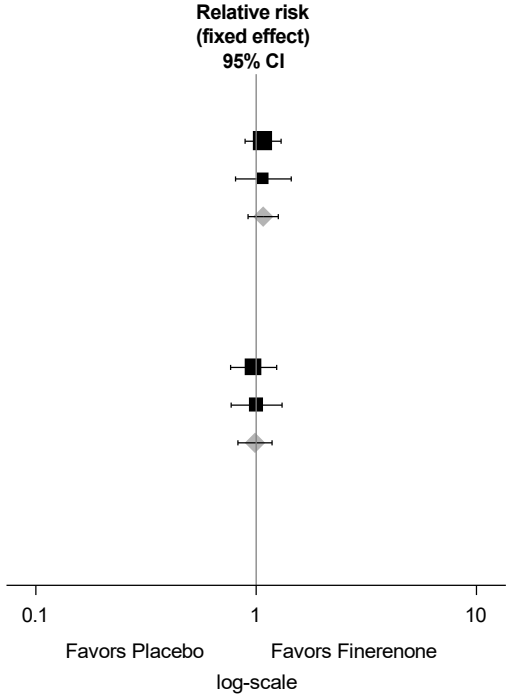
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	27 / 210	20 / 213	11.4	1.37 [0.79,2.36]	
FIGARO-DKD	177 / 1359	171 / 1362	88.6	1.04 [0.85,1.26]	
Total	204 / 1569	191 / 1575		1.07 [0.89,1.29]	Z=0.73, p=0.4640
Heterogeneity:	Q=0.88 (df=1)	p=0.3483	I^2=0.0%		
Very High					
FIDELIO-DKD	287 / 2412	283 / 2407	100.0	1.01 [0.87,1.18]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	287 / 2412	283 / 2407		1.01 [0.87,1.18]	Z=0.15, p=0.8792
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6424	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.11.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

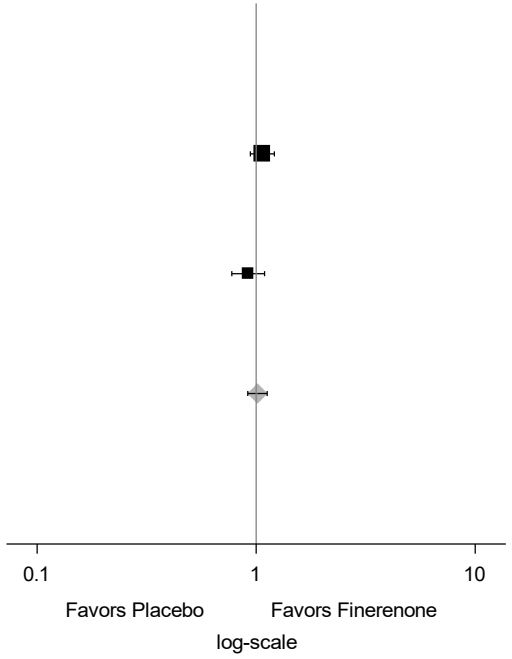
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	198 / 1559	183 / 1549	70.5	1.08 [0.89,1.30]	
FIGARO-DKD	83 / 639	76 / 631	29.5	1.08 [0.81,1.44]	
Total	281 / 2198	259 / 2180		1.08 [0.92,1.26]	Z=0.91, p=0.3636
Heterogeneity:	Q=0.00 (df=1)	p=0.9857	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	116 / 1063	120 / 1071	55.0	0.97 [0.77,1.24]	
FIGARO-DKD	94 / 720	95 / 731	45.0	1.00 [0.77,1.31]	
Total	210 / 1783	215 / 1802		0.99 [0.83,1.18]	Z=-0.14, p=0.8912
Heterogeneity:	Q=0.03 (df=1)	p=0.8655	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4809	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

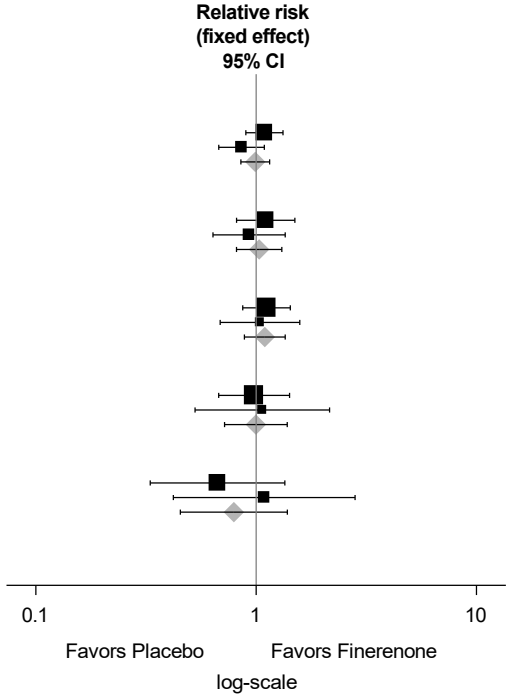
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	422 / 2622	395 / 2620	65.1	1.07 [0.94,1.21]	
FIGARO-DKD	208 / 1359	226 / 1362	34.9	0.92 [0.77,1.09]	
Total	630 / 3981	621 / 3982		1.01 [0.92,1.12]	Z=0.26, p=0.7932
Heterogeneity:	Q=1.87 (df=1)	p=0.1711	I^2=46.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.2.12.1: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

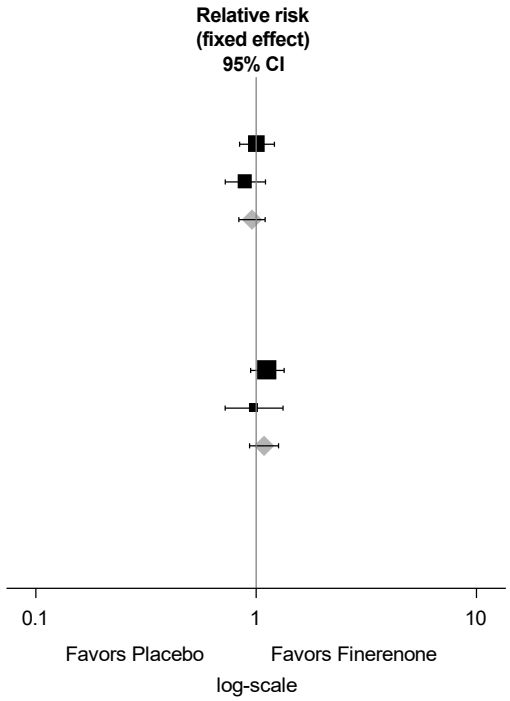
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	180 / 1078	163 / 1064	60.0	1.09 [0.90,1.32]	
FIGARO-DKD	104 / 640	121 / 639	40.0	0.86 [0.68,1.09]	
Total	284 / 1718	284 / 1703		0.99 [0.85,1.15]	Z=-0.13, p=0.9003
Heterogeneity:	Q=2.33 (df=1)	p=0.1272	I^2=57.0%		
North America					
FIDELIO-DKD	72 / 425	67 / 437	60.5	1.10 [0.81,1.50]	
FIGARO-DKD	43 / 267	47 / 271	39.5	0.93 [0.64,1.35]	
Total	115 / 692	114 / 708		1.03 [0.81,1.31]	Z=0.26, p=0.7964
Heterogeneity:	Q=0.49 (df=1)	p=0.4824	I^2=0.0%		
Asia					
FIDELIO-DKD	113 / 751	101 / 748	73.7	1.11 [0.87,1.43]	
FIGARO-DKD	39 / 288	38 / 292	26.3	1.04 [0.69,1.58]	
Total	152 / 1039	139 / 1040		1.09 [0.88,1.35]	Z=0.83, p=0.4069
Heterogeneity:	Q=0.08 (df=1)	p=0.7818	I^2=0.0%		
Latin America					
FIDELIO-DKD	46 / 274	47 / 274	78.3	0.98 [0.68,1.42]	
FIGARO-DKD	14 / 102	13 / 101	21.7	1.07 [0.53,2.15]	
Total	60 / 376	60 / 375		1.00 [0.72,1.38]	Z=-0.02, p=0.9864
Heterogeneity:	Q=0.04 (df=1)	p=0.8325	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 94	17 / 97	64.6	0.67 [0.33,1.35]	
FIGARO-DKD	8 / 62	7 / 59	35.4	1.09 [0.42,2.81]	
Total	19 / 156	24 / 156		0.79 [0.45,1.39]	Z=-0.82, p=0.4135
Heterogeneity:	Q=0.65 (df=1)	p=0.4185	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.37 (df=4)	p=0.8498	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12.2: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

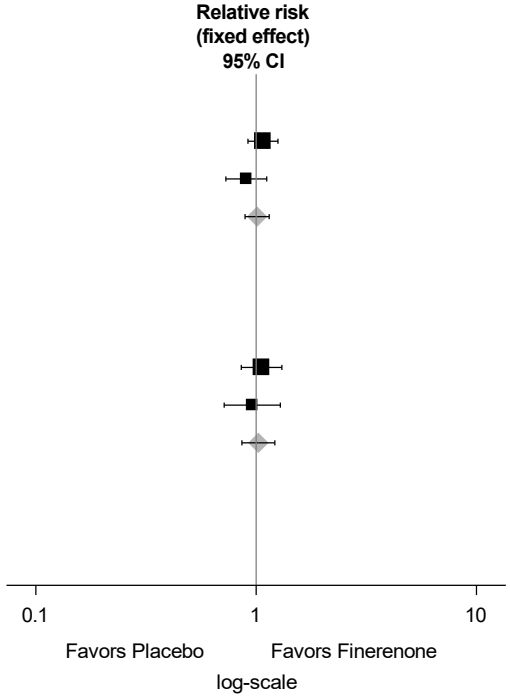
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	196 / 1215	194 / 1213	57.2	1.01 [0.84,1.21]	
FIGARO-DKD	138 / 865	152 / 851	42.8	0.89 [0.72,1.10]	
Total	334 / 2080	346 / 2064		0.96 [0.83,1.10]	Z=-0.62, p=0.5351
Heterogeneity:	Q=0.73 (df=1)	p=0.3913	I^2=0.0%		
Absent					
FIDELIO-DKD	226 / 1407	201 / 1407	74.9	1.12 [0.94,1.34]	
FIGARO-DKD	70 / 494	74 / 511	25.1	0.98 [0.72,1.32]	
Total	296 / 1901	275 / 1918		1.09 [0.93,1.26]	Z=1.07, p=0.2862
Heterogeneity:	Q=0.61 (df=1)	p=0.4358	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.46 (df=1)	p=0.2276	I^2=31.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12.3: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

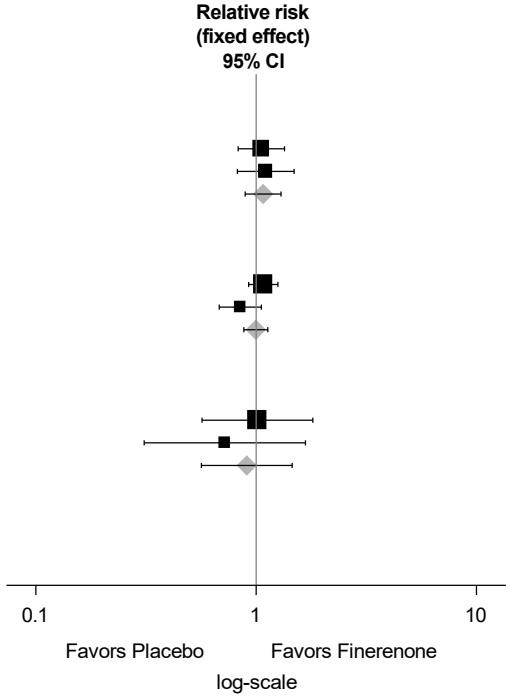
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	277 / 1737	253 / 1703	65.0	1.07 [0.92,1.26]	
FIGARO-DKD	135 / 924	151 / 932	35.0	0.90 [0.73,1.12]	
Total	412 / 2661	404 / 2635		1.01 [0.89,1.15]	Z=0.15, p=0.8792
Heterogeneity:	Q=1.66 (df=1)	p=0.1974	I^2=39.8%		
> 4.5					
FIDELIO-DKD	145 / 884	142 / 916	65.7	1.06 [0.86,1.31]	
FIGARO-DKD	73 / 435	75 / 429	34.3	0.96 [0.72,1.29]	
Total	218 / 1319	217 / 1345		1.02 [0.86,1.22]	Z=0.26, p=0.7929
Heterogeneity:	Q=0.28 (df=1)	p=0.5980	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9032	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12.4: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	114 / 724	108 / 724	60.0	1.06 [0.83,1.34]	
FIGARO-DKD	78 / 494	71 / 497	40.0	1.11 [0.82,1.49]	
Total	192 / 1218	179 / 1221		1.08 [0.89,1.30]	Z=0.76, p=0.4486
Heterogeneity:	Q=0.06 (df=1)	p=0.8137	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	288 / 1762	268 / 1766	67.5	1.08 [0.92,1.25]	
FIGARO-DKD	123 / 831	145 / 830	32.5	0.85 [0.68,1.06]	
Total	411 / 2593	413 / 2596		1.00 [0.88,1.13]	Z=-0.06, p=0.9507
Heterogeneity:	Q=3.08 (df=1)	p=0.0792	I^2=67.6%		
>= 160					
FIDELIO-DKD	20 / 133	19 / 128	67.9	1.01 [0.57,1.81]	
FIGARO-DKD	7 / 34	10 / 35	32.1	0.72 [0.31,1.67]	
Total	27 / 167	29 / 163		0.91 [0.56,1.46]	Z=-0.41, p=0.6850
Heterogeneity:	Q=0.43 (df=1)	p=0.5137	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=2)	p=0.7162	I^2=0.0%		

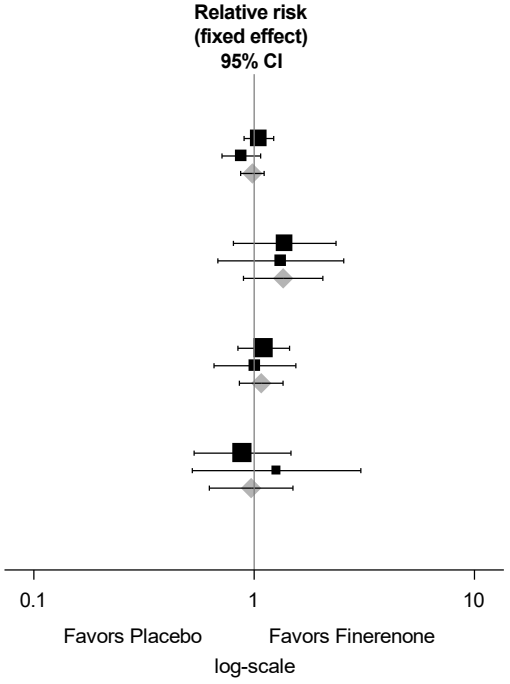


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12.5: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race

Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	273 / 1637	264 / 1663	63.0	1.05 [0.90,1.23]	
FIGARO-DKD	150 / 1013	168 / 992	37.0	0.87 [0.71,1.07]	
Total	423 / 2650	432 / 2655		0.98 [0.87,1.11]	Z=-0.30, p=0.7648
Heterogeneity:	Q=2.00 (df=1)	p=0.1575	I^2=50.0%		
Black					
FIDELIO-DKD	28 / 130	18 / 115	60.1	1.38 [0.80,2.35]	
FIGARO-DKD	12 / 43	15 / 71	39.9	1.32 [0.68,2.55]	
Total	40 / 173	33 / 186		1.35 [0.89,2.05]	Z=1.43, p=0.1523
Heterogeneity:	Q=0.01 (df=1)	p=0.9248	I^2=0.0%		
Asian					
FIDELIO-DKD	96 / 678	87 / 679	71.5	1.11 [0.84,1.45]	
FIGARO-DKD	36 / 251	36 / 253	28.5	1.01 [0.66,1.55]	
Total	132 / 929	123 / 932		1.08 [0.86,1.35]	Z=0.63, p=0.5265
Heterogeneity:	Q=0.13 (df=1)	p=0.7215	I^2=0.0%		
Others					
FIDELIO-DKD	25 / 177	26 / 163	75.2	0.89 [0.53,1.47]	
FIGARO-DKD	10 / 52	7 / 46	24.8	1.26 [0.52,3.05]	
Total	35 / 229	33 / 209		0.97 [0.63,1.50]	Z=-0.14, p=0.8868
Heterogeneity:	Q=0.47 (df=1)	p=0.4925	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.44 (df=3)	p=0.4870	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.

Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.

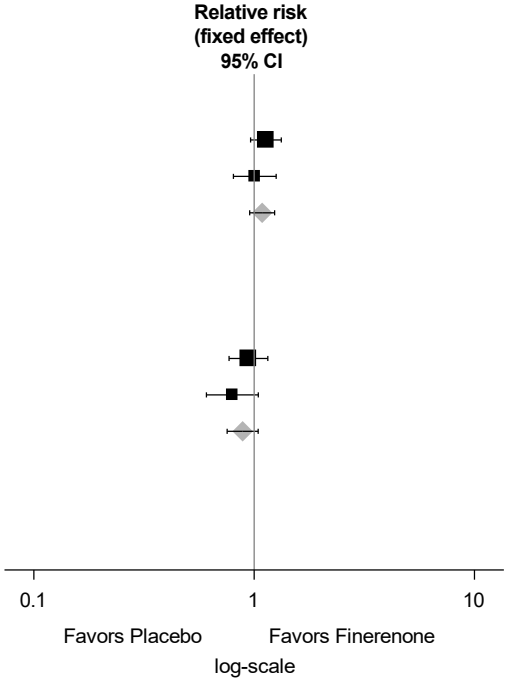
Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure A3.2.12.6: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

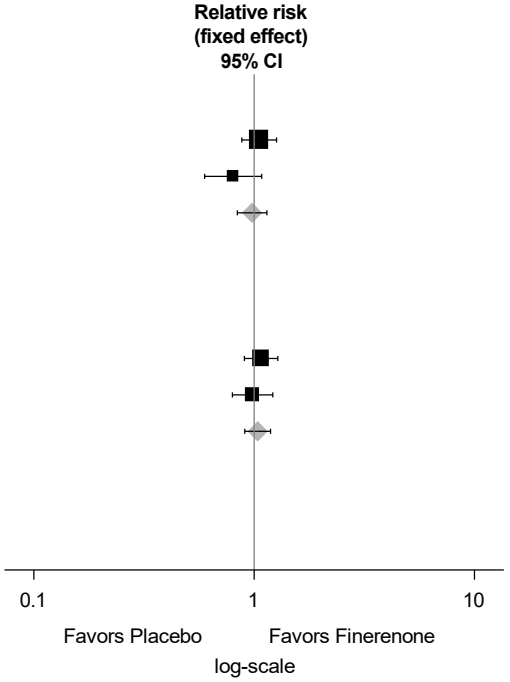
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	268 / 1800	247 / 1876	66.0	1.13 [0.96,1.33]	
FIGARO-DKD	131 / 917	133 / 937	34.0	1.01 [0.80,1.26]	
Total	399 / 2717	380 / 2813		1.09 [0.95,1.24]	Z=1.25, p=0.2095
Heterogeneity:	Q=0.69 (df=1)	p=0.4062	I^2=0.0%		
Female					
FIDELIO-DKD	154 / 822	148 / 744	64.1	0.94 [0.77,1.15]	
FIGARO-DKD	77 / 442	93 / 425	35.9	0.80 [0.61,1.04]	
Total	231 / 1264	241 / 1169		0.89 [0.75,1.04]	Z=-1.46, p=0.1451
Heterogeneity:	Q=0.95 (df=1)	p=0.3304	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.69 (df=1)	p=0.0546	I^2=72.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.12.7: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

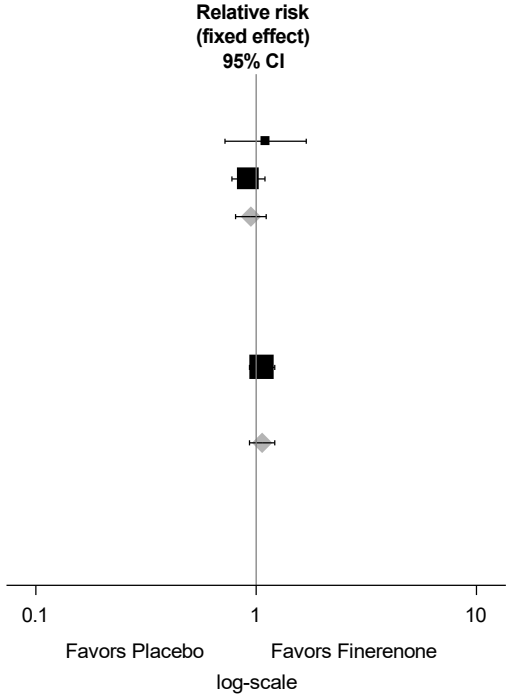
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	200 / 1106	185 / 1078	73.0	1.05 [0.88,1.26]	
FIGARO-DKD	62 / 337	77 / 336	27.0	0.80 [0.60,1.08]	
Total	262 / 1443	262 / 1414		0.98 [0.84,1.14]	Z=-0.27, p=0.7840
Heterogeneity:	Q=2.33 (df=1)	p=0.1269	I^2=57.1%		
>= 65					
FIDELIO-DKD	222 / 1516	210 / 1542	59.3	1.08 [0.90,1.28]	
FIGARO-DKD	146 / 1022	149 / 1026	40.7	0.98 [0.80,1.21]	
Total	368 / 2538	359 / 2568		1.04 [0.91,1.19]	Z=0.53, p=0.5964
Heterogeneity:	Q=0.40 (df=1)	p=0.5246	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.31 (df=1)	p=0.5793	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.2.12.8: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

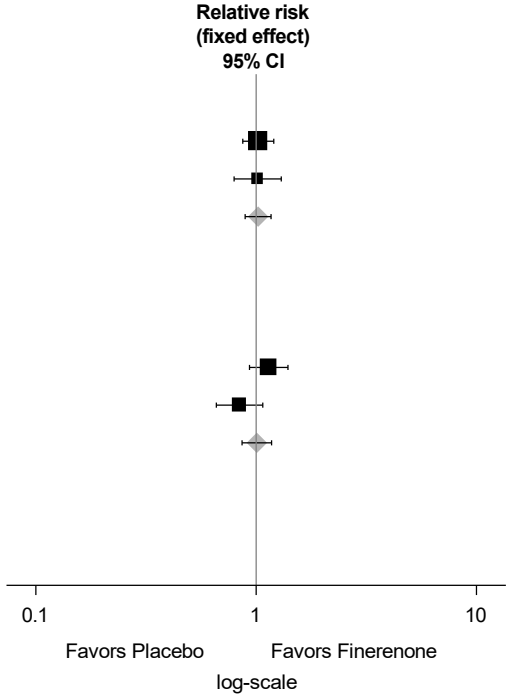
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	37 / 210	34 / 213	14.2	1.10 [0.72,1.69]	
FIGARO-DKD	208 / 1359	226 / 1362	85.8	0.92 [0.78,1.10]	
Total	245 / 1569	260 / 1575		0.95 [0.81,1.11]	Z=-0.68, p=0.4977
Heterogeneity:	Q=0.59 (df=1)	p=0.4429	I^2=0.0%		
Very High					
FIDELIO-DKD	385 / 2412	361 / 2407	100.0	1.06 [0.93,1.21]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	385 / 2412	361 / 2407		1.06 [0.93,1.21]	Z=0.92, p=0.3551
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.24 (df=1)	p=0.2663	I^2=19.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.2.12.9: KDQoL-36 - Forestplot for Relative Risk of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

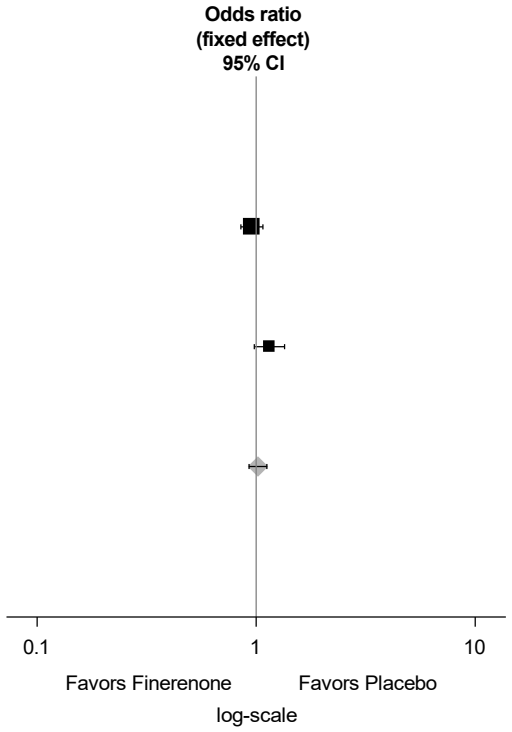
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	250 / 1559	243 / 1549	69.8	1.02 [0.87,1.20]	
FIGARO-DKD	107 / 639	104 / 631	30.2	1.02 [0.79,1.30]	
Total	357 / 2198	347 / 2180		1.02 [0.89,1.17]	Z=0.29, p=0.7708
Heterogeneity:	Q=0.00 (df=1)	p=0.9675	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	172 / 1063	152 / 1071	59.3	1.14 [0.93,1.39]	
FIGARO-DKD	101 / 720	122 / 731	40.7	0.84 [0.66,1.07]	
Total	273 / 1783	274 / 1802		1.01 [0.86,1.17]	Z=0.09, p=0.9311
Heterogeneity:	Q=3.59 (df=1)	p=0.0580	I^2=72.2%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, RR=relative risk, SoC=standard of care.
Note: For 'Total' the RR is estimated by a GLM with factors treatment group and study using a binomial distribution and log as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

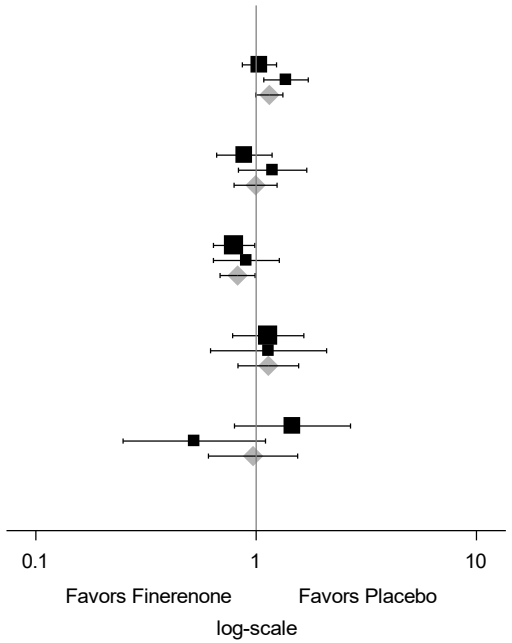
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	840 / 2622	865 / 2620	65.4	0.96 [0.85,1.07]	
FIGARO-DKD	480 / 1359	439 / 1362	34.6	1.15 [0.98,1.35]	
Total	1320 / 3981	1304 / 3982		1.02 [0.93,1.12]	Z=0.39, p=0.6949
Heterogeneity:	Q=3.37 (df=1)	p=0.0662	I^2=70.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.1.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

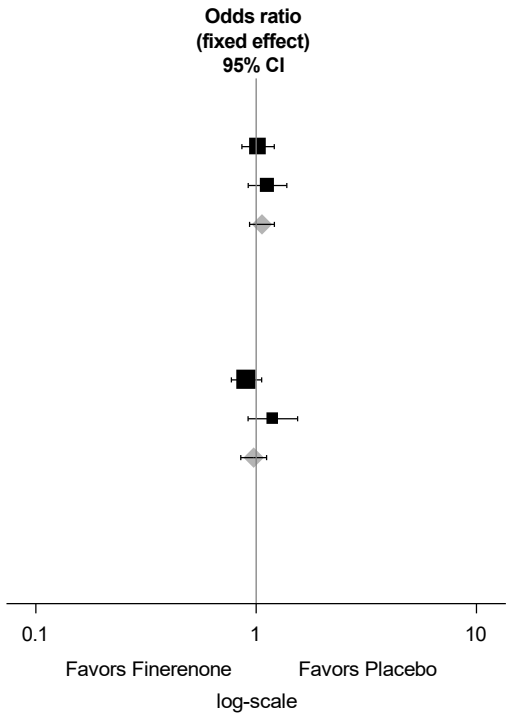
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	372 / 1078	359 / 1064	62.8	1.03 [0.87,1.24]	
FIGARO-DKD	240 / 640	195 / 639	37.2	1.37 [1.08,1.72]	
Total	612 / 1718	554 / 1703		1.15 [1.00,1.32]	Z=1.91, p=0.0565
Heterogeneity:	Q=3.45 (df=1)	p=0.0631	I^2=71.0%		
North America					
FIDELIO-DKD	125 / 425	140 / 437	60.3	0.88 [0.66,1.18]	
FIGARO-DKD	96 / 267	87 / 271	39.7	1.19 [0.83,1.70]	
Total	221 / 692	227 / 708		0.99 [0.79,1.24]	Z=-0.05, p=0.9566
Heterogeneity:	Q=1.58 (df=1)	p=0.2084	I^2=36.8%		
Asia					
FIDELIO-DKD	227 / 751	264 / 748	71.7	0.79 [0.64,0.99]	
FIGARO-DKD	94 / 288	102 / 292	28.3	0.90 [0.64,1.27]	
Total	321 / 1039	366 / 1040		0.82 [0.69,0.99]	Z=-2.08, p=0.0375
Heterogeneity:	Q=0.38 (df=1)	p=0.5375	I^2=0.0%		
Latin America					
FIDELIO-DKD	81 / 274	74 / 274	72.7	1.13 [0.78,1.65]	
FIGARO-DKD	31 / 102	28 / 101	27.3	1.14 [0.62,2.09]	
Total	112 / 376	102 / 375		1.14 [0.83,1.56]	Z=0.78, p=0.4326
Heterogeneity:	Q=0.00 (df=1)	p=0.9922	I^2=0.0%		
Others					
FIDELIO-DKD	35 / 94	28 / 97	60.1	1.46 [0.80,2.68]	
FIGARO-DKD	19 / 62	27 / 59	39.9	0.52 [0.25,1.10]	
Total	54 / 156	55 / 156		0.97 [0.61,1.54]	Z=-0.14, p=0.8911
Heterogeneity:	Q=4.39 (df=1)	p=0.0361	I^2=77.2%		
Subgroup Heterogeneity:	Q=8.46 (df=4)	p=0.0762	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

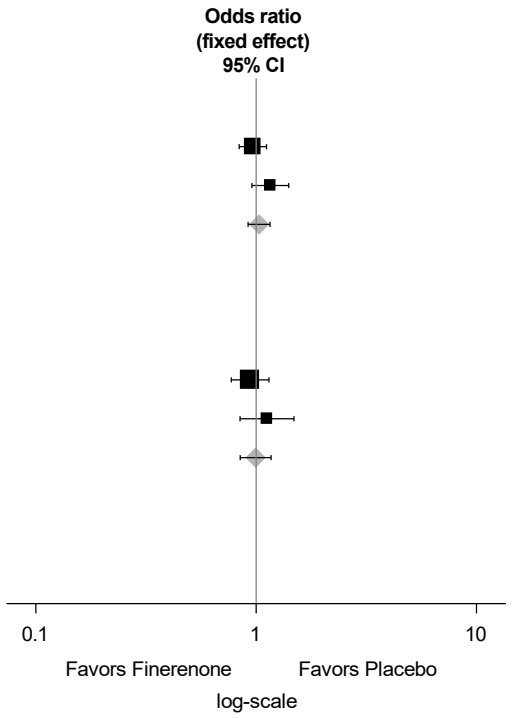
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	402 / 1215	396 / 1213	58.7	1.02 [0.86,1.21]	
FIGARO-DKD	295 / 865	268 / 851	41.3	1.13 [0.92,1.38]	
Total	697 / 2080	664 / 2064		1.06 [0.93,1.21]	Z=0.92, p=0.3587
Heterogeneity:	Q=0.54 (df=1)	p=0.4631	I^2=0.0%		
Absent					
FIDELIO-DKD	438 / 1407	469 / 1407	72.8	0.90 [0.77,1.06]	
FIGARO-DKD	185 / 494	171 / 511	27.2	1.19 [0.92,1.54]	
Total	623 / 1901	640 / 1918		0.97 [0.85,1.12]	Z=-0.38, p=0.7056
Heterogeneity:	Q=3.16 (df=1)	p=0.0753	I^2=68.4%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3637	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

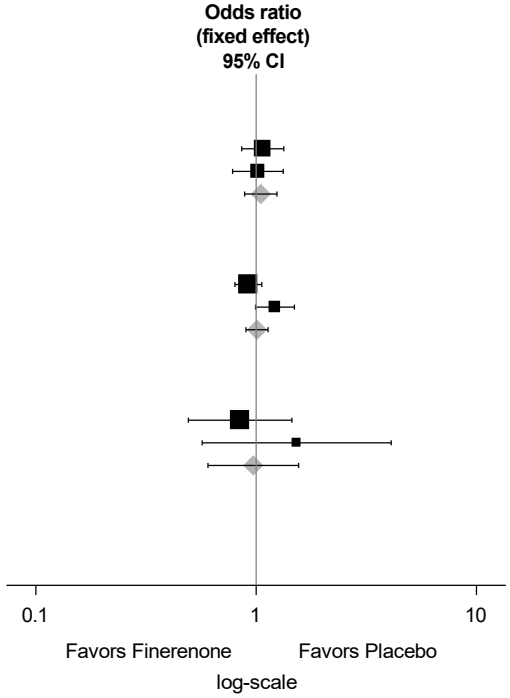
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	557 / 1737	559 / 1703	64.5	0.97 [0.84,1.11]	
FIGARO-DKD	327 / 924	299 / 932	35.5	1.16 [0.96,1.41]	
Total	884 / 2661	858 / 2635		1.03 [0.92,1.16]	Z=0.52, p=0.6053
Heterogeneity:	Q=2.23 (df=1)	p=0.1354	I^2=55.1%		
> 4.5					
FIDELIO-DKD	283 / 884	306 / 916	67.2	0.94 [0.77,1.14]	
FIGARO-DKD	153 / 435	140 / 429	32.8	1.12 [0.84,1.48]	
Total	436 / 1319	446 / 1345		0.99 [0.85,1.17]	Z=-0.06, p=0.9487
Heterogeneity:	Q=1.01 (df=1)	p=0.3142	I^2=1.3%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7250	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

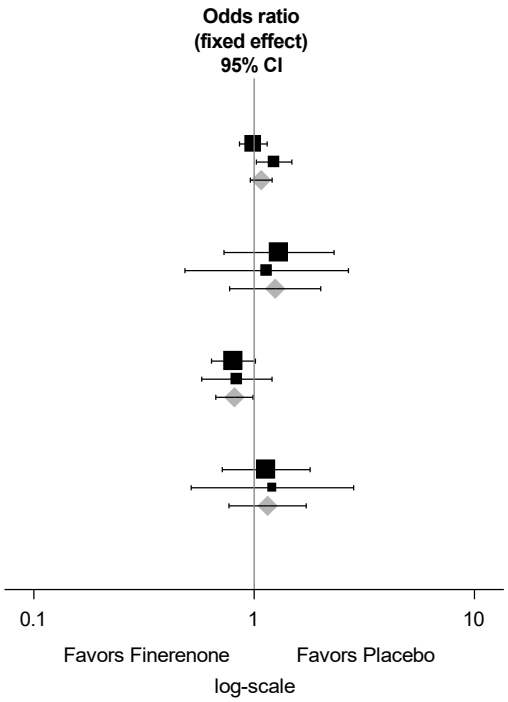
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	242 / 724	231 / 724	59.2	1.07 [0.86,1.33]	
FIGARO-DKD	164 / 494	163 / 497	40.8	1.02 [0.78,1.33]	
Total	406 / 1218	394 / 1221		1.05 [0.89,1.24]	Z=0.56, p=0.5753
Heterogeneity:	Q=0.08 (df=1)	p=0.7718	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	563 / 1762	596 / 1766	67.6	0.92 [0.80,1.06]	
FIGARO-DKD	302 / 831	265 / 830	32.4	1.22 [0.99,1.49]	
Total	865 / 2593	861 / 2596		1.01 [0.90,1.13]	Z=0.15, p=0.8835
Heterogeneity:	Q=4.86 (df=1)	p=0.0274	I^2=79.4%		
>= 160					
FIDELIO-DKD	35 / 133	38 / 128	76.9	0.85 [0.49,1.45]	
FIGARO-DKD	14 / 34	11 / 35	23.1	1.53 [0.57,4.10]	
Total	49 / 167	49 / 163		0.97 [0.60,1.56]	Z=-0.13, p=0.9004
Heterogeneity:	Q=1.06 (df=1)	p=0.3038	I^2=5.4%		
Subgroup Heterogeneity:	Q=0.19 (df=2)	p=0.9103	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

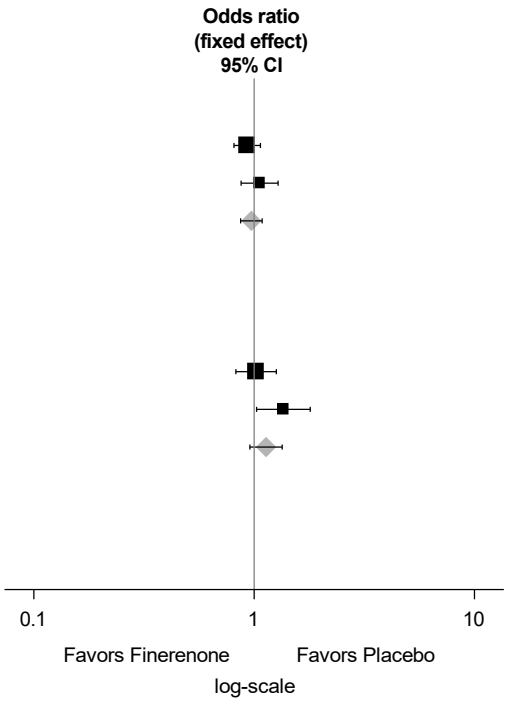
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	547 / 1637	559 / 1663	62.1	0.99 [0.86,1.15]	
FIGARO-DKD	368 / 1013	314 / 992	37.9	1.23 [1.02,1.48]	
Total	915 / 2650	873 / 2655		1.08 [0.96,1.21]	Z=1.27, p=0.2057
Heterogeneity:	Q=3.29 (df=1)	p=0.0696	I^2=69.6%		
Black					
FIDELIO-DKD	37 / 130	27 / 115	68.8	1.30 [0.73,2.31]	
FIGARO-DKD	12 / 43	18 / 71	31.2	1.14 [0.49,2.68]	
Total	49 / 173	45 / 186		1.25 [0.77,2.01]	Z=0.90, p=0.3663
Heterogeneity:	Q=0.06 (df=1)	p=0.8061	I^2=0.0%		
Asian					
FIDELIO-DKD	198 / 678	230 / 679	71.9	0.81 [0.64,1.01]	
FIGARO-DKD	82 / 251	93 / 253	28.1	0.83 [0.58,1.21]	
Total	280 / 929	323 / 932		0.81 [0.67,0.99]	Z=-2.08, p=0.0376
Heterogeneity:	Q=0.03 (df=1)	p=0.8707	I^2=0.0%		
Others					
FIDELIO-DKD	58 / 177	49 / 163	77.4	1.13 [0.72,1.79]	
FIGARO-DKD	18 / 52	14 / 46	22.6	1.21 [0.52,2.83]	
Total	76 / 229	63 / 209		1.15 [0.77,1.72]	Z=0.68, p=0.4954
Heterogeneity:	Q=0.02 (df=1)	p=0.8950	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.07 (df=3)	p=0.0698	I^2=57.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.1.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

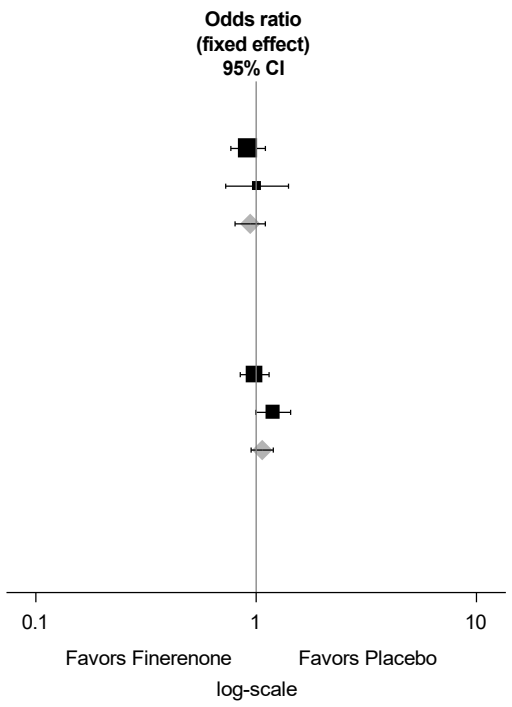
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	569 / 1800	623 / 1876	66.2	0.93 [0.81,1.07]	
FIGARO-DKD	310 / 917	305 / 937	33.8	1.06 [0.87,1.28]	
Total	879 / 2717	928 / 2813		0.97 [0.87,1.09]	Z=-0.51, p=0.6113
Heterogeneity:	Q=1.14 (df=1)	p=0.2853	I^2=12.4%		
Female					
FIDELIO-DKD	271 / 822	242 / 744	63.8	1.02 [0.83,1.26]	
FIGARO-DKD	170 / 442	134 / 425	36.2	1.36 [1.03,1.80]	
Total	441 / 1264	376 / 1169		1.13 [0.96,1.34]	Z=1.44, p=0.1502
Heterogeneity:	Q=2.54 (df=1)	p=0.1111	I^2=60.6%		
Subgroup Heterogeneity:	Q=2.19 (df=1)	p=0.1391	I^2=54.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.1.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

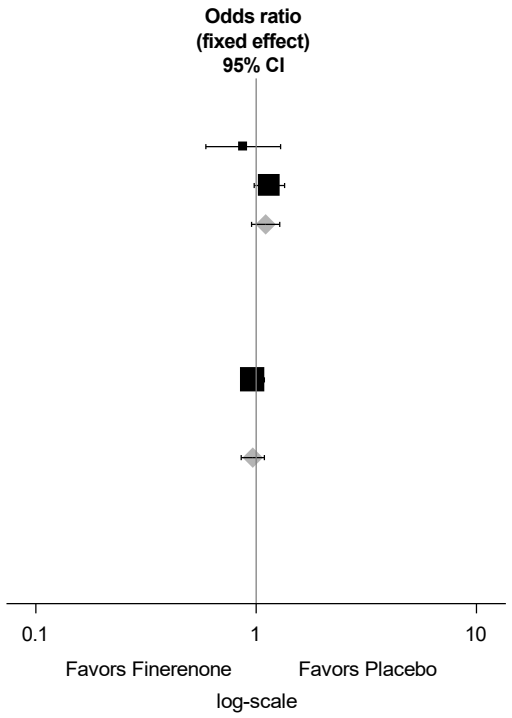
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	339 / 1106	350 / 1078	76.8	0.92 [0.77,1.10]	
FIGARO-DKD	103 / 337	102 / 336	23.2	1.01 [0.73,1.40]	
Total	442 / 1443	452 / 1414		0.94 [0.80,1.10]	Z=-0.77, p=0.4400
Heterogeneity:	Q=0.24 (df=1)	p=0.6234	I^2=0.0%		
>= 65					
FIDELIO-DKD	501 / 1516	515 / 1542	59.4	0.98 [0.85,1.14]	
FIGARO-DKD	377 / 1022	337 / 1026	40.6	1.20 [1.00,1.43]	
Total	878 / 2538	852 / 2568		1.07 [0.95,1.20]	Z=1.07, p=0.2866
Heterogeneity:	Q=2.59 (df=1)	p=0.1075	I^2=61.4%		
Subgroup Heterogeneity:	Q=1.57 (df=1)	p=0.2103	I^2=36.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.1.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

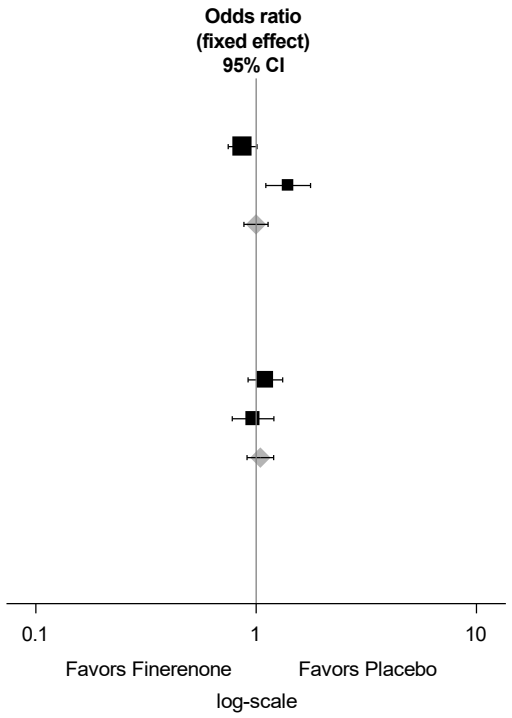
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	79 / 210	87 / 213	14.2	0.87 [0.59,1.29]	
FIGARO-DKD	480 / 1359	439 / 1362	85.8	1.15 [0.98,1.35]	
Total	559 / 1569	526 / 1575		1.10 [0.95,1.28]	Z=1.32, p=0.1865
Heterogeneity:	Q=1.62 (df=1)	p=0.2037	I^2=38.1%		
Very High					
FIDELIO-DKD	761 / 2412	778 / 2407	100.0	0.97 [0.86,1.09]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	761 / 2412	778 / 2407		0.97 [0.86,1.09]	Z=-0.57, p=0.5656
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.92 (df=1)	p=0.1660	I^2=47.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.1.9: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

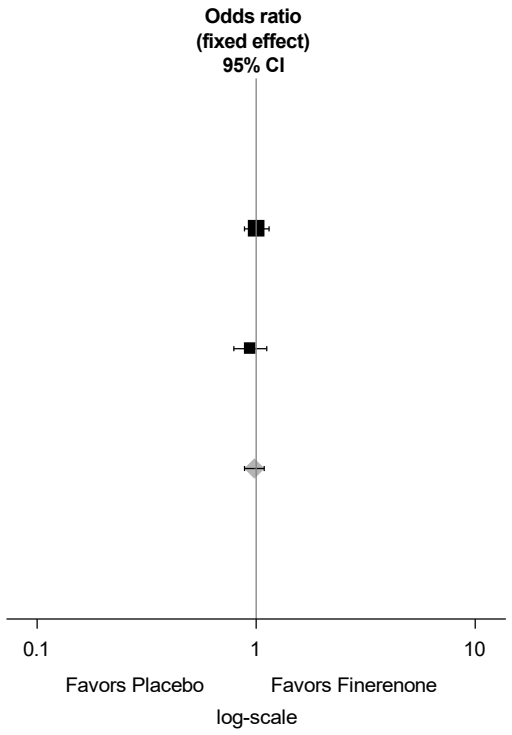
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	480 / 1559	525 / 1549	70.7	0.87 [0.75,1.01]	
FIGARO-DKD	239 / 639	189 / 631	29.3	1.40 [1.11,1.77]	
Total	719 / 2198	714 / 2180		1.00 [0.88,1.13]	Z=-0.03, p=0.9761
Heterogeneity:	Q=11.28 (df=1)	p=0.0008	I^2=91.1%		
45 - < 60					
FIDELIO-DKD	360 / 1063	340 / 1071	59.1	1.10 [0.92,1.32]	
FIGARO-DKD	241 / 720	250 / 731	40.9	0.97 [0.78,1.20]	
Total	601 / 1783	590 / 1802		1.04 [0.91,1.20]	Z=0.62, p=0.5385
Heterogeneity:	Q=0.80 (df=1)	p=0.3724	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6345	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

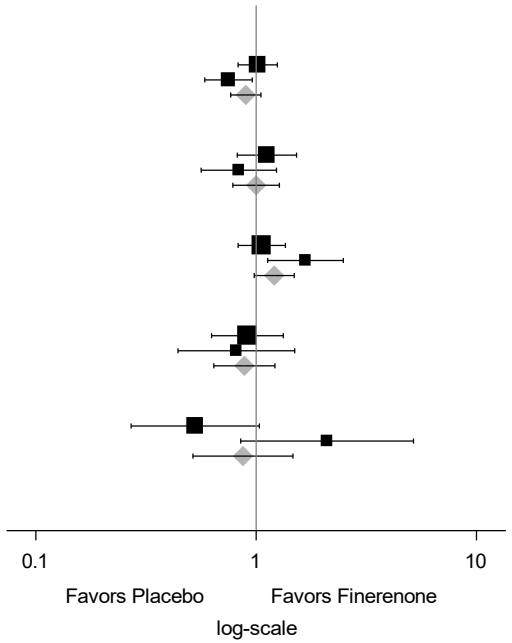
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	600 / 2622	597 / 2620	64.2	1.01 [0.88,1.15]	
FIGARO-DKD	337 / 1359	354 / 1362	35.8	0.94 [0.79,1.12]	
Total	937 / 3981	951 / 3982		0.98 [0.88,1.09]	Z=-0.36, p=0.7186
Heterogeneity:	Q=0.38 (df=1)	p=0.5357	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.2.1: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

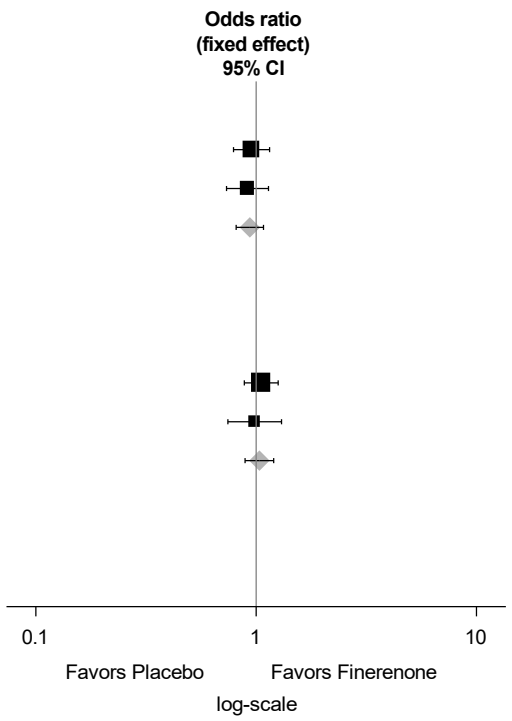
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	236 / 1078	230 / 1064	59.4	1.02 [0.83,1.25]	
FIGARO-DKD	154 / 640	190 / 639	40.6	0.75 [0.58,0.96]	
Total	390 / 1718	420 / 1703		0.90 [0.77,1.05]	Z=-1.34, p=0.1796
Heterogeneity:	Q=3.45 (df=1)	p=0.0631	I^2=71.0%		
North America					
FIDELIO-DKD	109 / 425	103 / 437	61.7	1.12 [0.82,1.53]	
FIGARO-DKD	61 / 267	71 / 271	38.3	0.83 [0.56,1.24]	
Total	170 / 692	174 / 708		1.00 [0.78,1.27]	Z=-0.00, p=0.9967
Heterogeneity:	Q=1.32 (df=1)	p=0.2512	I^2=24.0%		
Asia					
FIDELIO-DKD	164 / 751	156 / 748	71.9	1.06 [0.83,1.36]	
FIGARO-DKD	78 / 288	53 / 292	28.1	1.67 [1.13,2.49]	
Total	242 / 1039	209 / 1040		1.21 [0.98,1.49]	Z=1.77, p=0.0769
Heterogeneity:	Q=3.70 (df=1)	p=0.0544	I^2=73.0%		
Latin America					
FIDELIO-DKD	73 / 274	78 / 274	72.6	0.91 [0.63,1.33]	
FIGARO-DKD	27 / 102	31 / 101	27.4	0.81 [0.44,1.50]	
Total	100 / 376	109 / 375		0.88 [0.64,1.22]	Z=-0.76, p=0.4497
Heterogeneity:	Q=0.10 (df=1)	p=0.7515	I^2=0.0%		
Others					
FIDELIO-DKD	18 / 94	30 / 97	64.5	0.53 [0.27,1.03]	
FIGARO-DKD	17 / 62	9 / 59	35.5	2.10 [0.85,5.18]	
Total	35 / 156	39 / 156		0.87 [0.52,1.47]	Z=-0.52, p=0.6043
Heterogeneity:	Q=5.77 (df=1)	p=0.0163	I^2=82.7%		
Subgroup Heterogeneity:	Q=5.65 (df=4)	p=0.2273	I^2=29.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2.2: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

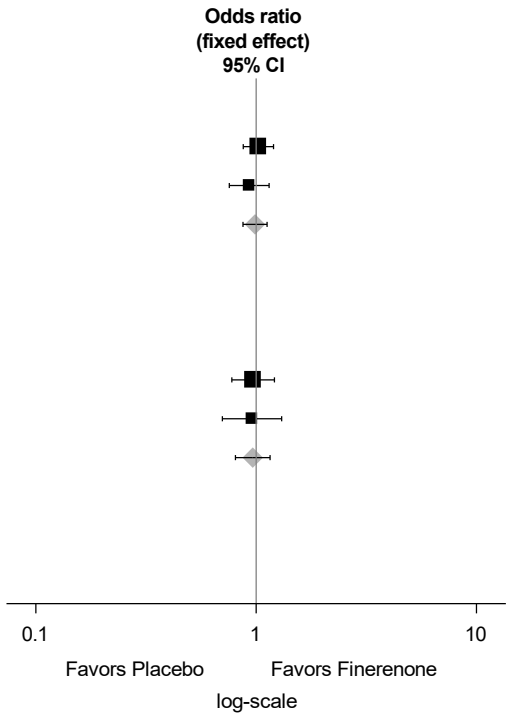
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	277 / 1215	287 / 1213	57.5	0.95 [0.79,1.15]	
FIGARO-DKD	207 / 865	218 / 851	42.5	0.91 [0.73,1.14]	
Total	484 / 2080	505 / 2064		0.94 [0.81,1.08]	Z=-0.91, p=0.3635
Heterogeneity:	Q=0.08 (df=1)	p=0.7750	I^2=0.0%		
Absent					
FIDELIO-DKD	323 / 1407	310 / 1407	71.5	1.05 [0.88,1.26]	
FIGARO-DKD	130 / 494	136 / 511	28.5	0.98 [0.74,1.30]	
Total	453 / 1901	446 / 1918		1.03 [0.89,1.20]	Z=0.44, p=0.6607
Heterogeneity:	Q=0.16 (df=1)	p=0.6862	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3446	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2.3: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

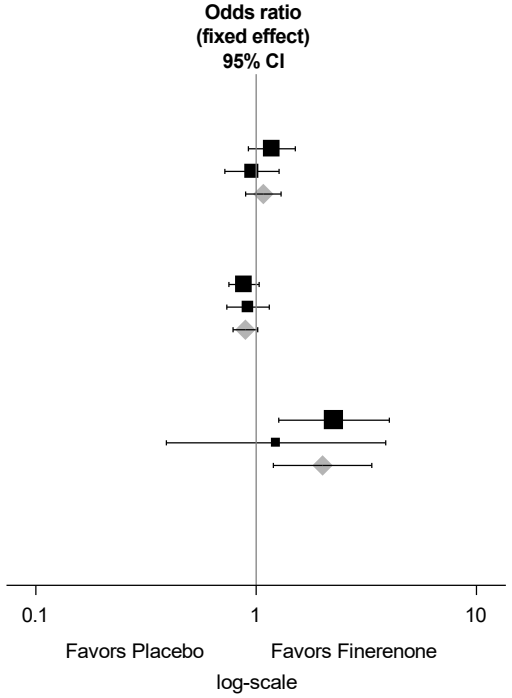
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	407 / 1737	392 / 1703	63.3	1.02 [0.87,1.20]	
FIGARO-DKD	232 / 924	247 / 932	36.7	0.93 [0.76,1.14]	
Total	639 / 2661	639 / 2635		0.99 [0.87,1.12]	Z=-0.19, p=0.8514
Heterogeneity:	Q=0.52 (df=1)	p=0.4717	I^2=0.0%		
> 4.5					
FIDELIO-DKD	193 / 884	205 / 916	65.9	0.97 [0.78,1.21]	
FIGARO-DKD	105 / 435	107 / 429	34.1	0.96 [0.70,1.31]	
Total	298 / 1319	312 / 1345		0.96 [0.81,1.16]	Z=-0.39, p=0.6985
Heterogeneity:	Q=0.00 (df=1)	p=0.9524	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8330	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2.4: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

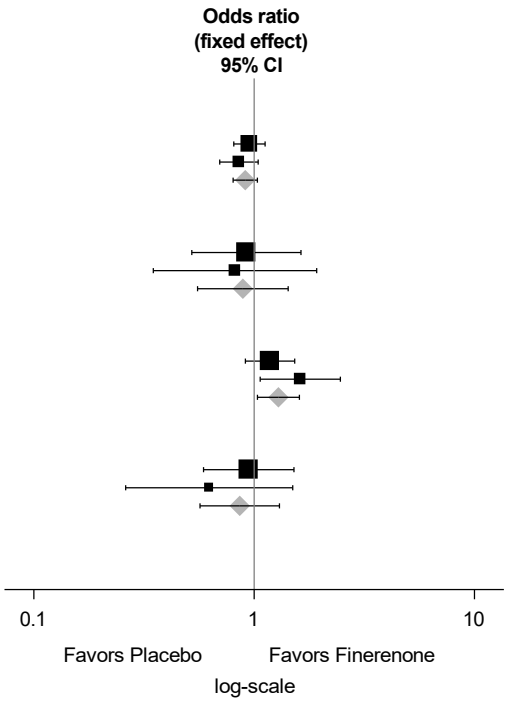
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	177 / 724	156 / 724	57.2	1.18 [0.92,1.51]	
FIGARO-DKD	127 / 494	132 / 497	42.8	0.96 [0.72,1.27]	
Total	304 / 1218	288 / 1221		1.08 [0.90,1.30]	Z=0.79, p=0.4277
Heterogeneity:	Q=1.18 (df=1)	p=0.2766	I^2=15.5%		
130 - < 160					
FIDELIO-DKD	378 / 1762	418 / 1766	66.3	0.88 [0.75,1.03]	
FIGARO-DKD	202 / 831	215 / 830	33.7	0.92 [0.74,1.15]	
Total	580 / 2593	633 / 2596		0.89 [0.79,1.02]	Z=-1.72, p=0.0859
Heterogeneity:	Q=0.09 (df=1)	p=0.7622	I^2=0.0%		
>= 160					
FIDELIO-DKD	44 / 133	23 / 128	79.7	2.26 [1.27,4.02]	
FIGARO-DKD	8 / 34	7 / 35	20.3	1.23 [0.39,3.87]	
Total	52 / 167	30 / 163		2.00 [1.20,3.35]	Z=2.64, p=0.0082
Heterogeneity:	Q=0.86 (df=1)	p=0.3545	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.41 (df=2)	p=0.0055	I^2=80.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2.5: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

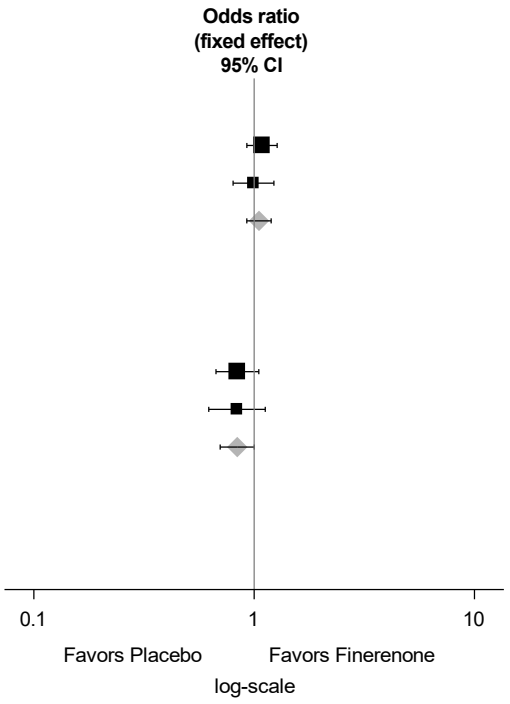
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	360 / 1637	380 / 1663	60.1	0.95 [0.81,1.12]	
FIGARO-DKD	244 / 1013	269 / 992	39.9	0.85 [0.70,1.04]	
Total	604 / 2650	649 / 2655		0.91 [0.80,1.03]	Z=-1.44, p=0.1497
Heterogeneity:	Q=0.69 (df=1)	p=0.4060	I^2=0.0%		
Black					
FIDELIO-DKD	33 / 130	31 / 115	69.1	0.92 [0.52,1.63]	
FIGARO-DKD	11 / 43	21 / 71	30.9	0.82 [0.35,1.92]	
Total	44 / 173	52 / 186		0.89 [0.55,1.43]	Z=-0.49, p=0.6245
Heterogeneity:	Q=0.05 (df=1)	p=0.8204	I^2=0.0%		
Asian					
FIDELIO-DKD	158 / 678	139 / 679	72.5	1.18 [0.91,1.53]	
FIGARO-DKD	69 / 251	48 / 253	27.5	1.62 [1.06,2.46]	
Total	227 / 929	187 / 932		1.29 [1.03,1.60]	Z=2.26, p=0.0235
Heterogeneity:	Q=1.59 (df=1)	p=0.2080	I^2=36.9%		
Others					
FIDELIO-DKD	49 / 177	47 / 163	77.3	0.94 [0.59,1.52]	
FIGARO-DKD	13 / 52	16 / 46	22.7	0.62 [0.26,1.50]	
Total	62 / 229	63 / 209		0.86 [0.57,1.30]	Z=-0.71, p=0.4762
Heterogeneity:	Q=0.67 (df=1)	p=0.4146	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.80 (df=3)	p=0.0504	I^2=61.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.2.6: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

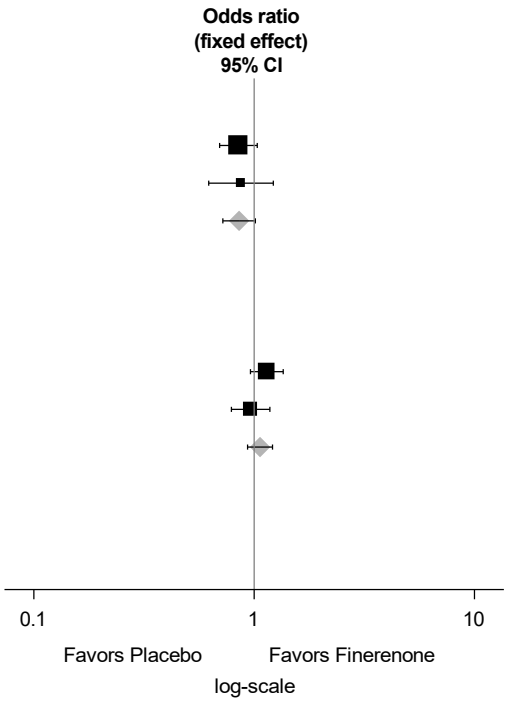
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	393 / 1800	384 / 1876	64.5	1.09 [0.93,1.27]	
FIGARO-DKD	219 / 917	225 / 937	35.5	0.99 [0.80,1.23]	
Total	612 / 2717	609 / 2813		1.05 [0.93,1.19]	Z=0.77, p=0.4390
Heterogeneity:	Q=0.43 (df=1)	p=0.5115	I^2=0.0%		
Female					
FIDELIO-DKD	207 / 822	213 / 744	63.5	0.84 [0.67,1.05]	
FIGARO-DKD	118 / 442	129 / 425	36.5	0.84 [0.62,1.12]	
Total	325 / 1264	342 / 1169		0.84 [0.70,1.00]	Z=-1.94, p=0.0518
Heterogeneity:	Q=0.00 (df=1)	p=0.9828	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.13 (df=1)	p=0.0421	I^2=75.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.2.7: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

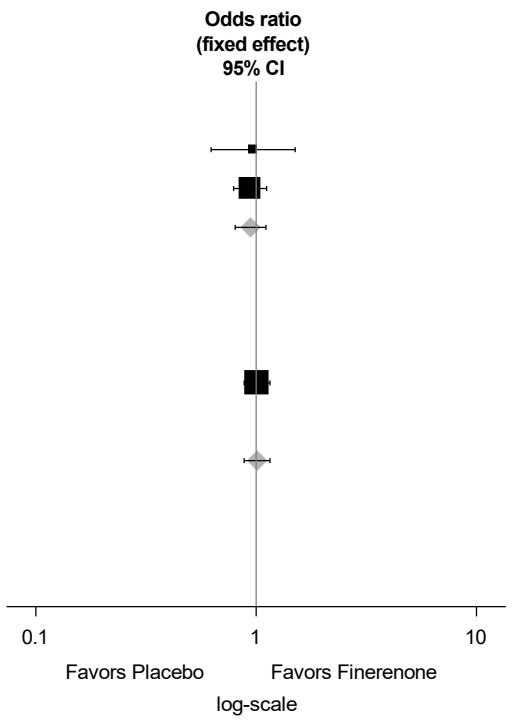
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	249 / 1106	275 / 1078	74.7	0.85 [0.70,1.03]	
FIGARO-DKD	89 / 337	98 / 336	25.3	0.87 [0.62,1.22]	
Total	338 / 1443	373 / 1414		0.85 [0.72,1.01]	Z=-1.82, p=0.0691
Heterogeneity:	Q=0.02 (df=1)	p=0.8926	I^2=0.0%		
>= 65					
FIDELIO-DKD	351 / 1516	322 / 1542	58.0	1.14 [0.96,1.35]	
FIGARO-DKD	248 / 1022	256 / 1026	42.0	0.96 [0.79,1.18]	
Total	599 / 2538	578 / 2568		1.06 [0.93,1.21]	Z=0.92, p=0.3570
Heterogeneity:	Q=1.58 (df=1)	p=0.2090	I^2=36.6%		
Subgroup Heterogeneity:	Q=4.01 (df=1)	p=0.0452	I^2=75.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.2.8: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

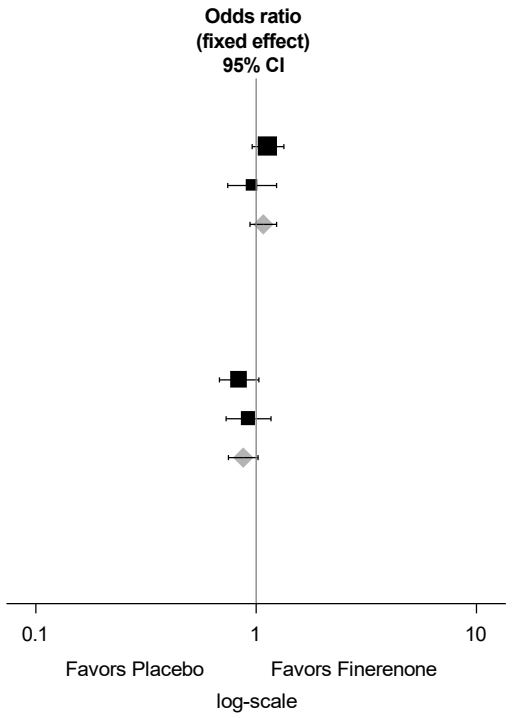
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	52 / 210	54 / 213	13.4	0.97 [0.62,1.50]	
FIGARO-DKD	337 / 1359	354 / 1362	86.6	0.94 [0.79,1.12]	
Total	389 / 1569	408 / 1575		0.94 [0.80,1.11]	Z=-0.72, p=0.4735
Heterogeneity:	Q=0.02 (df=1)	p=0.8958	I^2=0.0%		
Very High					
FIDELIO-DKD	548 / 2412	543 / 2407	100.0	1.01 [0.88,1.15]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	548 / 2412	543 / 2407		1.01 [0.88,1.15]	Z=0.13, p=0.8941
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=1)	p=0.5257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.2.9: EQ-5D VAS - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

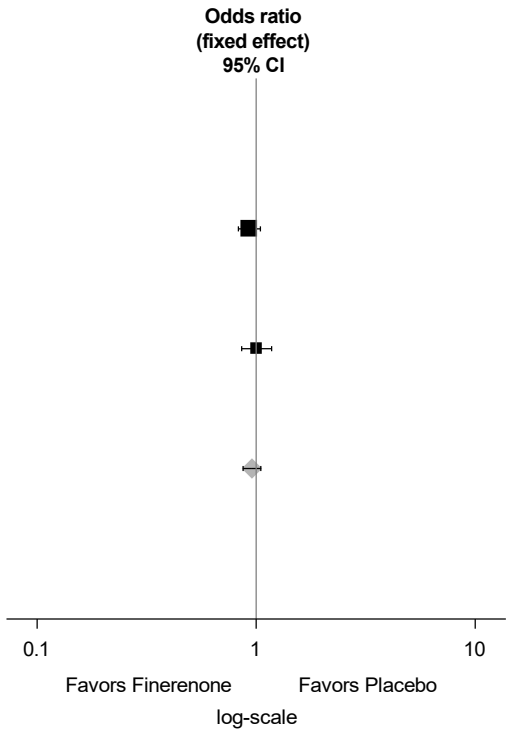
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	385 / 1559	348 / 1549	70.3	1.13 [0.96,1.34]	
FIGARO-DKD	155 / 639	158 / 631	29.7	0.96 [0.74,1.24]	
Total	540 / 2198	506 / 2180		1.08 [0.94,1.24]	Z=1.05, p=0.2930
Heterogeneity:	Q=1.14 (df=1)	p=0.2853	I^2=12.4%		
45 - < 60					
FIDELIO-DKD	215 / 1063	249 / 1071	56.4	0.84 [0.68,1.03]	
FIGARO-DKD	182 / 720	196 / 731	43.6	0.92 [0.73,1.17]	
Total	397 / 1783	445 / 1802		0.87 [0.75,1.02]	Z=-1.71, p=0.0870
Heterogeneity:	Q=0.38 (df=1)	p=0.5375	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.90 (df=1)	p=0.0482	I^2=74.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, EQ-5D=EuroQOL group 5-dimension, GLM=generalized linear model, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care, VAS=Visual Analogue Scale.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

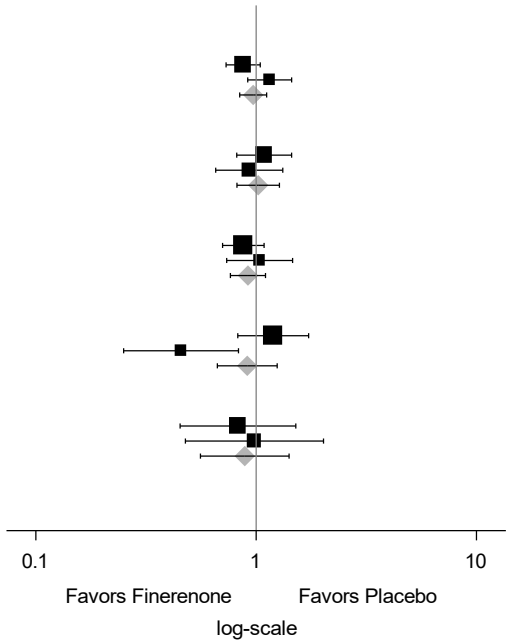
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	836 / 2622	876 / 2620	64.9	0.93 [0.83,1.05]	
FIGARO-DKD	482 / 1359	482 / 1362	35.1	1.01 [0.86,1.18]	
Total	1318 / 3981	1358 / 3982		0.96 [0.87,1.05]	Z=-0.93, p=0.3507
Heterogeneity:	Q=0.59 (df=1)	p=0.4433	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.3.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

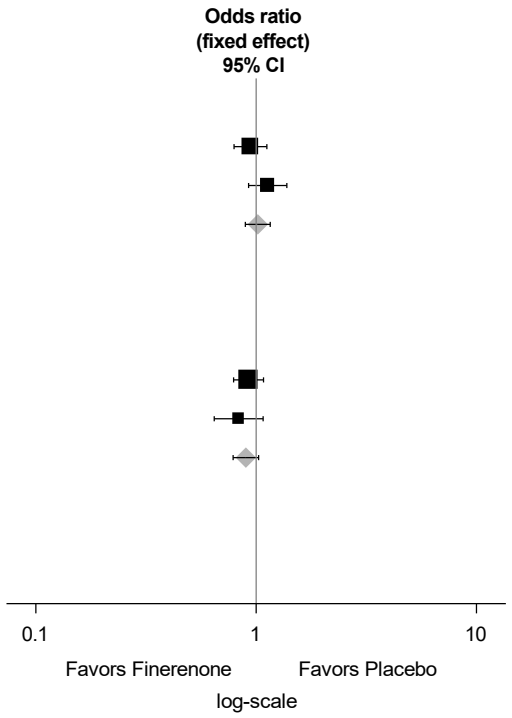
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	353 / 1078	381 / 1064	62.3	0.87 [0.73,1.04]	
FIGARO-DKD	237 / 640	216 / 639	37.7	1.15 [0.92,1.45]	
Total	590 / 1718	597 / 1703		0.97 [0.84,1.12]	Z=-0.44, p=0.6625
Heterogeneity:	Q=3.49 (df=1)	p=0.0616	I^2=71.4%		
North America					
FIDELIO-DKD	139 / 425	135 / 437	59.9	1.09 [0.82,1.45]	
FIGARO-DKD	96 / 267	102 / 271	40.1	0.93 [0.66,1.32]	
Total	235 / 692	237 / 708		1.02 [0.82,1.28]	Z=0.19, p=0.8524
Heterogeneity:	Q=0.46 (df=1)	p=0.4995	I^2=0.0%		
Asia					
FIDELIO-DKD	231 / 751	252 / 748	71.6	0.87 [0.70,1.09]	
FIGARO-DKD	98 / 288	97 / 292	28.4	1.04 [0.73,1.46]	
Total	329 / 1039	349 / 1040		0.92 [0.76,1.10]	Z=-0.92, p=0.3586
Heterogeneity:	Q=0.67 (df=1)	p=0.4117	I^2=0.0%		
Latin America					
FIDELIO-DKD	84 / 274	74 / 274	72.4	1.19 [0.83,1.73]	
FIGARO-DKD	25 / 102	42 / 101	27.6	0.46 [0.25,0.83]	
Total	109 / 376	116 / 375		0.91 [0.67,1.25]	Z=-0.58, p=0.5590
Heterogeneity:	Q=7.17 (df=1)	p=0.0074	I^2=86.0%		
Others					
FIDELIO-DKD	29 / 94	34 / 97	58.8	0.83 [0.45,1.51]	
FIGARO-DKD	26 / 62	25 / 59	41.2	0.98 [0.48,2.02]	
Total	55 / 156	59 / 156		0.89 [0.56,1.41]	Z=-0.50, p=0.6137
Heterogeneity:	Q=0.13 (df=1)	p=0.7197	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=4)	p=0.9440	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

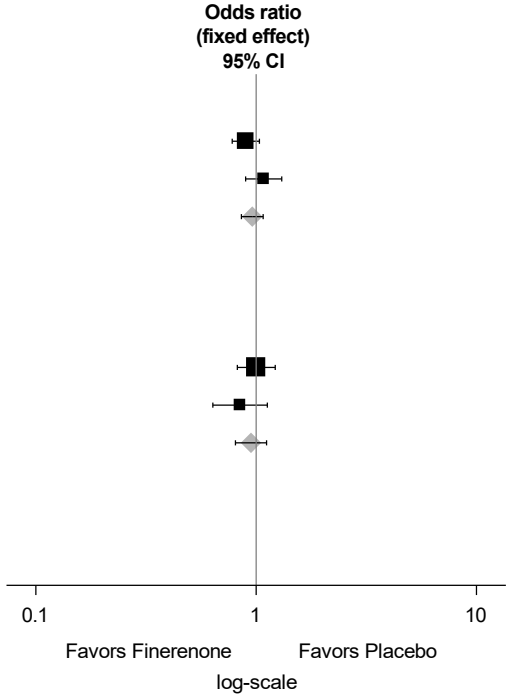
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	374 / 1215	389 / 1213	57.6	0.94 [0.79,1.12]	
FIGARO-DKD	306 / 865	278 / 851	42.4	1.13 [0.92,1.38]	
Total	680 / 2080	667 / 2064		1.02 [0.89,1.16]	Z=0.25, p=0.8007
Heterogeneity:	Q=1.80 (df=1)	p=0.1792	I^2=44.6%		
Absent					
FIDELIO-DKD	462 / 1407	487 / 1407	72.7	0.92 [0.79,1.08]	
FIGARO-DKD	176 / 494	204 / 511	27.3	0.83 [0.65,1.08]	
Total	638 / 1901	691 / 1918		0.90 [0.79,1.03]	Z=-1.58, p=0.1134
Heterogeneity:	Q=0.46 (df=1)	p=0.4989	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.71 (df=1)	p=0.1904	I^2=41.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

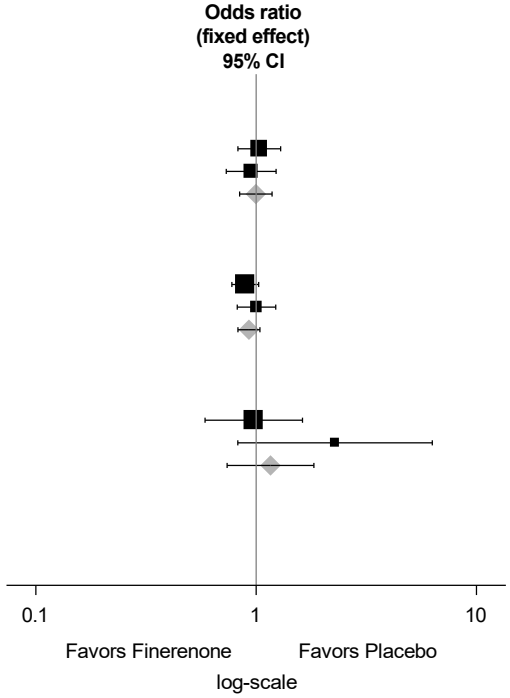
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	553 / 1737	583 / 1703	63.8	0.90 [0.78,1.03]	
FIGARO-DKD	348 / 924	334 / 932	36.2	1.08 [0.90,1.31]	
Total	901 / 2661	917 / 2635		0.96 [0.86,1.08]	Z=-0.70, p=0.4818
Heterogeneity:	Q=2.40 (df=1)	p=0.1210	I^2=58.4%		
> 4.5					
FIDELIO-DKD	283 / 884	293 / 916	67.4	1.00 [0.82,1.22]	
FIGARO-DKD	134 / 435	148 / 429	32.6	0.85 [0.64,1.12]	
Total	417 / 1319	441 / 1345		0.95 [0.81,1.11]	Z=-0.65, p=0.5145
Heterogeneity:	Q=0.92 (df=1)	p=0.3386	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8952	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

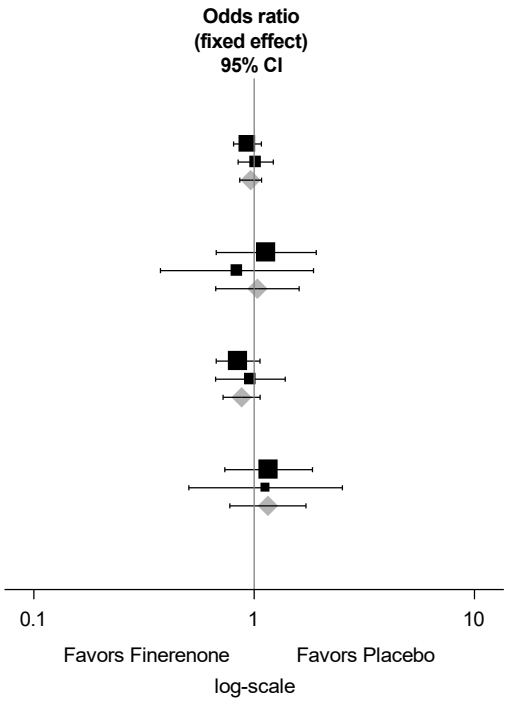
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	225 / 724	220 / 724	57.6	1.03 [0.83,1.29]	
FIGARO-DKD	172 / 494	179 / 497	42.4	0.95 [0.73,1.23]	
Total	397 / 1218	399 / 1221		1.00 [0.84,1.18]	Z=-0.04, p=0.9677
Heterogeneity:	Q=0.23 (df=1)	p=0.6279	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	565 / 1762	611 / 1766	67.3	0.89 [0.78,1.03]	
FIGARO-DKD	295 / 831	294 / 830	32.7	1.00 [0.82,1.23]	
Total	860 / 2593	905 / 2596		0.93 [0.83,1.04]	Z=-1.29, p=0.1970
Heterogeneity:	Q=0.88 (df=1)	p=0.3478	I^2=0.0%		
>= 160					
FIDELIO-DKD	46 / 133	45 / 128	79.9	0.98 [0.59,1.62]	
FIGARO-DKD	15 / 34	9 / 35	20.1	2.28 [0.83,6.30]	
Total	61 / 167	54 / 163		1.16 [0.74,1.83]	Z=0.65, p=0.5174
Heterogeneity:	Q=2.15 (df=1)	p=0.1429	I^2=53.4%		
Subgroup Heterogeneity:	Q=1.21 (df=2)	p=0.5455	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

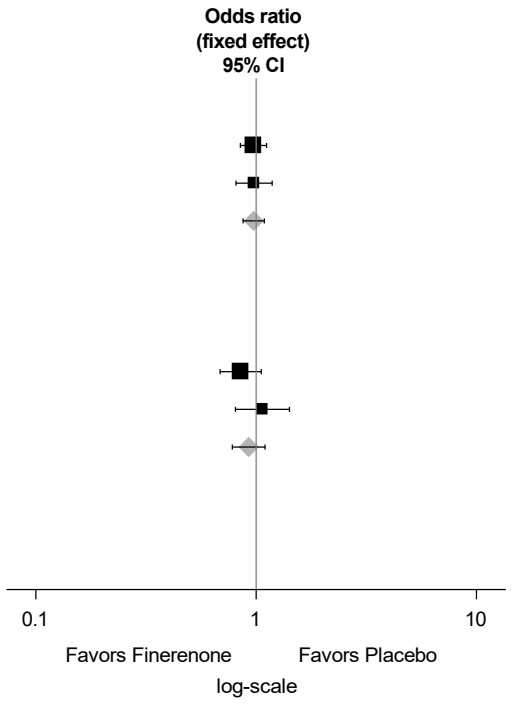
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	525 / 1637	559 / 1663	61.5	0.93 [0.81,1.08]	
FIGARO-DKD	356 / 1013	345 / 992	38.5	1.02 [0.85,1.22]	
Total	881 / 2650	904 / 2655		0.96 [0.86,1.08]	Z=-0.63, p=0.5263
Heterogeneity:	Q=0.52 (df=1)	p=0.4715	I^2=0.0%		
Black					
FIDELIO-DKD	49 / 130	40 / 115	70.1	1.13 [0.67,1.91]	
FIGARO-DKD	14 / 43	26 / 71	29.9	0.84 [0.38,1.86]	
Total	63 / 173	66 / 186		1.03 [0.67,1.60]	Z=0.15, p=0.8784
Heterogeneity:	Q=0.39 (df=1)	p=0.5307	I^2=0.0%		
Asian					
FIDELIO-DKD	203 / 678	228 / 679	71.7	0.85 [0.67,1.06]	
FIGARO-DKD	89 / 251	92 / 253	28.3	0.96 [0.67,1.38]	
Total	292 / 929	320 / 932		0.88 [0.72,1.06]	Z=-1.33, p=0.1831
Heterogeneity:	Q=0.34 (df=1)	p=0.5576	I^2=0.0%		
Others					
FIDELIO-DKD	59 / 177	49 / 163	75.4	1.16 [0.74,1.84]	
FIGARO-DKD	23 / 52	19 / 46	24.6	1.13 [0.51,2.51]	
Total	82 / 229	68 / 209		1.15 [0.78,1.72]	Z=0.71, p=0.4796
Heterogeneity:	Q=0.00 (df=1)	p=0.9465	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.78 (df=3)	p=0.6203	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

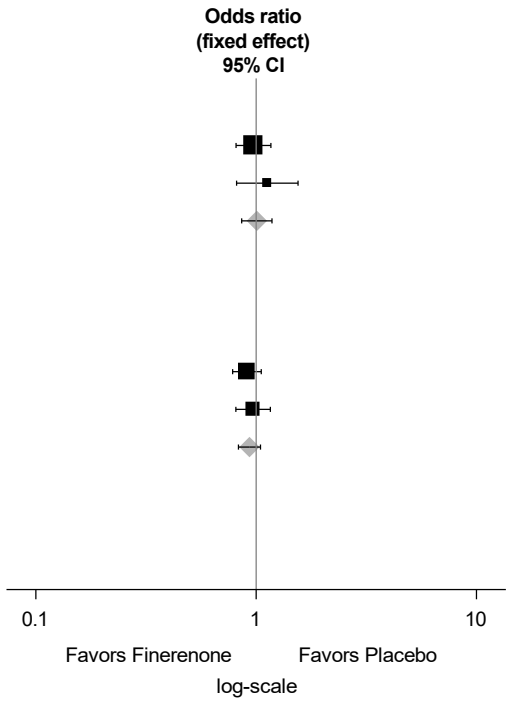
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	598 / 1800	635 / 1876	65.6	0.97 [0.85,1.12]	
FIGARO-DKD	331 / 917	343 / 937	34.4	0.98 [0.81,1.18]	
Total	929 / 2717	978 / 2813		0.97 [0.87,1.09]	Z=-0.46, p=0.6458
Heterogeneity:	Q=0.00 (df=1)	p=0.9595	I^2=0.0%		
Female					
FIDELIO-DKD	238 / 822	241 / 744	63.3	0.85 [0.69,1.05]	
FIGARO-DKD	151 / 442	139 / 425	36.7	1.07 [0.81,1.42]	
Total	389 / 1264	380 / 1169		0.92 [0.78,1.10]	Z=-0.90, p=0.3698
Heterogeneity:	Q=1.58 (df=1)	p=0.2094	I^2=36.5%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6154	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

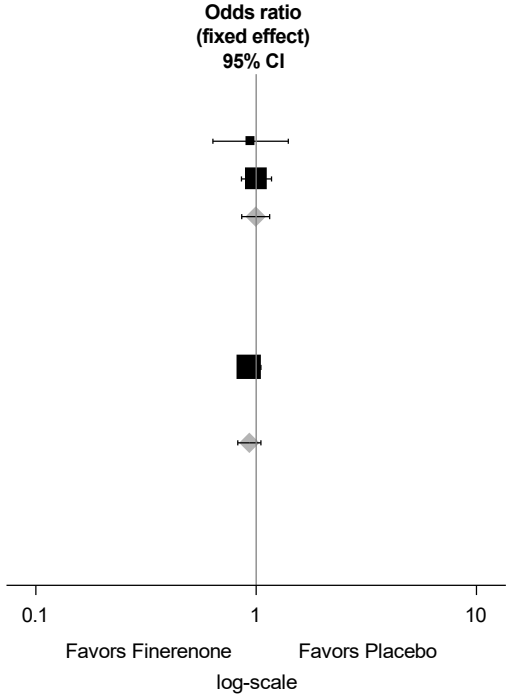
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	335 / 1106	333 / 1078	75.7	0.97 [0.81,1.17]	
FIGARO-DKD	116 / 337	107 / 336	24.3	1.12 [0.81,1.55]	
Total	451 / 1443	440 / 1414		1.01 [0.86,1.18]	Z=0.09, p=0.9322
Heterogeneity:	Q=0.59 (df=1)	p=0.4426	I^2=0.0%		
>= 65					
FIDELIO-DKD	501 / 1516	543 / 1542	59.2	0.91 [0.78,1.05]	
FIGARO-DKD	366 / 1022	375 / 1026	40.8	0.97 [0.81,1.16]	
Total	867 / 2538	918 / 2568		0.93 [0.83,1.05]	Z=-1.19, p=0.2325
Heterogeneity:	Q=0.29 (df=1)	p=0.5897	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

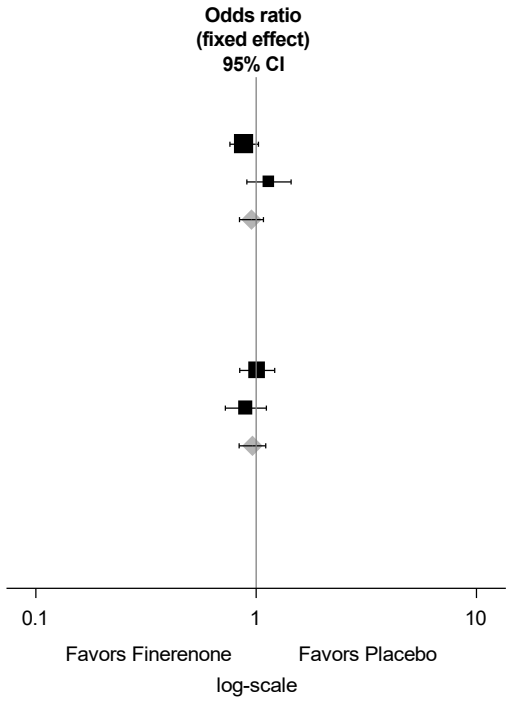
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 210	81 / 213	13.7	0.94 [0.64,1.40]	
FIGARO-DKD	482 / 1359	482 / 1362	86.3	1.00 [0.86,1.17]	
Total	559 / 1569	563 / 1575		0.99 [0.86,1.15]	Z=-0.07, p=0.9461
Heterogeneity:	Q=0.08 (df=1)	p=0.7759	I^2=0.0%		
Very High					
FIDELIO-DKD	759 / 2412	795 / 2407	100.0	0.93 [0.83,1.05]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	759 / 2412	795 / 2407		0.93 [0.83,1.05]	Z=-1.16, p=0.2464
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4920	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.3.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

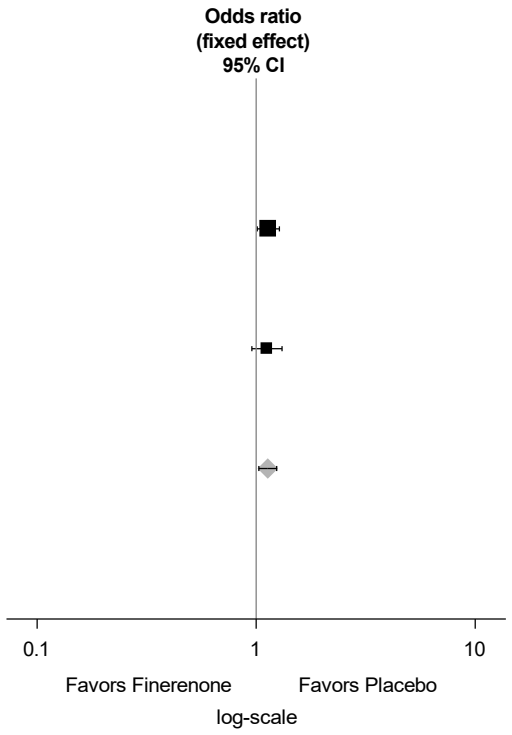
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	500 / 1559	540 / 1549	70.7	0.88 [0.76,1.02]	
FIGARO-DKD	231 / 639	209 / 631	29.3	1.14 [0.91,1.44]	
Total	731 / 2198	749 / 2180		0.95 [0.84,1.08]	Z=-0.77, p=0.4410
Heterogeneity:	Q=3.41 (df=1)	p=0.0650	I^2=70.6%		
45 - < 60					
FIDELIO-DKD	336 / 1063	336 / 1071	57.9	1.01 [0.84,1.21]	
FIGARO-DKD	251 / 720	273 / 731	42.1	0.90 [0.72,1.11]	
Total	587 / 1783	609 / 1802		0.96 [0.84,1.11]	Z=-0.55, p=0.5823
Heterogeneity:	Q=0.68 (df=1)	p=0.4088	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9146	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

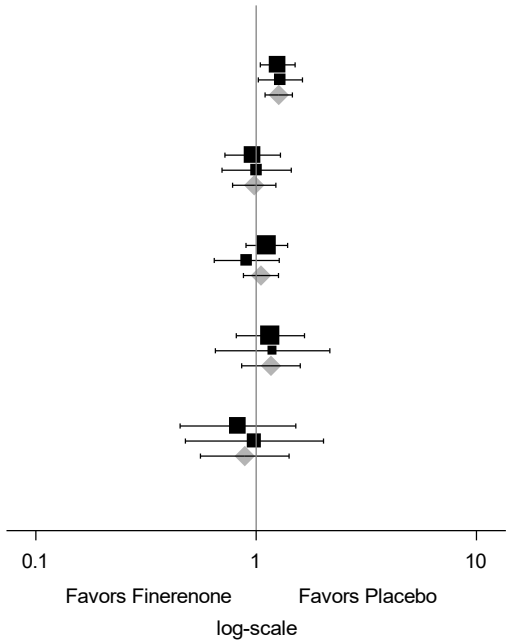
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	873 / 2622	800 / 2620	64.9	1.14 [1.01,1.28]	
FIGARO-DKD	486 / 1359	453 / 1362	35.1	1.12 [0.96,1.31]	
Total	1359 / 3981	1253 / 3982		1.13 [1.03,1.24]	Z=2.55, p=0.0109
Heterogeneity:	Q=0.02 (df=1)	p=0.8846	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.4.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

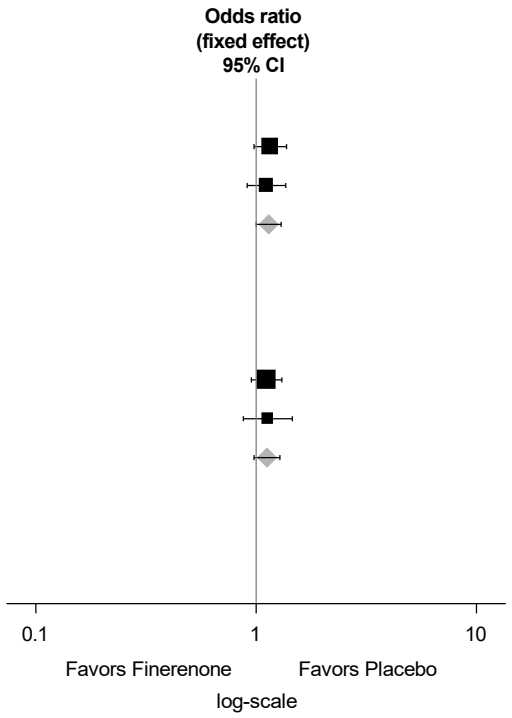
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	373 / 1078	316 / 1064	61.7	1.25 [1.04,1.50]	
FIGARO-DKD	241 / 640	204 / 639	38.3	1.29 [1.02,1.62]	
Total	614 / 1718	520 / 1703		1.27 [1.10,1.46]	Z=3.24, p=0.0012
Heterogeneity:	Q=0.03 (df=1)	p=0.8517	I^2=0.0%		
North America					
FIDELIO-DKD	128 / 425	135 / 437	60.9	0.96 [0.72,1.29]	
FIGARO-DKD	86 / 267	87 / 271	39.1	1.00 [0.70,1.44]	
Total	214 / 692	222 / 708		0.98 [0.78,1.23]	Z=-0.18, p=0.8601
Heterogeneity:	Q=0.03 (df=1)	p=0.8610	I^2=0.0%		
Asia					
FIDELIO-DKD	248 / 751	229 / 748	70.9	1.12 [0.90,1.39]	
FIGARO-DKD	100 / 288	108 / 292	29.1	0.91 [0.65,1.27]	
Total	348 / 1039	337 / 1040		1.05 [0.88,1.26]	Z=0.54, p=0.5919
Heterogeneity:	Q=1.04 (df=1)	p=0.3086	I^2=3.6%		
Latin America					
FIDELIO-DKD	95 / 274	86 / 274	73.8	1.16 [0.81,1.66]	
FIGARO-DKD	33 / 102	29 / 101	26.2	1.19 [0.65,2.16]	
Total	128 / 376	115 / 375		1.17 [0.86,1.59]	Z=0.99, p=0.3221
Heterogeneity:	Q=0.00 (df=1)	p=0.9480	I^2=0.0%		
Others					
FIDELIO-DKD	29 / 94	34 / 97	58.8	0.83 [0.45,1.51]	
FIGARO-DKD	26 / 62	25 / 59	41.2	0.98 [0.48,2.02]	
Total	55 / 156	59 / 156		0.89 [0.56,1.41]	Z=-0.50, p=0.6137
Heterogeneity:	Q=0.13 (df=1)	p=0.7197	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.64 (df=4)	p=0.2279	I^2=29.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

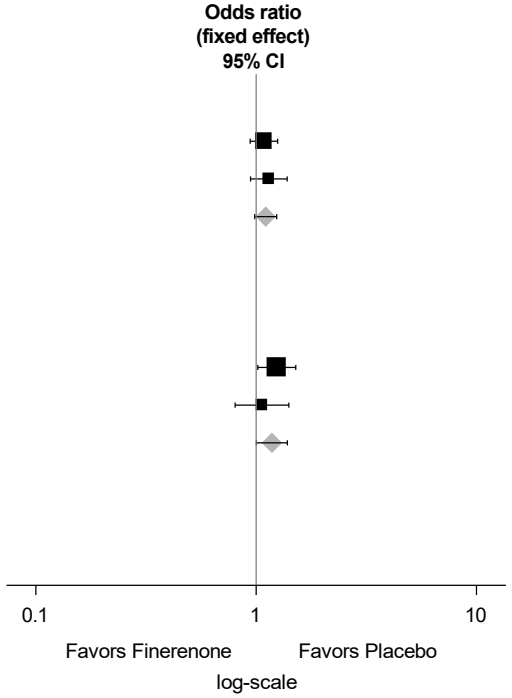
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	416 / 1215	376 / 1213	58.5	1.16 [0.98,1.37]	
FIGARO-DKD	295 / 865	270 / 851	41.5	1.11 [0.91,1.36]	
Total	711 / 2080	646 / 2064		1.14 [1.00,1.30]	Z=1.98, p=0.0480
Heterogeneity:	Q=0.09 (df=1)	p=0.7667	I^2=0.0%		
Absent					
FIDELIO-DKD	457 / 1407	424 / 1407	72.0	1.12 [0.95,1.31]	
FIGARO-DKD	191 / 494	183 / 511	28.0	1.13 [0.87,1.46]	
Total	648 / 1901	607 / 1918		1.12 [0.98,1.28]	Z=1.63, p=0.1025
Heterogeneity:	Q=0.01 (df=1)	p=0.9328	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8486	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

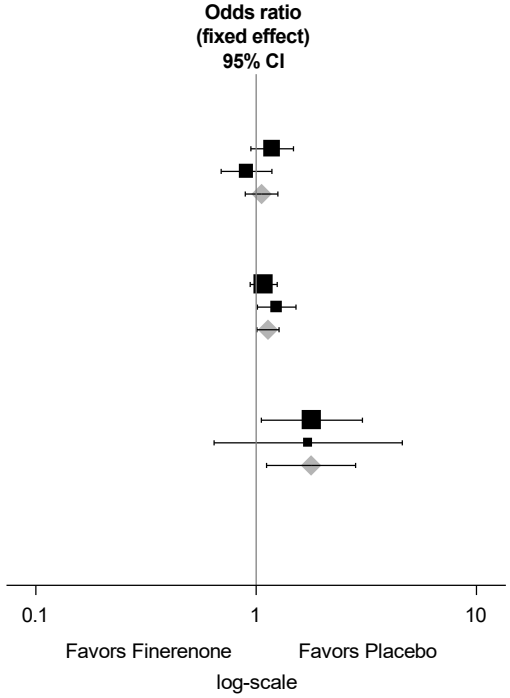
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	568 / 1737	527 / 1703	64.0	1.08 [0.94,1.25]	
FIGARO-DKD	333 / 924	308 / 932	36.0	1.14 [0.94,1.38]	
Total	901 / 2661	835 / 2635		1.10 [0.98,1.24]	Z=1.70, p=0.0898
Heterogeneity:	Q=0.18 (df=1)	p=0.6733	I^2=0.0%		
> 4.5					
FIDELIO-DKD	305 / 884	273 / 916	66.7	1.24 [1.02,1.51]	
FIGARO-DKD	153 / 435	145 / 429	33.3	1.06 [0.80,1.41]	
Total	458 / 1319	418 / 1345		1.18 [1.00,1.39]	Z=1.99, p=0.0468
Heterogeneity:	Q=0.78 (df=1)	p=0.3768	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

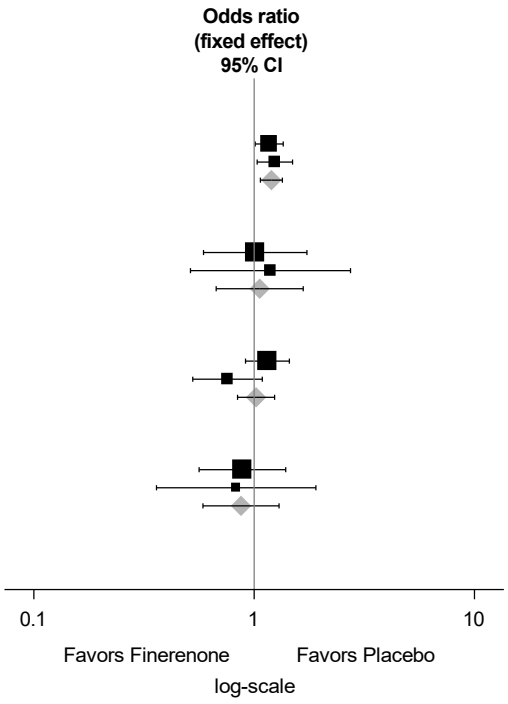
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	239 / 724	213 / 724	58.7	1.18 [0.95,1.48]	
FIGARO-DKD	157 / 494	169 / 497	41.3	0.90 [0.69,1.18]	
Total	396 / 1218	382 / 1221		1.06 [0.89,1.25]	Z=0.65, p=0.5149
Heterogeneity:	Q=2.30 (df=1)	p=0.1290	I^2=56.6%		
130 - < 160					
FIDELIO-DKD	583 / 1762	554 / 1766	67.1	1.08 [0.94,1.25]	
FIGARO-DKD	314 / 831	273 / 830	32.9	1.24 [1.01,1.52]	
Total	897 / 2593	827 / 2596		1.13 [1.01,1.27]	Z=2.09, p=0.0365
Heterogeneity:	Q=1.17 (df=1)	p=0.2795	I^2=14.5%		
>= 160					
FIDELIO-DKD	51 / 133	33 / 128	77.6	1.79 [1.06,3.04]	
FIGARO-DKD	15 / 34	11 / 35	22.4	1.72 [0.64,4.61]	
Total	66 / 167	44 / 163		1.78 [1.11,2.83]	Z=2.42, p=0.0156
Heterogeneity:	Q=0.00 (df=1)	p=0.9458	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.19 (df=2)	p=0.1232	I^2=52.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

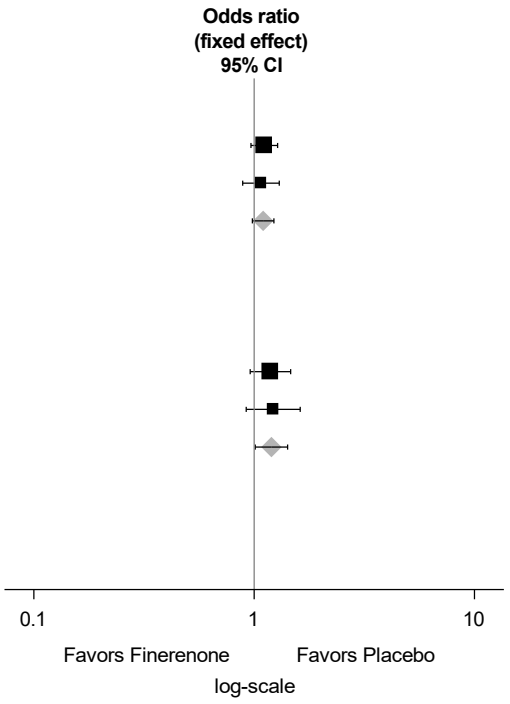
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	552 / 1637	504 / 1663	61.4	1.17 [1.01,1.35]	
FIGARO-DKD	372 / 1013	316 / 992	38.6	1.24 [1.03,1.49]	
Total	924 / 2650	820 / 2655		1.20 [1.07,1.34]	Z=3.07, p=0.0021
Heterogeneity:	Q=0.24 (df=1)	p=0.6217	I^2=0.0%		
Black					
FIDELIO-DKD	41 / 130	36 / 115	70.5	1.01 [0.59,1.74]	
FIGARO-DKD	13 / 43	19 / 71	29.5	1.19 [0.51,2.74]	
Total	54 / 173	55 / 186		1.06 [0.67,1.67]	Z=0.25, p=0.8034
Heterogeneity:	Q=0.10 (df=1)	p=0.7533	I^2=0.0%		
Asian					
FIDELIO-DKD	224 / 678	204 / 679	71.5	1.15 [0.91,1.44]	
FIGARO-DKD	84 / 251	101 / 253	28.5	0.76 [0.53,1.09]	
Total	308 / 929	305 / 932		1.02 [0.84,1.24]	Z=0.20, p=0.8415
Heterogeneity:	Q=3.62 (df=1)	p=0.0570	I^2=72.4%		
Others					
FIDELIO-DKD	56 / 177	56 / 163	77.2	0.88 [0.56,1.39]	
FIGARO-DKD	17 / 52	17 / 46	22.8	0.83 [0.36,1.91]	
Total	73 / 229	73 / 209		0.87 [0.59,1.30]	Z=-0.68, p=0.4971
Heterogeneity:	Q=0.02 (df=1)	p=0.8930	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.76 (df=3)	p=0.2884	I^2=20.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.4.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

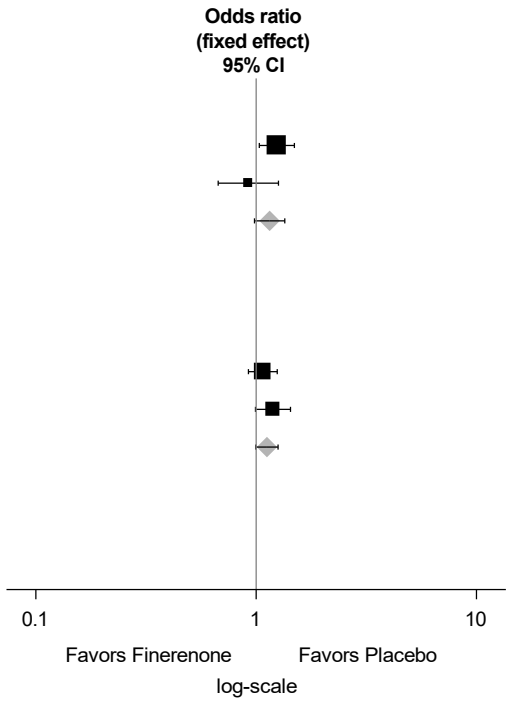
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	587 / 1800	569 / 1876	65.3	1.11 [0.97,1.28]	
FIGARO-DKD	327 / 917	319 / 937	34.7	1.07 [0.89,1.30]	
Total	914 / 2717	888 / 2813		1.10 [0.98,1.23]	Z=1.63, p=0.1025
Heterogeneity:	Q=0.08 (df=1)	p=0.7740	I^2=0.0%		
Female					
FIDELIO-DKD	286 / 822	231 / 744	64.0	1.18 [0.96,1.46]	
FIGARO-DKD	159 / 442	134 / 425	36.0	1.22 [0.92,1.62]	
Total	445 / 1264	365 / 1169		1.20 [1.01,1.42]	Z=2.09, p=0.0368
Heterogeneity:	Q=0.03 (df=1)	p=0.8709	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.70 (df=1)	p=0.4043	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.4.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

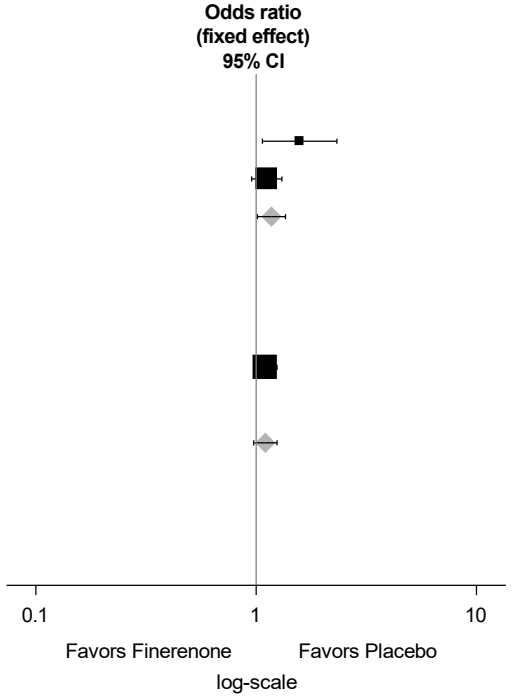
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	358 / 1106	300 / 1078	74.7	1.24 [1.03,1.49]	
FIGARO-DKD	118 / 337	124 / 336	25.3	0.92 [0.67,1.26]	
Total	476 / 1443	424 / 1414		1.15 [0.98,1.35]	Z=1.74, p=0.0815
Heterogeneity:	Q=2.57 (df=1)	p=0.1088	I^2=61.1%		
>= 65					
FIDELIO-DKD	515 / 1516	500 / 1542	59.6	1.07 [0.92,1.25]	
FIGARO-DKD	368 / 1022	329 / 1026	40.4	1.19 [0.99,1.43]	
Total	883 / 2538	829 / 2568		1.12 [1.00,1.26]	Z=1.90, p=0.0579
Heterogeneity:	Q=0.77 (df=1)	p=0.3807	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7784	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.4.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

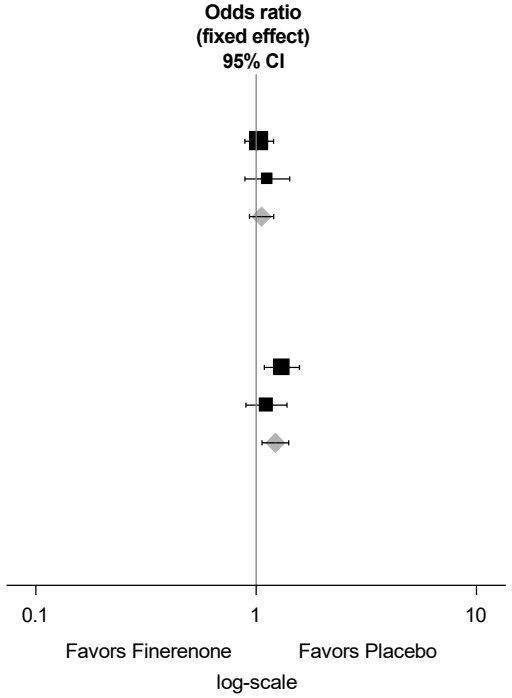
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	99 / 210	77 / 213	14.2	1.58 [1.07,2.33]	
FIGARO-DKD	486 / 1359	453 / 1362	85.8	1.12 [0.95,1.31]	
Total	585 / 1569	530 / 1575		1.17 [1.01,1.36]	Z=2.14, p=0.0326
Heterogeneity:	Q=2.57 (df=1)	p=0.1089	I^2=61.1%		
Very High					
FIDELIO-DKD	774 / 2412	723 / 2407	100.0	1.10 [0.97,1.24]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	774 / 2412	723 / 2407		1.10 [0.97,1.24]	Z=1.54, p=0.1238
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5115	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.4.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

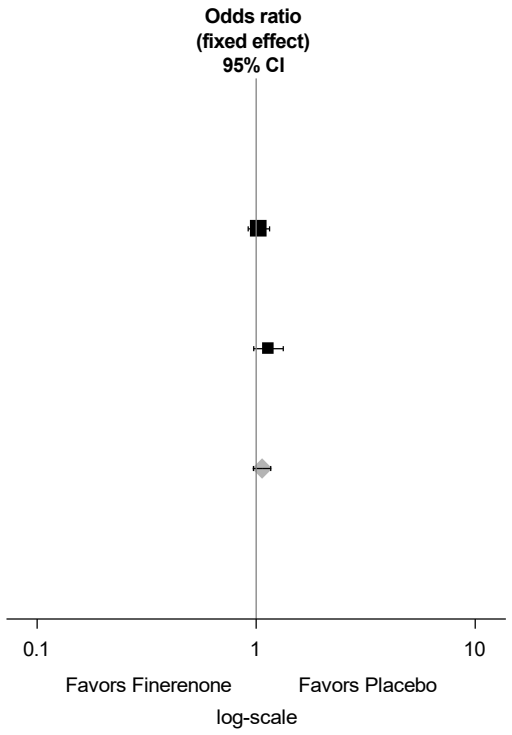
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	510 / 1559	496 / 1549	70.8	1.03 [0.89,1.20]	
FIGARO-DKD	219 / 639	200 / 631	29.2	1.12 [0.89,1.42]	
Total	729 / 2198	696 / 2180		1.06 [0.93,1.20]	Z=0.87, p=0.3816
Heterogeneity:	Q=0.36 (df=1)	p=0.5494	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	363 / 1063	304 / 1071	57.8	1.31 [1.09,1.57]	
FIGARO-DKD	267 / 720	253 / 731	42.2	1.11 [0.90,1.38]	
Total	630 / 1783	557 / 1802		1.22 [1.06,1.41]	Z=2.82, p=0.0048
Heterogeneity:	Q=1.25 (df=1)	p=0.2634	I^2=20.1%		
Subgroup Heterogeneity:	Q=2.26 (df=1)	p=0.1330	I^2=55.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

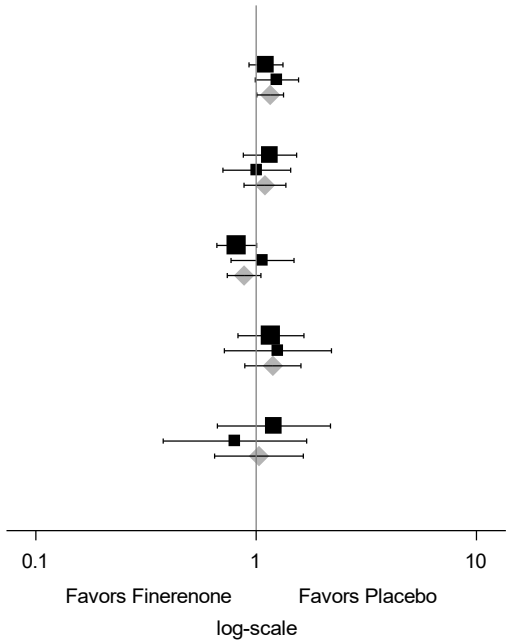
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	973 / 2622	955 / 2620	65.6	1.03 [0.92,1.15]	
FIGARO-DKD	543 / 1359	504 / 1362	34.4	1.14 [0.97,1.33]	
Total	1516 / 3981	1459 / 3982		1.06 [0.97,1.17]	Z=1.34, p=0.1807
Heterogeneity:	Q=1.07 (df=1)	p=0.3009	I^2=6.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.5.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

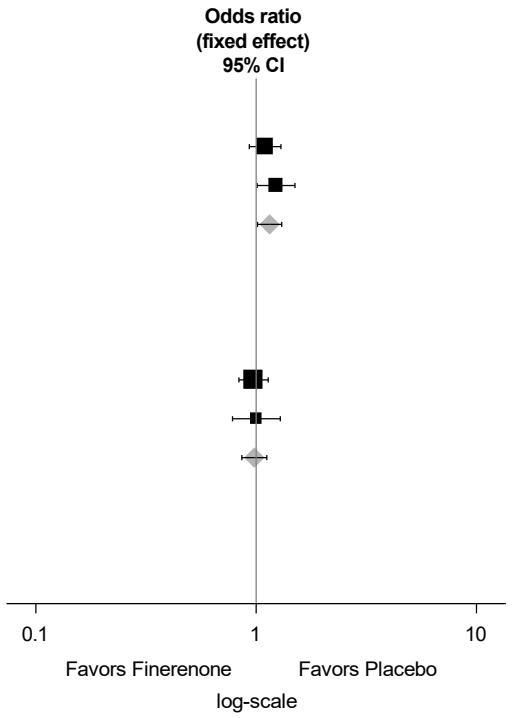
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	392 / 1078	362 / 1064	61.9	1.11 [0.93,1.32]	
FIGARO-DKD	259 / 640	226 / 639	38.1	1.24 [0.99,1.56]	
Total	651 / 1718	588 / 1703		1.16 [1.01,1.33]	Z=2.05, p=0.0401
Heterogeneity:	Q=0.61 (df=1)	p=0.4361	I^2=0.0%		
North America					
FIDELIO-DKD	160 / 425	150 / 437	61.8	1.16 [0.87,1.53]	
FIGARO-DKD	94 / 267	95 / 271	38.2	1.01 [0.71,1.43]	
Total	254 / 692	245 / 708		1.10 [0.88,1.36]	Z=0.82, p=0.4114
Heterogeneity:	Q=0.36 (df=1)	p=0.5491	I^2=0.0%		
Asia					
FIDELIO-DKD	275 / 751	310 / 748	71.5	0.82 [0.66,1.00]	
FIGARO-DKD	125 / 288	122 / 292	28.5	1.07 [0.77,1.49]	
Total	400 / 1039	432 / 1040		0.88 [0.74,1.05]	Z=-1.41, p=0.1588
Heterogeneity:	Q=1.84 (df=1)	p=0.1751	I^2=45.6%		
Latin America					
FIDELIO-DKD	110 / 274	100 / 274	72.5	1.17 [0.83,1.65]	
FIGARO-DKD	45 / 102	39 / 101	27.5	1.26 [0.72,2.20]	
Total	155 / 376	139 / 375		1.19 [0.89,1.60]	Z=1.17, p=0.2439
Heterogeneity:	Q=0.05 (df=1)	p=0.8284	I^2=0.0%		
Others					
FIDELIO-DKD	36 / 94	33 / 97	61.7	1.20 [0.67,2.17]	
FIGARO-DKD	20 / 62	22 / 59	38.3	0.80 [0.38,1.69]	
Total	56 / 156	55 / 156		1.03 [0.65,1.64]	Z=0.12, p=0.9019
Heterogeneity:	Q=0.70 (df=1)	p=0.4028	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.47 (df=4)	p=0.1670	I^2=38.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

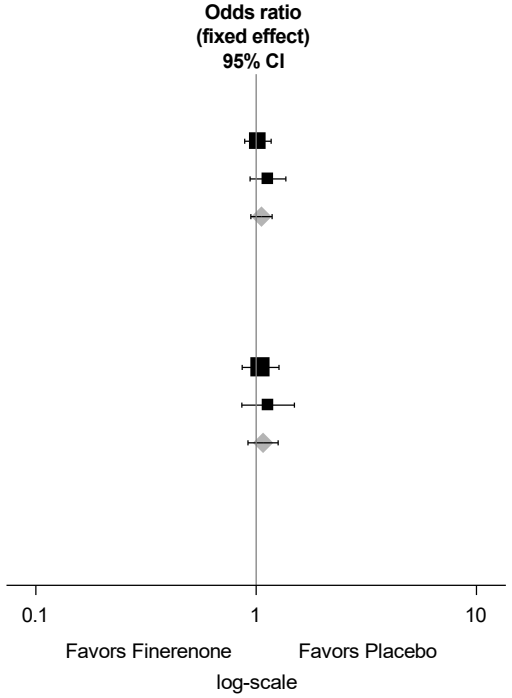
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	456 / 1215	429 / 1213	58.8	1.10 [0.93,1.30]	
FIGARO-DKD	331 / 865	285 / 851	41.2	1.23 [1.01,1.50]	
Total	787 / 2080	714 / 2064		1.15 [1.01,1.31]	Z=2.17, p=0.0298
Heterogeneity:	Q=0.76 (df=1)	p=0.3843	I^2=0.0%		
Absent					
FIDELIO-DKD	517 / 1407	526 / 1407	72.7	0.97 [0.83,1.13]	
FIGARO-DKD	212 / 494	219 / 511	27.3	1.00 [0.78,1.29]	
Total	729 / 1901	745 / 1918		0.98 [0.86,1.12]	Z=-0.29, p=0.7719
Heterogeneity:	Q=0.04 (df=1)	p=0.8421	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.97 (df=1)	p=0.0850	I^2=66.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

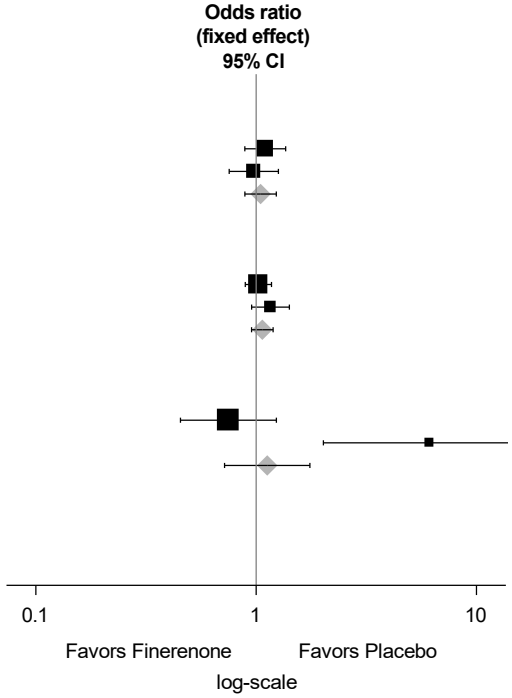
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	649 / 1737	629 / 1703	64.6	1.02 [0.89,1.17]	
FIGARO-DKD	371 / 924	347 / 932	35.4	1.13 [0.94,1.36]	
Total	1020 / 2661	976 / 2635		1.06 [0.95,1.18]	Z=0.98, p=0.3284
Heterogeneity:	Q=0.78 (df=1)	p=0.3771	I^2=0.0%		
> 4.5					
FIDELIO-DKD	324 / 884	326 / 916	67.1	1.05 [0.86,1.27]	
FIGARO-DKD	172 / 435	157 / 429	32.9	1.13 [0.86,1.49]	
Total	496 / 1319	483 / 1345		1.07 [0.92,1.26]	Z=0.90, p=0.3707
Heterogeneity:	Q=0.21 (df=1)	p=0.6450	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8666	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

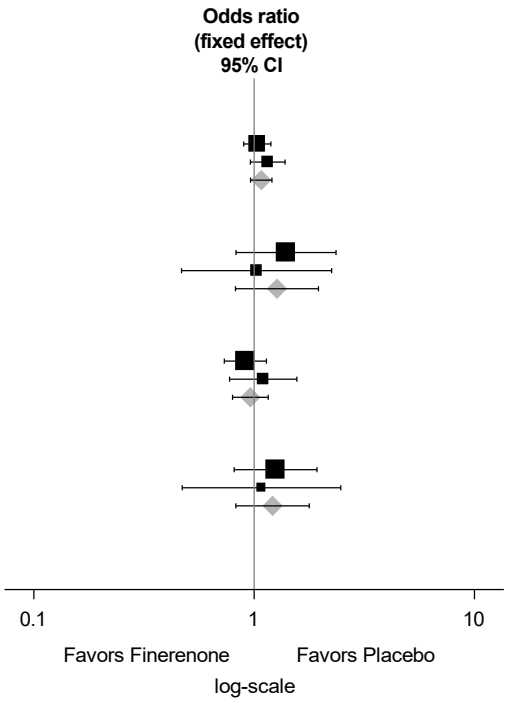
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	276 / 724	260 / 724	59.2	1.10 [0.89,1.36]	
FIGARO-DKD	184 / 494	188 / 497	40.8	0.98 [0.75,1.26]	
Total	460 / 1218	448 / 1221		1.05 [0.89,1.23]	Z=0.55, p=0.5825
Heterogeneity:	Q=0.49 (df=1)	p=0.4832	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	650 / 1762	642 / 1766	67.5	1.02 [0.89,1.17]	
FIGARO-DKD	340 / 831	310 / 830	32.5	1.16 [0.95,1.41]	
Total	990 / 2593	952 / 2596		1.07 [0.95,1.19]	Z=1.12, p=0.2622
Heterogeneity:	Q=1.07 (df=1)	p=0.3013	I^2=6.4%		
>= 160					
FIDELIO-DKD	46 / 133	53 / 128	83.0	0.75 [0.45,1.24]	
FIGARO-DKD	19 / 34	6 / 35	17.0	6.12 [2.02,18.57]	
Total	65 / 167	59 / 163		1.12 [0.72,1.75]	Z=0.51, p=0.6117
Heterogeneity:	Q=11.49 (df=1)	p=0.0007	I^2=91.3%		
Subgroup Heterogeneity:	Q=0.09 (df=2)	p=0.9548	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

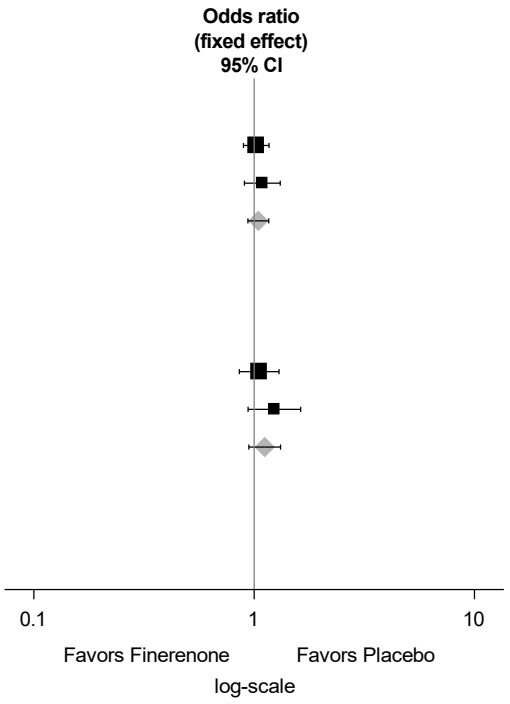
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	596 / 1637	593 / 1663	61.9	1.03 [0.90,1.19]	
FIGARO-DKD	394 / 1013	353 / 992	38.1	1.15 [0.96,1.38]	
Total	990 / 2650	946 / 2655		1.08 [0.96,1.20]	Z=1.30, p=0.1940
Heterogeneity:	Q=0.86 (df=1)	p=0.3530	I^2=0.0%		
Black					
FIDELIO-DKD	53 / 130	38 / 115	69.2	1.39 [0.83,2.35]	
FIGARO-DKD	16 / 43	26 / 71	30.8	1.03 [0.47,2.25]	
Total	69 / 173	64 / 186		1.27 [0.82,1.96]	Z=1.08, p=0.2820
Heterogeneity:	Q=0.41 (df=1)	p=0.5228	I^2=0.0%		
Asian					
FIDELIO-DKD	246 / 678	261 / 679	71.9	0.91 [0.73,1.14]	
FIGARO-DKD	114 / 251	109 / 253	28.1	1.10 [0.77,1.56]	
Total	360 / 929	370 / 932		0.96 [0.80,1.16]	Z=-0.42, p=0.6775
Heterogeneity:	Q=0.78 (df=1)	p=0.3774	I^2=0.0%		
Others					
FIDELIO-DKD	78 / 177	63 / 163	78.6	1.25 [0.81,1.93]	
FIGARO-DKD	19 / 52	16 / 46	21.4	1.08 [0.47,2.47]	
Total	97 / 229	79 / 209		1.21 [0.83,1.78]	Z=0.98, p=0.3264
Heterogeneity:	Q=0.10 (df=1)	p=0.7578	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.26 (df=3)	p=0.5204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.5.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

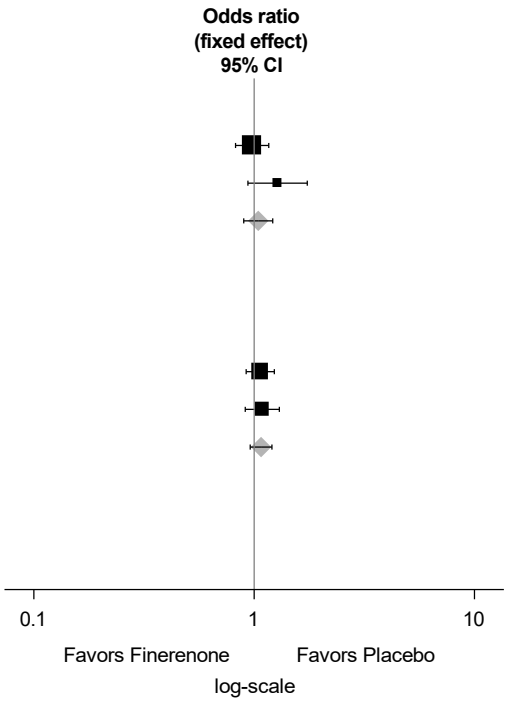
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	677 / 1800	696 / 1876	66.2	1.02 [0.89,1.17]	
FIGARO-DKD	364 / 917	353 / 937	33.8	1.09 [0.90,1.31]	
Total	1041 / 2717	1049 / 2813		1.04 [0.94,1.16]	Z=0.78, p=0.4353
Heterogeneity:	Q=0.29 (df=1)	p=0.5888	I^2=0.0%		
Female					
FIDELIO-DKD	296 / 822	259 / 744	63.7	1.05 [0.86,1.30]	
FIGARO-DKD	179 / 442	151 / 425	36.3	1.24 [0.94,1.63]	
Total	475 / 1264	410 / 1169		1.12 [0.95,1.32]	Z=1.30, p=0.1926
Heterogeneity:	Q=0.82 (df=1)	p=0.3663	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.44 (df=1)	p=0.5087	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.5.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

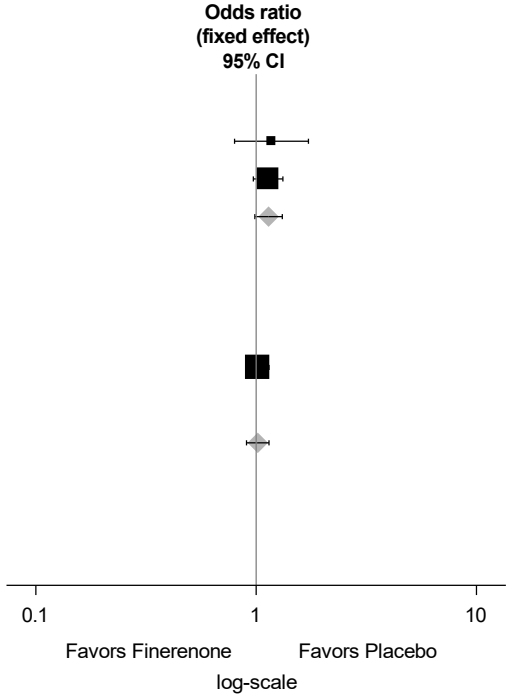
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	408 / 1106	403 / 1078	76.1	0.98 [0.82,1.16]	
FIGARO-DKD	142 / 337	122 / 336	23.9	1.28 [0.94,1.74]	
Total	550 / 1443	525 / 1414		1.04 [0.90,1.21]	Z=0.55, p=0.5831
Heterogeneity:	Q=2.15 (df=1)	p=0.1425	I^2=53.5%		
>= 65					
FIDELIO-DKD	565 / 1516	552 / 1542	59.5	1.07 [0.92,1.23]	
FIGARO-DKD	401 / 1022	382 / 1026	40.5	1.09 [0.91,1.30]	
Total	966 / 2538	934 / 2568		1.07 [0.96,1.20]	Z=1.25, p=0.2128
Heterogeneity:	Q=0.03 (df=1)	p=0.8558	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7580	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.5.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

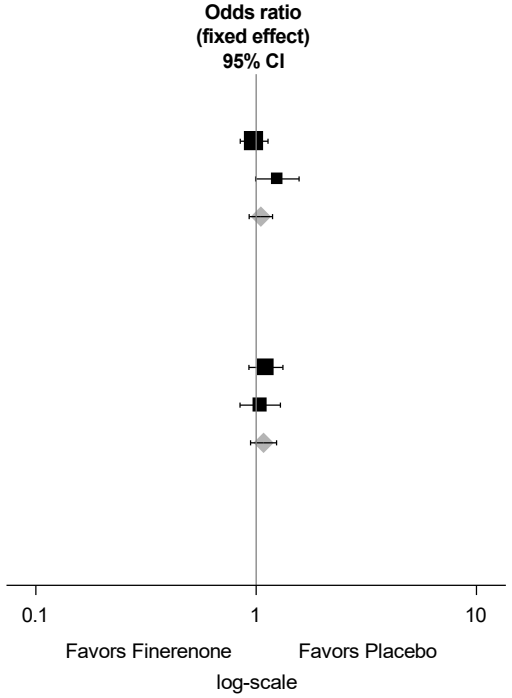
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	93 / 210	86 / 213	13.8	1.17 [0.80,1.73]	
FIGARO-DKD	543 / 1359	504 / 1362	86.2	1.13 [0.97,1.32]	
Total	636 / 1569	590 / 1575		1.14 [0.99,1.31]	Z=1.77, p=0.0766
Heterogeneity:	Q=0.03 (df=1)	p=0.8670	I^2=0.0%		
Very High					
FIDELIO-DKD	880 / 2412	869 / 2407	100.0	1.02 [0.90,1.14]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	880 / 2412	869 / 2407		1.02 [0.90,1.14]	Z=0.28, p=0.7832
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=1)	p=0.2317	I^2=30.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.5.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

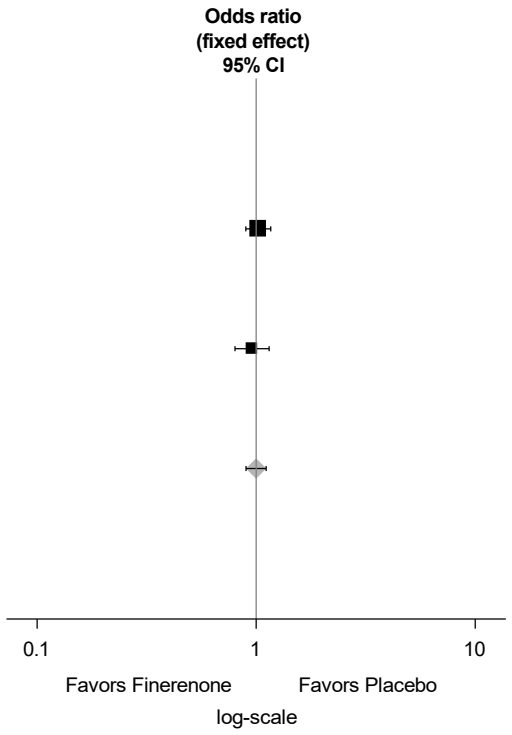
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	586 / 1559	590 / 1549	71.1	0.98 [0.85,1.13]	
FIGARO-DKD	258 / 639	222 / 631	28.9	1.25 [0.99,1.57]	
Total	844 / 2198	812 / 2180		1.05 [0.93,1.19]	Z=0.79, p=0.4324
Heterogeneity:	Q=3.11 (df=1)	p=0.0779	I^2=67.8%		
45 - < 60					
FIDELIO-DKD	387 / 1063	365 / 1071	58.5	1.11 [0.93,1.32]	
FIGARO-DKD	285 / 720	282 / 731	41.5	1.04 [0.84,1.29]	
Total	672 / 1783	647 / 1802		1.08 [0.94,1.24]	Z=1.11, p=0.2657
Heterogeneity:	Q=0.18 (df=1)	p=0.6714	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7620	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

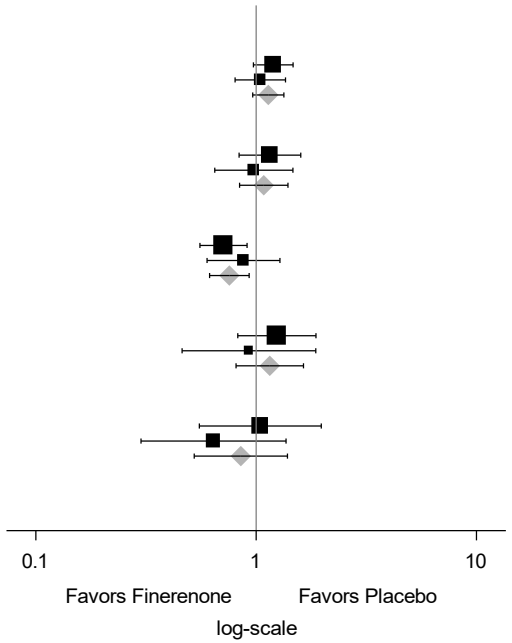
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	578 / 2622	568 / 2620	65.2	1.02 [0.90,1.17]	
FIGARO-DKD	306 / 1359	317 / 1362	34.8	0.96 [0.80,1.15]	
Total	884 / 3981	885 / 3982		1.00 [0.90,1.11]	Z=-0.02, p=0.9858
Heterogeneity:	Q=0.33 (df=1)	p=0.5635	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.6.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

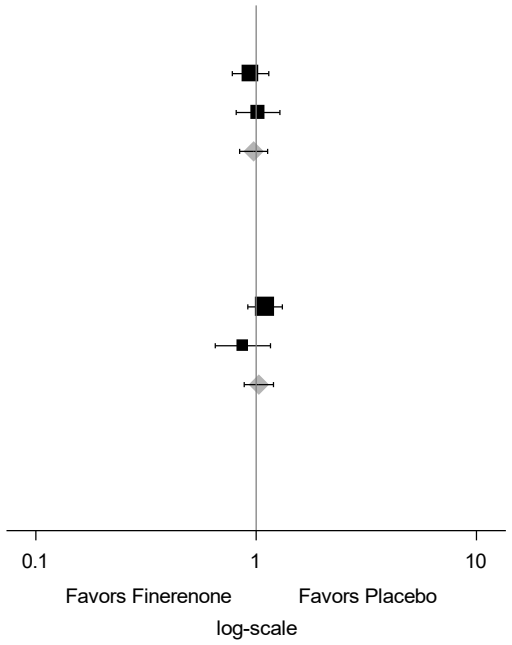
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	246 / 1078	211 / 1064	61.8	1.20 [0.97,1.47]	
FIGARO-DKD	145 / 640	140 / 639	38.2	1.04 [0.80,1.36]	
Total	391 / 1718	351 / 1703		1.14 [0.96,1.34]	Z=1.53, p=0.1270
Heterogeneity:	Q=0.63 (df=1)	p=0.4290	I^2=0.0%		
North America					
FIDELIO-DKD	99 / 425	91 / 437	61.6	1.15 [0.84,1.59]	
FIGARO-DKD	58 / 267	60 / 271	38.4	0.98 [0.65,1.47]	
Total	157 / 692	151 / 708		1.08 [0.84,1.39]	Z=0.61, p=0.5390
Heterogeneity:	Q=0.40 (df=1)	p=0.5264	I^2=0.0%		
Asia					
FIDELIO-DKD	143 / 751	186 / 748	70.5	0.71 [0.56,0.91]	
FIGARO-DKD	66 / 288	74 / 292	29.5	0.88 [0.60,1.28]	
Total	209 / 1039	260 / 1040		0.76 [0.61,0.93]	Z=-2.66, p=0.0079
Heterogeneity:	Q=0.82 (df=1)	p=0.3665	I^2=0.0%		
Latin America					
FIDELIO-DKD	64 / 274	54 / 274	74.5	1.24 [0.83,1.87]	
FIGARO-DKD	19 / 102	20 / 101	25.5	0.93 [0.46,1.86]	
Total	83 / 376	74 / 375		1.15 [0.81,1.64]	Z=0.79, p=0.4293
Heterogeneity:	Q=0.50 (df=1)	p=0.4793	I^2=0.0%		
Others					
FIDELIO-DKD	26 / 94	26 / 97	58.6	1.04 [0.55,1.97]	
FIGARO-DKD	18 / 62	23 / 59	41.4	0.64 [0.30,1.37]	
Total	44 / 156	49 / 156		0.85 [0.52,1.39]	Z=-0.65, p=0.5189
Heterogeneity:	Q=0.94 (df=1)	p=0.3331	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.80 (df=4)	p=0.0289	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

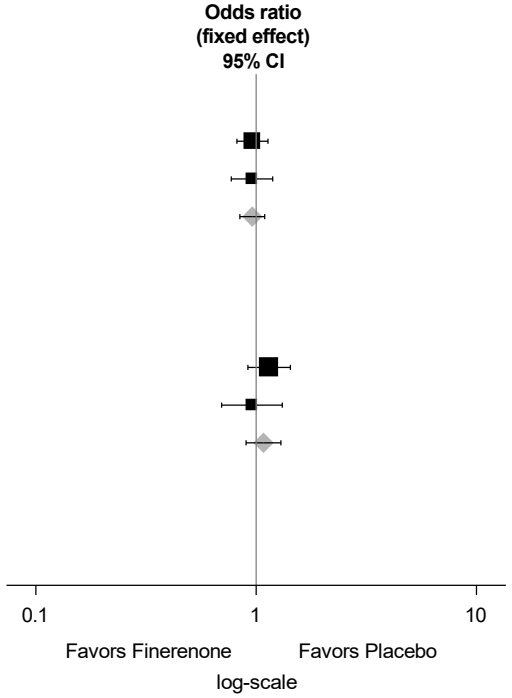
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	267 / 1215	279 / 1213	58.9	0.94 [0.78,1.14]	
FIGARO-DKD	192 / 865	186 / 851	41.1	1.02 [0.81,1.28]	
Total	459 / 2080	465 / 2064		0.97 [0.84,1.13]	Z=-0.36, p=0.7220
Heterogeneity:	Q=0.27 (df=1)	p=0.6044	I^2=0.0%		
Absent					
FIDELIO-DKD	311 / 1407	289 / 1407	71.9	1.10 [0.92,1.31]	
FIGARO-DKD	114 / 494	131 / 511	28.1	0.87 [0.65,1.16]	
Total	425 / 1901	420 / 1918		1.03 [0.88,1.20]	Z=0.36, p=0.7213
Heterogeneity:	Q=1.79 (df=1)	p=0.1811	I^2=44.1%		
Subgroup Heterogeneity:	Q=0.25 (df=1)	p=0.6145	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

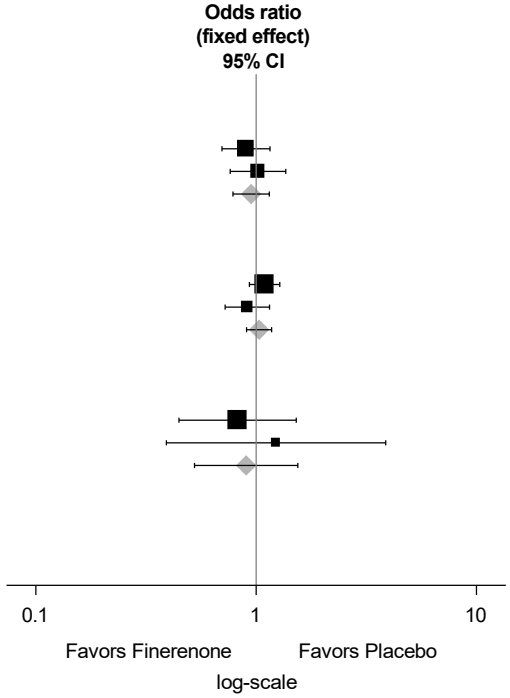
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	370 / 1737	374 / 1703	64.0	0.96 [0.82,1.13]	
FIGARO-DKD	208 / 924	217 / 932	36.0	0.96 [0.77,1.19]	
Total	578 / 2661	591 / 2635		0.96 [0.84,1.09]	Z=-0.61, p=0.5394
Heterogeneity:	Q=0.00 (df=1)	p=0.9722	I^2=0.0%		
> 4.5					
FIDELIO-DKD	208 / 884	194 / 916	67.1	1.15 [0.92,1.43]	
FIGARO-DKD	98 / 435	100 / 429	32.9	0.96 [0.70,1.31]	
Total	306 / 1319	294 / 1345		1.08 [0.90,1.29]	Z=0.82, p=0.4098
Heterogeneity:	Q=0.83 (df=1)	p=0.3630	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.06 (df=1)	p=0.3042	I^2=5.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

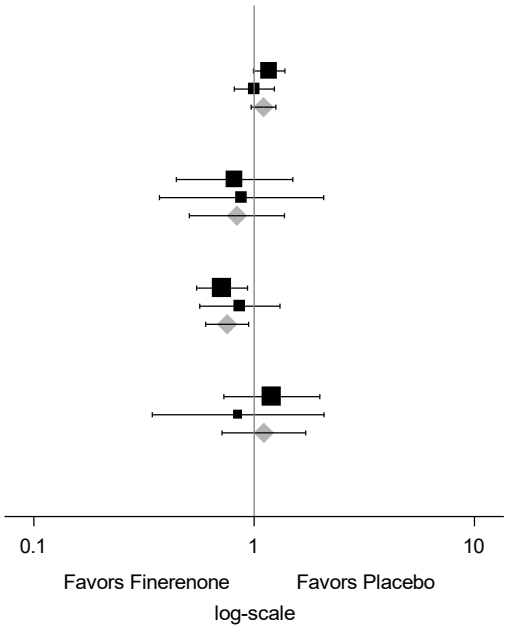
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	149 / 724	162 / 724	57.2	0.90 [0.70,1.16]	
FIGARO-DKD	121 / 494	120 / 497	42.8	1.02 [0.76,1.36]	
Total	270 / 1218	282 / 1221		0.95 [0.78,1.15]	Z=-0.55, p=0.5853
Heterogeneity:	Q=0.41 (df=1)	p=0.5216	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	405 / 1762	379 / 1766	68.1	1.09 [0.93,1.28]	
FIGARO-DKD	177 / 831	190 / 830	31.9	0.91 [0.72,1.15]	
Total	582 / 2593	569 / 2596		1.03 [0.90,1.18]	Z=0.46, p=0.6479
Heterogeneity:	Q=1.59 (df=1)	p=0.2076	I^2=37.0%		
>= 160					
FIDELIO-DKD	24 / 133	27 / 128	77.8	0.82 [0.45,1.52]	
FIGARO-DKD	8 / 34	7 / 35	22.2	1.23 [0.39,3.87]	
Total	32 / 167	34 / 163		0.90 [0.52,1.55]	Z=-0.38, p=0.7041
Heterogeneity:	Q=0.37 (df=1)	p=0.5448	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=2)	p=0.7224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

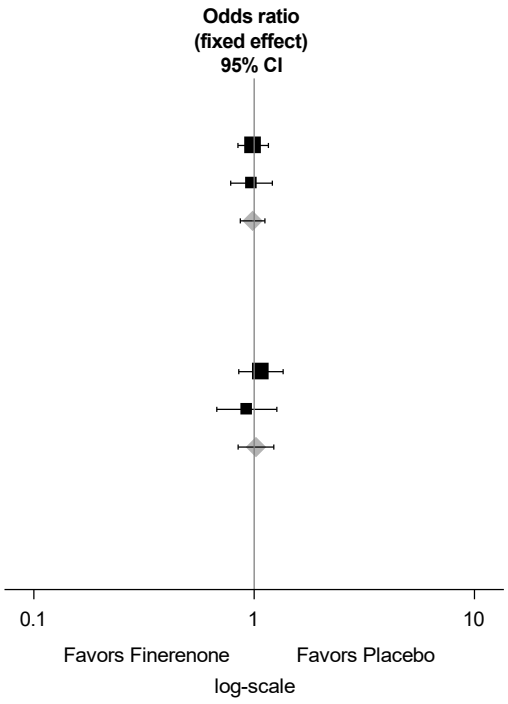
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	387 / 1637	348 / 1663	61.9	1.17 [0.99,1.38]	
FIGARO-DKD	229 / 1013	224 / 992	38.1	1.00 [0.81,1.23]	
Total	616 / 2650	572 / 2655		1.10 [0.97,1.25]	Z=1.48, p=0.1380
Heterogeneity:	Q=1.31 (df=1)	p=0.2521	I^2=23.8%		
Black					
FIDELIO-DKD	26 / 130	27 / 115	66.5	0.81 [0.44,1.50]	
FIGARO-DKD	11 / 43	20 / 71	33.5	0.88 [0.37,2.07]	
Total	37 / 173	47 / 186		0.83 [0.51,1.37]	Z=-0.71, p=0.4769
Heterogeneity:	Q=0.02 (df=1)	p=0.8918	I^2=0.0%		
Asian					
FIDELIO-DKD	120 / 678	157 / 679	71.3	0.72 [0.55,0.93]	
FIGARO-DKD	53 / 251	60 / 253	28.7	0.86 [0.57,1.31]	
Total	173 / 929	217 / 932		0.75 [0.60,0.94]	Z=-2.47, p=0.0137
Heterogeneity:	Q=0.54 (df=1)	p=0.4633	I^2=0.0%		
Others					
FIDELIO-DKD	45 / 177	36 / 163	76.2	1.20 [0.73,1.99]	
FIGARO-DKD	13 / 52	13 / 46	23.8	0.85 [0.34,2.08]	
Total	58 / 229	49 / 209		1.11 [0.71,1.71]	Z=0.45, p=0.6502
Heterogeneity:	Q=0.45 (df=1)	p=0.5028	I^2=0.0%		
Subgroup Heterogeneity:	Q=8.99 (df=3)	p=0.0294	I^2=66.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.6.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

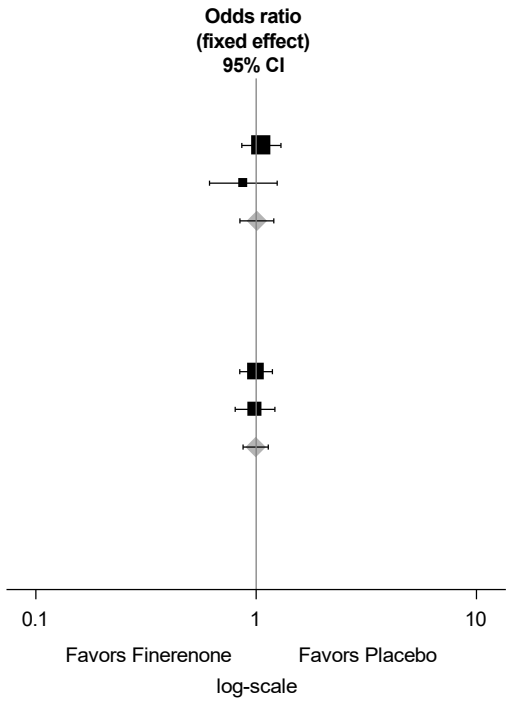
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	374 / 1800	393 / 1876	65.2	0.99 [0.84,1.16]	
FIGARO-DKD	205 / 917	214 / 937	34.8	0.97 [0.78,1.21]	
Total	579 / 2717	607 / 2813		0.98 [0.87,1.12]	Z=-0.25, p=0.8027
Heterogeneity:	Q=0.02 (df=1)	p=0.9001	I^2=0.0%		
Female					
FIDELIO-DKD	204 / 822	175 / 744	64.7	1.07 [0.85,1.35]	
FIGARO-DKD	101 / 442	103 / 425	35.3	0.93 [0.68,1.27]	
Total	305 / 1264	278 / 1169		1.02 [0.85,1.23]	Z=0.20, p=0.8446
Heterogeneity:	Q=0.55 (df=1)	p=0.4583	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7618	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.6.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

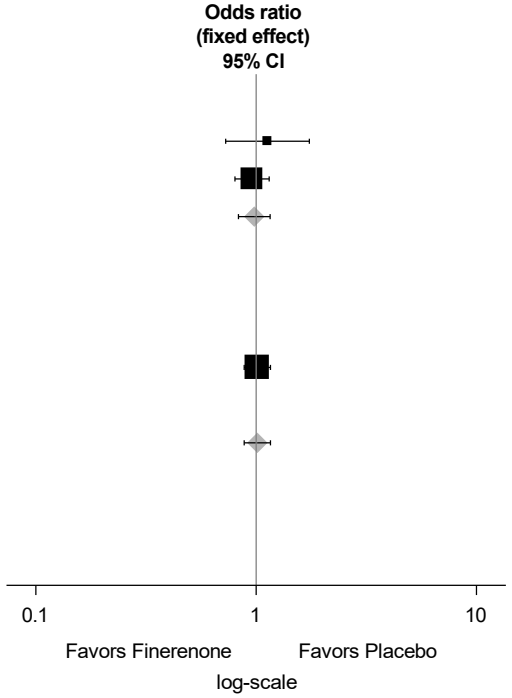
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	242 / 1106	226 / 1078	75.0	1.06 [0.86,1.30]	
FIGARO-DKD	77 / 337	85 / 336	25.0	0.87 [0.61,1.25]	
Total	319 / 1443	311 / 1414		1.01 [0.84,1.20]	Z=0.08, p=0.9367
Heterogeneity:	Q=0.82 (df=1)	p=0.3660	I^2=0.0%		
>= 65					
FIDELIO-DKD	336 / 1516	342 / 1542	59.6	1.00 [0.84,1.19]	
FIGARO-DKD	229 / 1022	232 / 1026	40.4	0.99 [0.80,1.22]	
Total	565 / 2538	574 / 2568		0.99 [0.87,1.13]	Z=-0.08, p=0.9374
Heterogeneity:	Q=0.01 (df=1)	p=0.9368	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9119	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.6.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

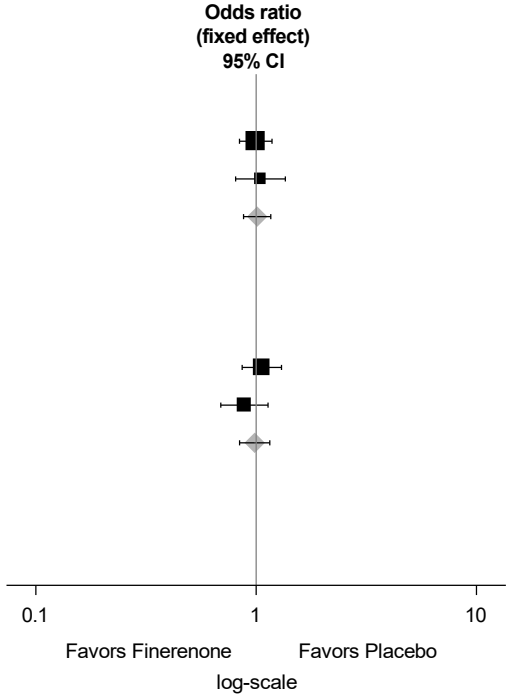
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	56 / 210	52 / 213	14.3	1.13 [0.73,1.74]	
FIGARO-DKD	306 / 1359	317 / 1362	85.7	0.96 [0.80,1.15]	
Total	362 / 1569	369 / 1575		0.98 [0.83,1.16]	Z=-0.23, p=0.8148
Heterogeneity:	Q=0.45 (df=1)	p=0.5029	I^2=0.0%		
Very High					
FIDELIO-DKD	522 / 2412	516 / 2407	100.0	1.01 [0.88,1.16]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	522 / 2412	516 / 2407		1.01 [0.88,1.16]	Z=0.17, p=0.8630
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7715	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.6.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

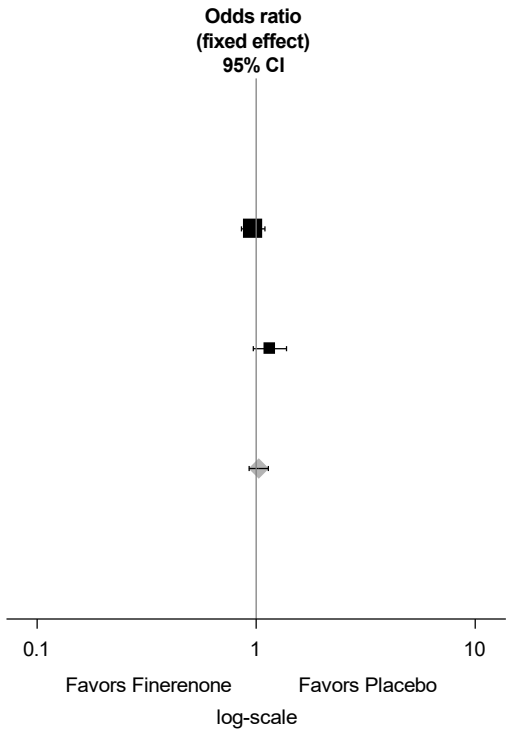
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	341 / 1559	340 / 1549	70.0	1.00 [0.84,1.18]	
FIGARO-DKD	152 / 639	145 / 631	30.0	1.05 [0.81,1.36]	
Total	493 / 2198	485 / 2180		1.01 [0.88,1.16]	Z=0.14, p=0.8864
Heterogeneity:	Q=0.10 (df=1)	p=0.7544	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	237 / 1063	228 / 1071	59.0	1.06 [0.86,1.30]	
FIGARO-DKD	154 / 720	172 / 731	41.0	0.88 [0.69,1.13]	
Total	391 / 1783	400 / 1802		0.98 [0.84,1.15]	Z=-0.19, p=0.8472
Heterogeneity:	Q=1.23 (df=1)	p=0.2666	I^2=19.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8112	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

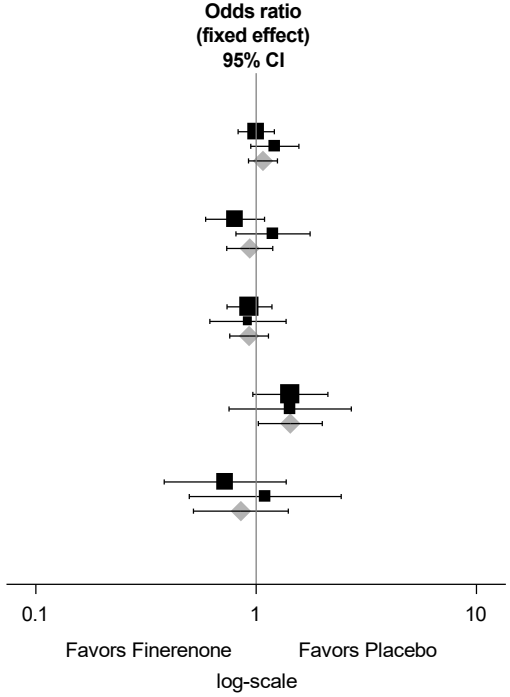
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	677 / 2622	692 / 2620	66.7	0.97 [0.86,1.10]	
FIGARO-DKD	355 / 1359	319 / 1362	33.3	1.16 [0.97,1.38]	
Total	1032 / 3981	1011 / 3982		1.03 [0.93,1.14]	Z=0.52, p=0.5999
Heterogeneity:	Q=2.60 (df=1)	p=0.1071	I^2=61.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.7.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

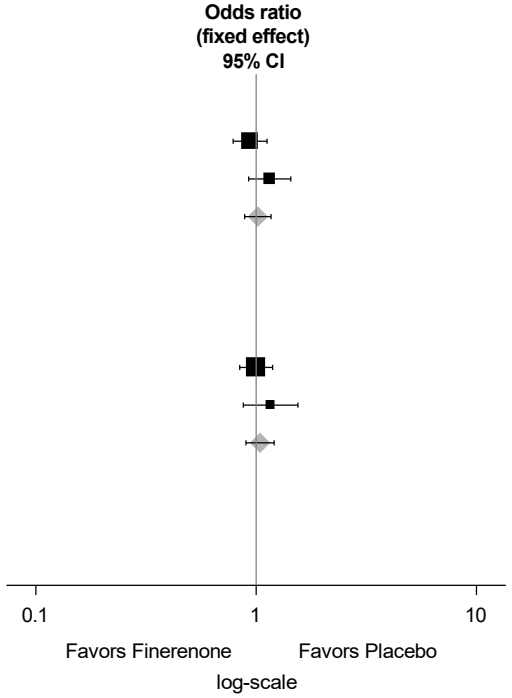
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	298 / 1078	294 / 1064	63.8	1.00 [0.83,1.21]	
FIGARO-DKD	176 / 640	152 / 639	36.2	1.22 [0.95,1.56]	
Total	474 / 1718	446 / 1703		1.07 [0.92,1.25]	Z=0.92, p=0.3572
Heterogeneity:	Q=1.46 (df=1)	p=0.2263	I^2=31.7%		
North America					
FIDELIO-DKD	99 / 425	120 / 437	61.3	0.80 [0.59,1.09]	
FIGARO-DKD	73 / 267	65 / 271	38.7	1.19 [0.81,1.76]	
Total	172 / 692	185 / 708		0.94 [0.74,1.19]	Z=-0.55, p=0.5842
Heterogeneity:	Q=2.47 (df=1)	p=0.1164	I^2=59.4%		
Asia					
FIDELIO-DKD	181 / 751	190 / 748	74.2	0.93 [0.74,1.18]	
FIGARO-DKD	59 / 288	64 / 292	25.8	0.92 [0.62,1.37]	
Total	240 / 1039	254 / 1040		0.93 [0.76,1.14]	Z=-0.72, p=0.4738
Heterogeneity:	Q=0.00 (df=1)	p=0.9462	I^2=0.0%		
Latin America					
FIDELIO-DKD	76 / 274	58 / 274	72.6	1.43 [0.97,2.12]	
FIGARO-DKD	29 / 102	22 / 101	27.4	1.43 [0.75,2.70]	
Total	105 / 376	80 / 375		1.43 [1.02,2.00]	Z=2.09, p=0.0365
Heterogeneity:	Q=0.00 (df=1)	p=0.9957	I^2=0.0%		
Others					
FIDELIO-DKD	23 / 94	30 / 97	60.8	0.72 [0.38,1.37]	
FIGARO-DKD	18 / 62	16 / 59	39.2	1.10 [0.50,2.43]	
Total	41 / 156	46 / 156		0.85 [0.52,1.40]	Z=-0.63, p=0.5271
Heterogeneity:	Q=0.65 (df=1)	p=0.4205	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.15 (df=4)	p=0.1880	I^2=35.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

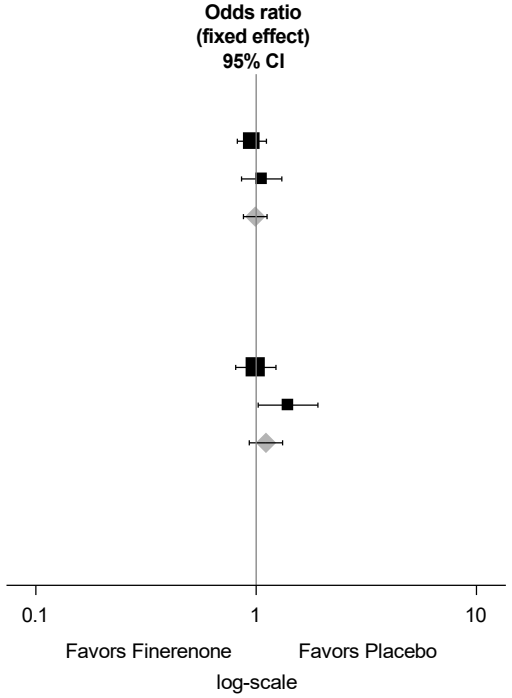
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	333 / 1215	348 / 1213	60.7	0.94 [0.79,1.12]	
FIGARO-DKD	224 / 865	198 / 851	39.3	1.15 [0.92,1.44]	
Total	557 / 2080	546 / 2064		1.02 [0.89,1.17]	Z=0.25, p=0.8056
Heterogeneity:	Q=2.03 (df=1)	p=0.1540	I^2=50.8%		
Absent					
FIDELIO-DKD	344 / 1407	344 / 1407	73.4	1.00 [0.84,1.19]	
FIGARO-DKD	131 / 494	121 / 511	26.6	1.16 [0.87,1.55]	
Total	475 / 1901	465 / 1918		1.04 [0.90,1.21]	Z=0.54, p=0.5921
Heterogeneity:	Q=0.79 (df=1)	p=0.3740	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8236	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

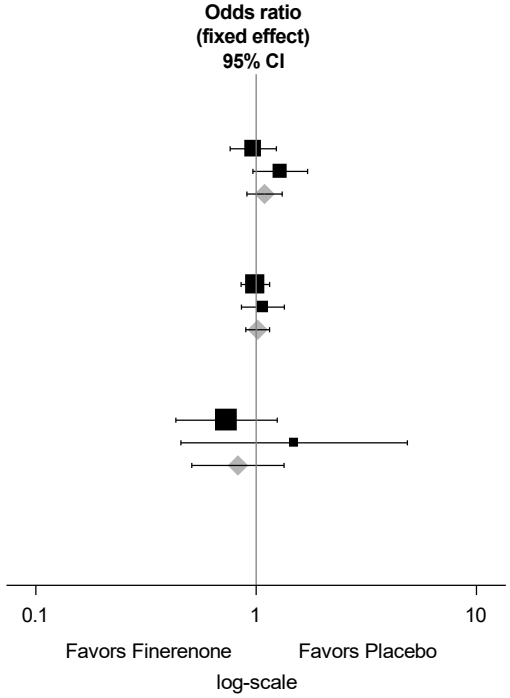
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	446 / 1737	452 / 1703	65.7	0.96 [0.82,1.11]	
FIGARO-DKD	235 / 924	227 / 932	34.3	1.06 [0.86,1.31]	
Total	681 / 2661	679 / 2635		0.99 [0.88,1.12]	Z=-0.15, p=0.8779
Heterogeneity:	Q=0.60 (df=1)	p=0.4395	I^2=0.0%		
> 4.5					
FIDELIO-DKD	231 / 884	240 / 916	68.8	1.00 [0.81,1.23]	
FIGARO-DKD	120 / 435	92 / 429	31.2	1.40 [1.02,1.91]	
Total	351 / 1319	332 / 1345		1.11 [0.93,1.32]	Z=1.15, p=0.2504
Heterogeneity:	Q=3.08 (df=1)	p=0.0793	I^2=67.5%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3046	I^2=5.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

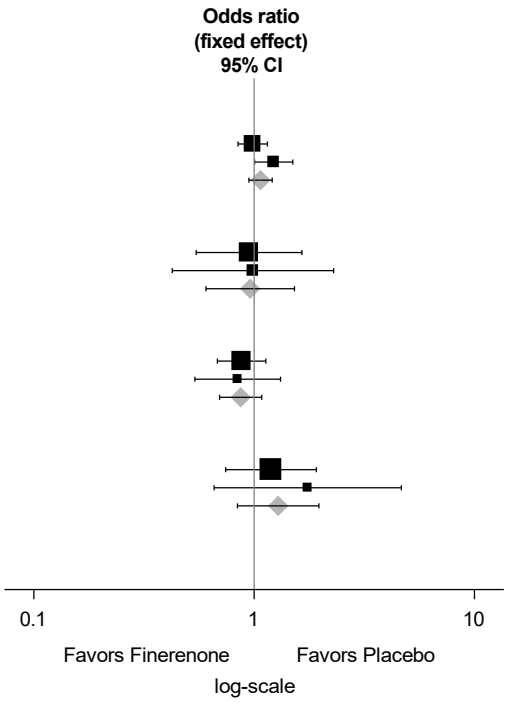
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	171 / 724	175 / 724	58.3	0.97 [0.76,1.24]	
FIGARO-DKD	139 / 494	116 / 497	41.7	1.29 [0.97,1.71]	
Total	310 / 1218	291 / 1221		1.09 [0.91,1.31]	Z=0.93, p=0.3528
Heterogeneity:	Q=2.18 (df=1)	p=0.1397	I^2=54.1%		
130 - < 160					
FIDELIO-DKD	470 / 1762	474 / 1766	69.3	0.99 [0.85,1.15]	
FIGARO-DKD	208 / 831	197 / 830	30.7	1.07 [0.86,1.34]	
Total	678 / 2593	671 / 2596		1.02 [0.90,1.15]	Z=0.25, p=0.8043
Heterogeneity:	Q=0.33 (df=1)	p=0.5664	I^2=0.0%		
>= 160					
FIDELIO-DKD	36 / 133	43 / 128	83.3	0.73 [0.43,1.25]	
FIGARO-DKD	8 / 34	6 / 35	16.7	1.49 [0.46,4.86]	
Total	44 / 167	49 / 163		0.83 [0.51,1.34]	Z=-0.77, p=0.4383
Heterogeneity:	Q=1.14 (df=1)	p=0.2855	I^2=12.3%		
Subgroup Heterogeneity:	Q=1.23 (df=2)	p=0.5416	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

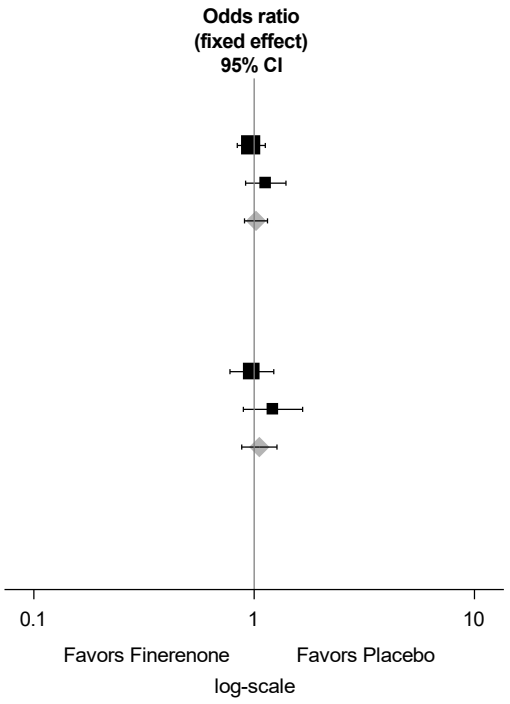
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	439 / 1637	451 / 1663	62.8	0.98 [0.84,1.15]	
FIGARO-DKD	285 / 1013	240 / 992	37.2	1.23 [1.00,1.50]	
Total	724 / 2650	691 / 2655		1.07 [0.95,1.21]	Z=1.07, p=0.2840
Heterogeneity:	Q=2.92 (df=1)	p=0.0876	I^2=65.7%		
Black					
FIDELIO-DKD	37 / 130	34 / 115	70.0	0.95 [0.55,1.65]	
FIGARO-DKD	12 / 43	20 / 71	30.0	0.99 [0.42,2.29]	
Total	49 / 173	54 / 186		0.96 [0.60,1.52]	Z=-0.18, p=0.8607
Heterogeneity:	Q=0.01 (df=1)	p=0.9371	I^2=0.0%		
Asian					
FIDELIO-DKD	148 / 678	164 / 679	75.8	0.88 [0.68,1.13]	
FIGARO-DKD	44 / 251	51 / 253	24.2	0.84 [0.54,1.32]	
Total	192 / 929	215 / 932		0.87 [0.70,1.08]	Z=-1.26, p=0.2089
Heterogeneity:	Q=0.02 (df=1)	p=0.8766	I^2=0.0%		
Others					
FIDELIO-DKD	53 / 177	43 / 163	81.0	1.19 [0.74,1.92]	
FIGARO-DKD	14 / 52	8 / 46	19.0	1.75 [0.66,4.65]	
Total	67 / 229	51 / 209		1.28 [0.84,1.97]	Z=1.15, p=0.2485
Heterogeneity:	Q=0.48 (df=1)	p=0.4894	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.79 (df=3)	p=0.2851	I^2=20.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.7.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

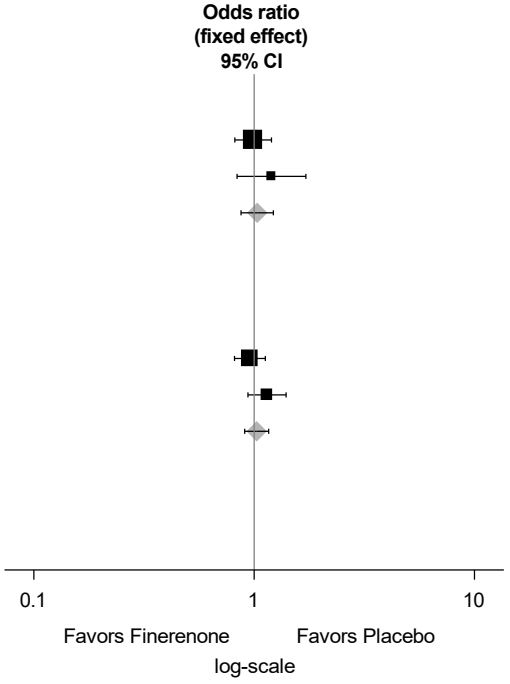
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	473 / 1800	504 / 1876	67.5	0.97 [0.84,1.12]	
FIGARO-DKD	238 / 917	222 / 937	32.5	1.13 [0.91,1.39]	
Total	711 / 2717	726 / 2813		1.02 [0.90,1.15]	Z=0.31, p=0.7553
Heterogeneity:	Q=1.34 (df=1)	p=0.2478	I^2=25.1%		
Female					
FIDELIO-DKD	204 / 822	188 / 744	64.7	0.98 [0.78,1.23]	
FIGARO-DKD	117 / 442	97 / 425	35.3	1.22 [0.89,1.66]	
Total	321 / 1264	285 / 1169		1.06 [0.88,1.27]	Z=0.58, p=0.5646
Heterogeneity:	Q=1.26 (df=1)	p=0.2614	I^2=20.7%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.7.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

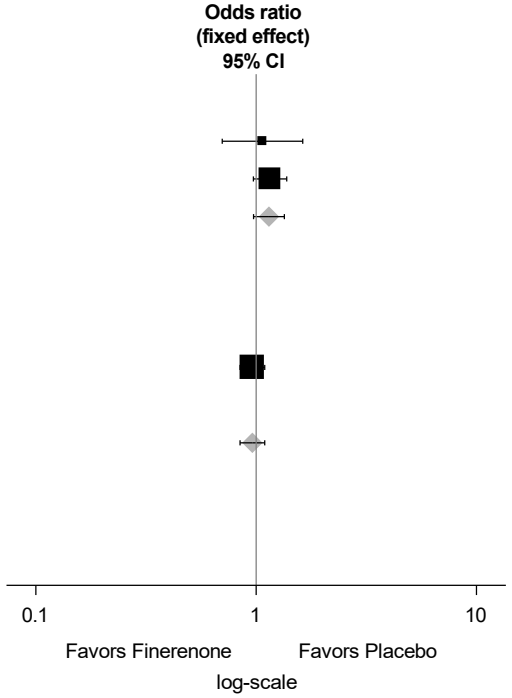
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	285 / 1106	280 / 1078	77.9	0.99 [0.82,1.20]	
FIGARO-DKD	83 / 337	72 / 336	22.1	1.20 [0.84,1.72]	
Total	368 / 1443	352 / 1414		1.03 [0.87,1.22]	Z=0.37, p=0.7132
Heterogeneity:	Q=0.85 (df=1)	p=0.3569	I^2=0.0%		
>= 65					
FIDELIO-DKD	392 / 1516	412 / 1542	60.5	0.96 [0.81,1.12]	
FIGARO-DKD	272 / 1022	247 / 1026	39.5	1.14 [0.94,1.40]	
Total	664 / 2538	659 / 2568		1.03 [0.91,1.16]	Z=0.41, p=0.6815
Heterogeneity:	Q=1.87 (df=1)	p=0.1715	I^2=46.5%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9593	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.7.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

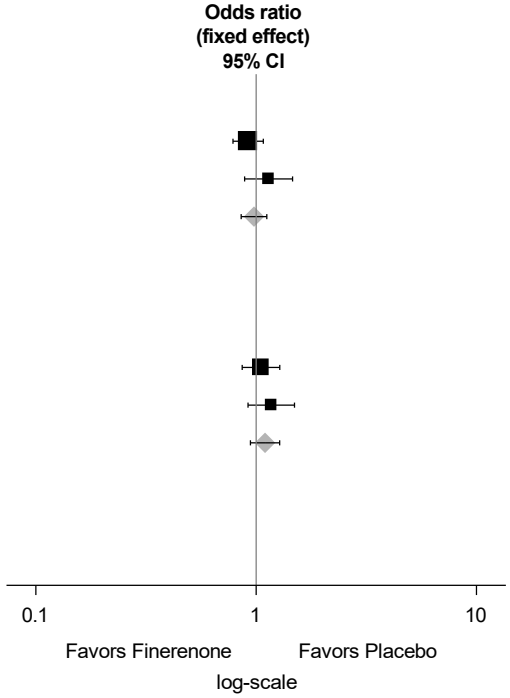
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	60 / 213	14.6	1.07 [0.70,1.63]	
FIGARO-DKD	355 / 1359	319 / 1362	85.4	1.16 [0.97,1.38]	
Total	417 / 1569	379 / 1575		1.14 [0.97,1.34]	Z=1.62, p=0.1042
Heterogeneity:	Q=0.12 (df=1)	p=0.7338	I^2=0.0%		
Very High					
FIDELIO-DKD	615 / 2412	632 / 2407	100.0	0.96 [0.84,1.09]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	615 / 2412	632 / 2407		0.96 [0.84,1.09]	Z=-0.60, p=0.5474
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.70 (df=1)	p=0.1001	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.7.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Worsening of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

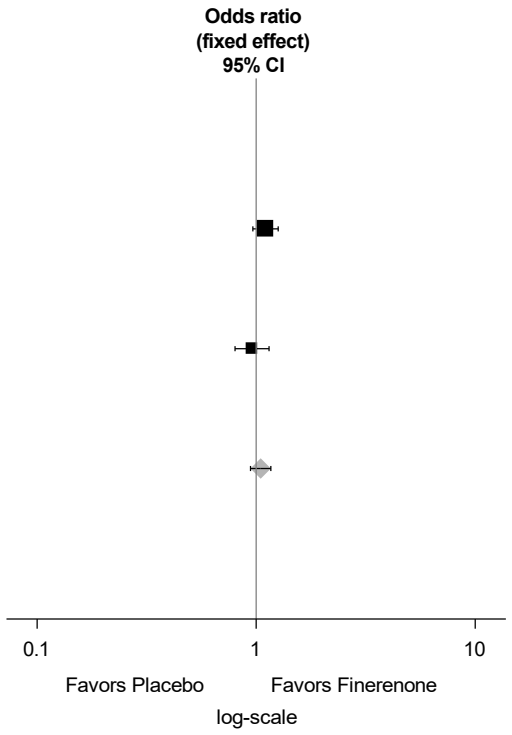
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	408 / 1559	431 / 1549	71.4	0.92 [0.78,1.08]	
FIGARO-DKD	175 / 639	157 / 631	28.6	1.14 [0.89,1.46]	
Total	583 / 2198	588 / 2180		0.98 [0.85,1.12]	Z=-0.33, p=0.7381
Heterogeneity:	Q=2.00 (df=1)	p=0.1576	I^2=49.9%		
45 - < 60					
FIDELIO-DKD	269 / 1063	261 / 1071	60.4	1.05 [0.86,1.28]	
FIGARO-DKD	180 / 720	162 / 731	39.6	1.17 [0.92,1.49]	
Total	449 / 1783	423 / 1802		1.10 [0.94,1.28]	Z=1.19, p=0.2339
Heterogeneity:	Q=0.46 (df=1)	p=0.4997	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.24 (df=1)	p=0.2647	I^2=19.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

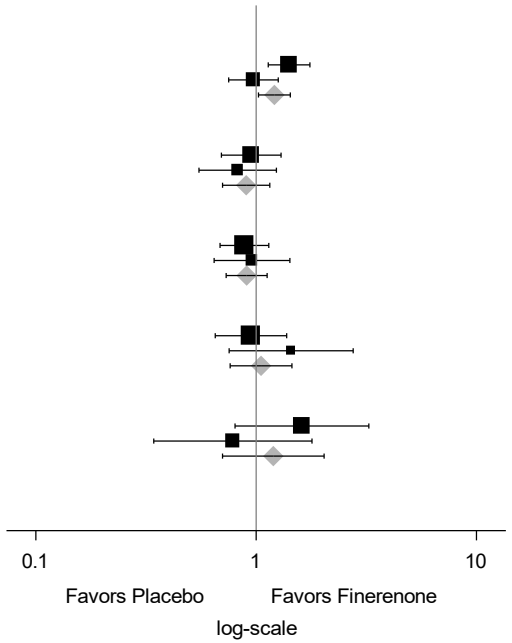
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	574 / 2622	532 / 2620	64.3	1.10 [0.97,1.26]	
FIGARO-DKD	307 / 1359	318 / 1362	35.7	0.96 [0.80,1.14]	
Total	881 / 3981	850 / 3982		1.05 [0.94,1.17]	Z=0.87, p=0.3858
Heterogeneity:	Q=1.55 (df=1)	p=0.2129	I^2=35.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.8.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

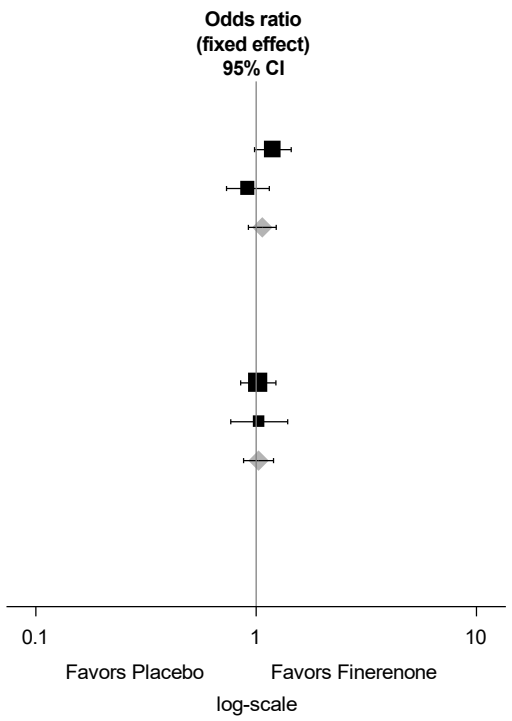
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	233 / 1078	174 / 1064	58.6	1.41 [1.13,1.75]	
FIGARO-DKD	148 / 640	151 / 639	41.4	0.97 [0.75,1.26]	
Total	381 / 1718	325 / 1703		1.21 [1.02,1.43]	Z=2.24, p=0.0248
Heterogeneity:	Q=4.65 (df=1)	p=0.0311	I^2=78.5%		
North America					
FIDELIO-DKD	101 / 425	108 / 437	62.8	0.95 [0.70,1.30]	
FIGARO-DKD	56 / 267	66 / 271	37.2	0.82 [0.55,1.24]	
Total	157 / 692	174 / 708		0.90 [0.70,1.15]	Z=-0.83, p=0.4069
Heterogeneity:	Q=0.29 (df=1)	p=0.5873	I^2=0.0%		
Asia					
FIDELIO-DKD	141 / 751	155 / 748	70.8	0.88 [0.69,1.14]	
FIGARO-DKD	61 / 288	64 / 292	29.2	0.96 [0.64,1.42]	
Total	202 / 1039	219 / 1040		0.91 [0.73,1.12]	Z=-0.91, p=0.3612
Heterogeneity:	Q=0.11 (df=1)	p=0.7412	I^2=0.0%		
Latin America					
FIDELIO-DKD	75 / 274	78 / 274	75.1	0.95 [0.65,1.38]	
FIGARO-DKD	28 / 102	21 / 101	24.9	1.44 [0.75,2.76]	
Total	103 / 376	99 / 375		1.05 [0.76,1.45]	Z=0.31, p=0.7569
Heterogeneity:	Q=1.21 (df=1)	p=0.2710	I^2=17.5%		
Others					
FIDELIO-DKD	24 / 94	17 / 97	58.3	1.61 [0.80,3.25]	
FIGARO-DKD	14 / 62	16 / 59	41.7	0.78 [0.34,1.79]	
Total	38 / 156	33 / 156		1.20 [0.70,2.03]	Z=0.66, p=0.5080
Heterogeneity:	Q=1.71 (df=1)	p=0.1914	I^2=41.4%		
Subgroup Heterogeneity:	Q=6.35 (df=4)	p=0.1746	I^2=37.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

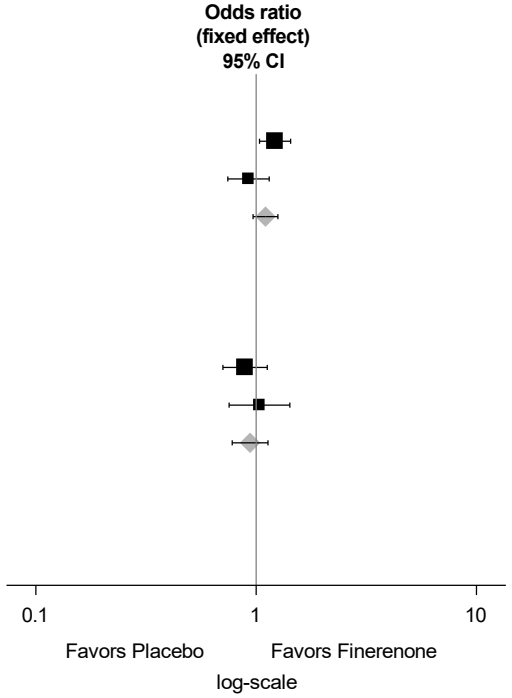
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	288 / 1215	251 / 1213	57.6	1.19 [0.98,1.44]	
FIGARO-DKD	196 / 865	206 / 851	42.4	0.92 [0.73,1.15]	
Total	484 / 2080	457 / 2064		1.07 [0.92,1.23]	Z=0.86, p=0.3881
Heterogeneity:	Q=3.01 (df=1)	p=0.0825	I^2=66.8%		
Absent					
FIDELIO-DKD	286 / 1407	281 / 1407	72.3	1.02 [0.85,1.23]	
FIGARO-DKD	111 / 494	112 / 511	27.7	1.03 [0.77,1.39]	
Total	397 / 1901	393 / 1918		1.03 [0.88,1.20]	Z=0.31, p=0.7561
Heterogeneity:	Q=0.00 (df=1)	p=0.9559	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7192	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

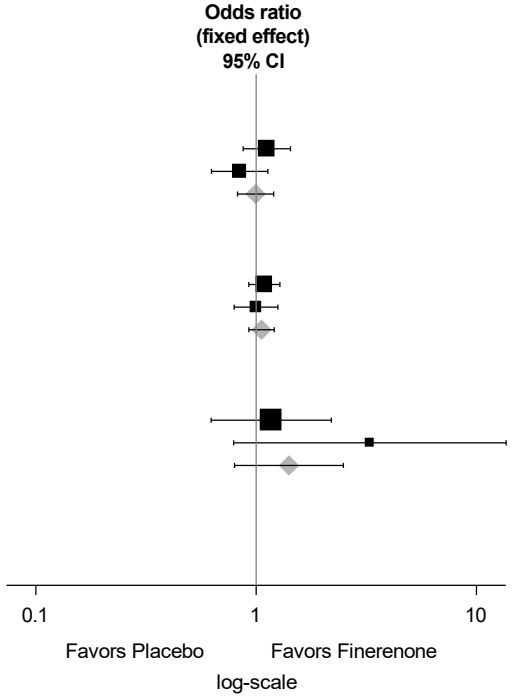
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	406 / 1737	341 / 1703	63.9	1.22 [1.04,1.43]	
FIGARO-DKD	206 / 924	221 / 932	36.1	0.92 [0.74,1.15]	
Total	612 / 2661	562 / 2635		1.10 [0.97,1.26]	Z=1.47, p=0.1414
Heterogeneity:	Q=4.04 (df=1)	p=0.0444	I^2=75.3%		
> 4.5					
FIDELIO-DKD	168 / 884	191 / 916	65.2	0.89 [0.71,1.12]	
FIGARO-DKD	101 / 435	97 / 429	34.8	1.04 [0.75,1.42]	
Total	269 / 1319	288 / 1345		0.94 [0.78,1.13]	Z=-0.67, p=0.5047
Heterogeneity:	Q=0.56 (df=1)	p=0.4536	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.92 (df=1)	p=0.1656	I^2=48.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

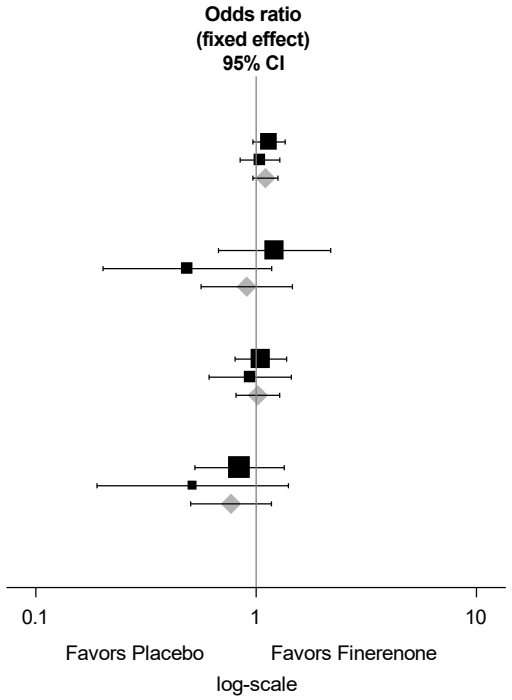
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	169 / 724	155 / 724	58.7	1.12 [0.87,1.43]	
FIGARO-DKD	108 / 494	124 / 497	41.3	0.84 [0.63,1.13]	
Total	277 / 1218	279 / 1221		0.99 [0.82,1.20]	Z=-0.06, p=0.9501
Heterogeneity:	Q=2.09 (df=1)	p=0.1482	I^2=52.2%		
130 - < 160					
FIDELIO-DKD	379 / 1762	355 / 1766	66.4	1.09 [0.93,1.28]	
FIGARO-DKD	191 / 831	191 / 830	33.6	1.00 [0.79,1.25]	
Total	570 / 2593	546 / 2596		1.06 [0.93,1.21]	Z=0.83, p=0.4057
Heterogeneity:	Q=0.37 (df=1)	p=0.5432	I^2=0.0%		
>= 160					
FIDELIO-DKD	26 / 133	22 / 128	83.7	1.17 [0.62,2.19]	
FIGARO-DKD	8 / 34	3 / 35	16.3	3.28 [0.79,13.64]	
Total	34 / 167	25 / 163		1.41 [0.80,2.49]	Z=1.18, p=0.2376
Heterogeneity:	Q=1.69 (df=1)	p=0.1939	I^2=40.8%		
Subgroup Heterogeneity:	Q=1.36 (df=2)	p=0.5068	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

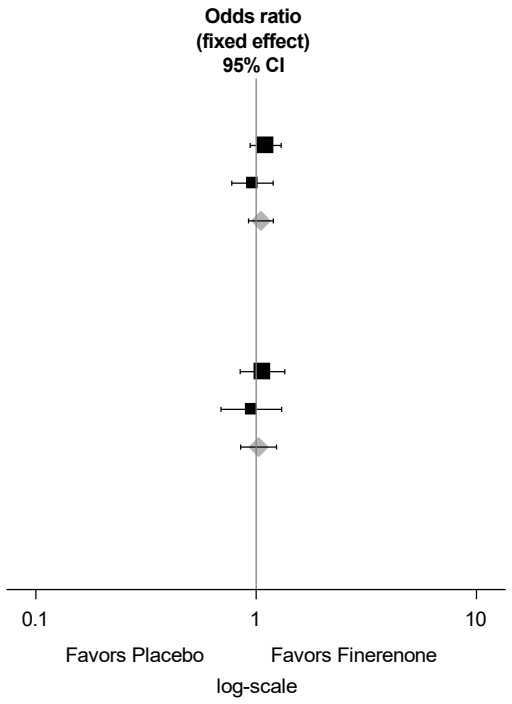
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	357 / 1637	326 / 1663	60.2	1.14 [0.97,1.35]	
FIGARO-DKD	239 / 1013	227 / 992	39.8	1.04 [0.85,1.28]	
Total	596 / 2650	553 / 2655		1.10 [0.97,1.26]	Z=1.45, p=0.1470
Heterogeneity:	Q=0.48 (df=1)	p=0.4878	I^2=0.0%		
Black					
FIDELIO-DKD	34 / 130	26 / 115	69.3	1.21 [0.67,2.18]	
FIGARO-DKD	9 / 43	25 / 71	30.7	0.49 [0.20,1.18]	
Total	43 / 173	51 / 186		0.91 [0.56,1.46]	Z=-0.40, p=0.6861
Heterogeneity:	Q=2.85 (df=1)	p=0.0913	I^2=64.9%		
Asian					
FIDELIO-DKD	134 / 678	129 / 679	71.8	1.05 [0.80,1.37]	
FIGARO-DKD	51 / 251	54 / 253	28.2	0.94 [0.61,1.44]	
Total	185 / 929	183 / 932		1.02 [0.81,1.28]	Z=0.15, p=0.8792
Heterogeneity:	Q=0.18 (df=1)	p=0.6676	I^2=0.0%		
Others					
FIDELIO-DKD	49 / 177	51 / 163	82.1	0.84 [0.53,1.34]	
FIGARO-DKD	8 / 52	12 / 46	17.9	0.52 [0.19,1.40]	
Total	57 / 229	63 / 209		0.77 [0.50,1.17]	Z=-1.22, p=0.2227
Heterogeneity:	Q=0.76 (df=1)	p=0.3845	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.04 (df=3)	p=0.3851	I^2=1.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.8.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

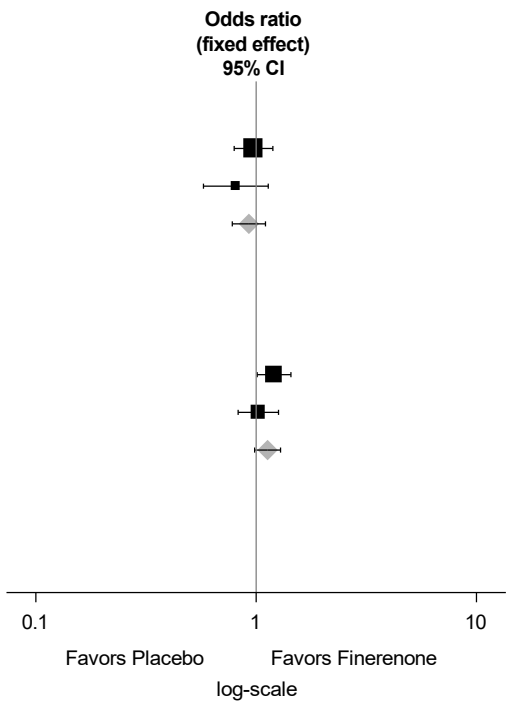
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	373 / 1800	359 / 1876	64.1	1.10 [0.94,1.30]	
FIGARO-DKD	208 / 917	219 / 937	35.9	0.96 [0.77,1.19]	
Total	581 / 2717	578 / 2813		1.05 [0.92,1.20]	Z=0.75, p=0.4521
Heterogeneity:	Q=1.01 (df=1)	p=0.3156	I^2=0.7%		
Female					
FIDELIO-DKD	201 / 822	173 / 744	65.0	1.07 [0.85,1.35]	
FIGARO-DKD	99 / 442	99 / 425	35.0	0.95 [0.69,1.31]	
Total	300 / 1264	272 / 1169		1.03 [0.85,1.24]	Z=0.26, p=0.7928
Heterogeneity:	Q=0.34 (df=1)	p=0.5603	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8327	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.8.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

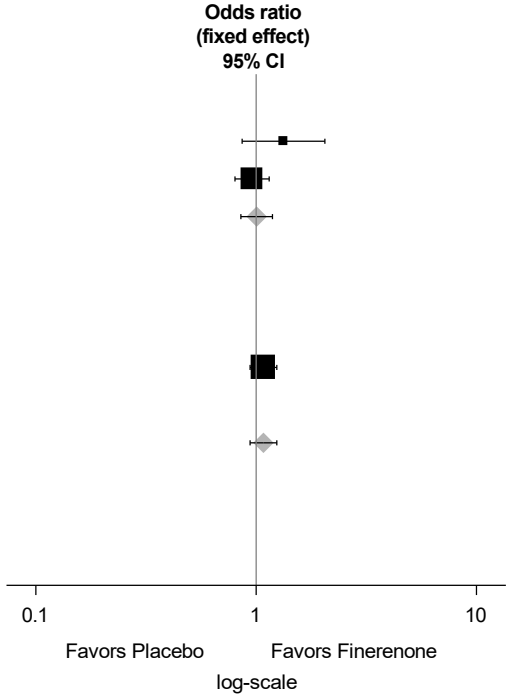
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	242 / 1106	241 / 1078	73.7	0.97 [0.79,1.19]	
FIGARO-DKD	86 / 337	100 / 336	26.3	0.81 [0.58,1.13]	
Total	328 / 1443	341 / 1414		0.93 [0.78,1.10]	Z=-0.86, p=0.3890
Heterogeneity:	Q=0.84 (df=1)	p=0.3583	I^2=0.0%		
>= 65					
FIDELIO-DKD	332 / 1516	291 / 1542	58.9	1.21 [1.01,1.44]	
FIGARO-DKD	221 / 1022	218 / 1026	41.1	1.02 [0.83,1.26]	
Total	553 / 2538	509 / 2568		1.13 [0.98,1.29]	Z=1.73, p=0.0838
Heterogeneity:	Q=1.37 (df=1)	p=0.2411	I^2=27.2%		
Subgroup Heterogeneity:	Q=3.04 (df=1)	p=0.0814	I^2=67.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.8.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

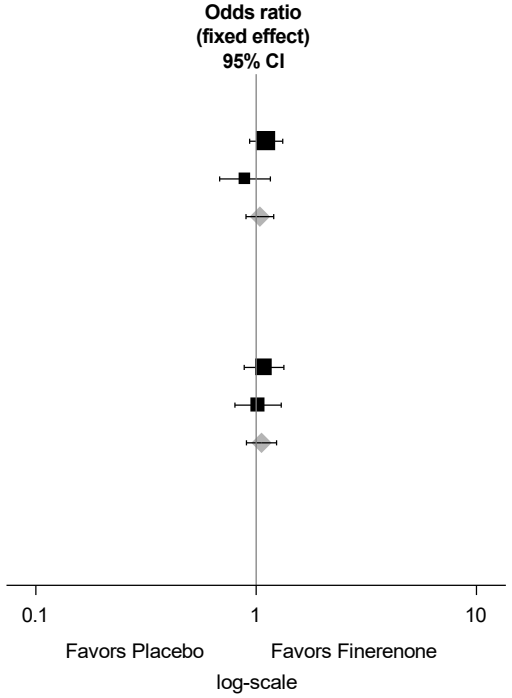
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	62 / 210	51 / 213	14.6	1.33 [0.86,2.05]	
FIGARO-DKD	307 / 1359	318 / 1362	85.4	0.96 [0.80,1.15]	
Total	369 / 1569	369 / 1575		1.01 [0.85,1.19]	Z=0.06, p=0.9500
Heterogeneity:	Q=1.89 (df=1)	p=0.1687	I^2=47.2%		
Very High					
FIDELIO-DKD	512 / 2412	481 / 2407	100.0	1.08 [0.94,1.24]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	512 / 2412	481 / 2407		1.08 [0.94,1.24]	Z=1.07, p=0.2859
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5212	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.8.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Physical Component Summary of at least MID=8 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

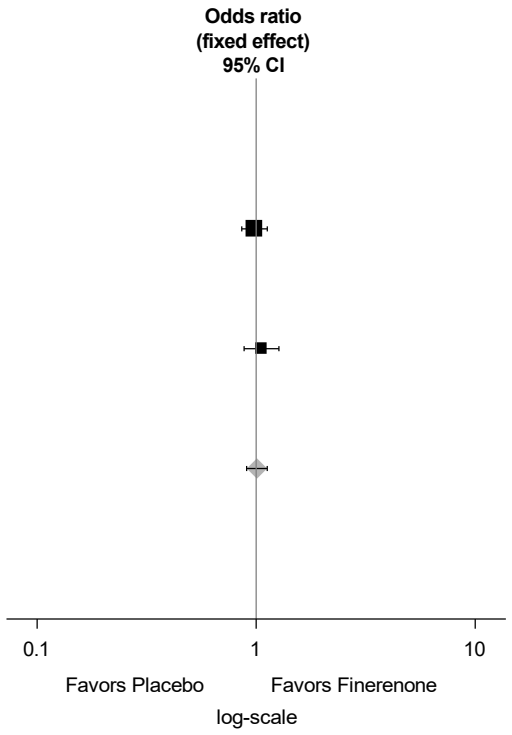
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	340 / 1559	311 / 1549	70.2	1.11 [0.93,1.32]	
FIGARO-DKD	135 / 639	146 / 631	29.8	0.89 [0.68,1.16]	
Total	475 / 2198	457 / 2180		1.04 [0.90,1.20]	Z=0.52, p=0.6017
Heterogeneity:	Q=1.88 (df=1)	p=0.1705	I^2=46.8%		
45 - < 60					
FIDELIO-DKD	234 / 1063	221 / 1071	57.7	1.09 [0.88,1.34]	
FIGARO-DKD	172 / 720	172 / 731	42.3	1.02 [0.80,1.30]	
Total	406 / 1783	393 / 1802		1.06 [0.90,1.24]	Z=0.70, p=0.4870
Heterogeneity:	Q=0.15 (df=1)	p=0.7015	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8743	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

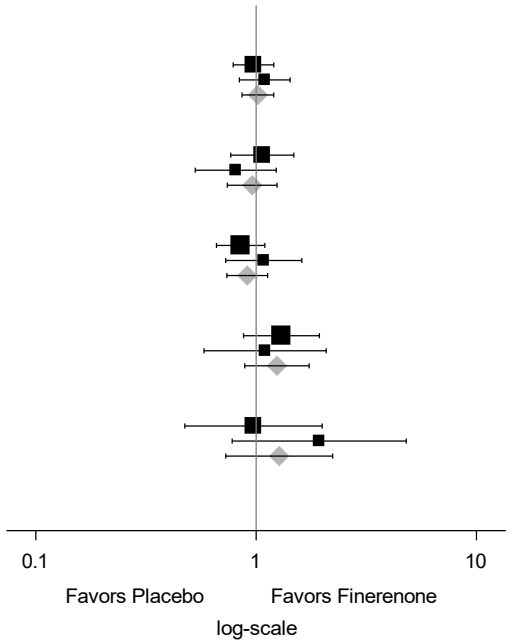
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	533 / 2622	540 / 2620	65.0	0.98 [0.86,1.12]	
FIGARO-DKD	299 / 1359	287 / 1362	35.0	1.06 [0.88,1.27]	
Total	832 / 3981	827 / 3982		1.01 [0.90,1.12]	Z=0.14, p=0.8849
Heterogeneity:	Q=0.40 (df=1)	p=0.5257	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.9.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

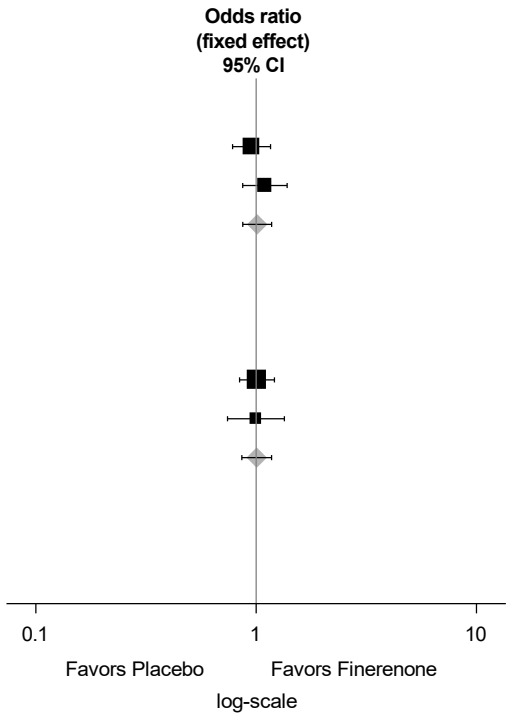
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	212 / 1078	214 / 1064	61.0	0.97 [0.79,1.20]	
FIGARO-DKD	145 / 640	135 / 639	39.0	1.09 [0.84,1.43]	
Total	357 / 1718	349 / 1703		1.02 [0.86,1.20]	Z=0.21, p=0.8328
Heterogeneity:	Q=0.46 (df=1)	p=0.4977	I^2=0.0%		
North America					
FIDELIO-DKD	90 / 425	88 / 437	62.2	1.07 [0.77,1.48]	
FIGARO-DKD	49 / 267	59 / 271	37.8	0.81 [0.53,1.23]	
Total	139 / 692	147 / 708		0.96 [0.74,1.24]	Z=-0.31, p=0.7544
Heterogeneity:	Q=1.02 (df=1)	p=0.3117	I^2=2.3%		
Asia					
FIDELIO-DKD	142 / 751	161 / 748	71.3	0.85 [0.66,1.09]	
FIGARO-DKD	63 / 288	60 / 292	28.7	1.08 [0.73,1.61]	
Total	205 / 1039	221 / 1040		0.91 [0.74,1.13]	Z=-0.86, p=0.3919
Heterogeneity:	Q=1.01 (df=1)	p=0.3149	I^2=1.0%		
Latin America					
FIDELIO-DKD	71 / 274	58 / 274	72.2	1.30 [0.88,1.94]	
FIGARO-DKD	26 / 102	24 / 101	27.8	1.10 [0.58,2.08]	
Total	97 / 376	82 / 375		1.24 [0.89,1.74]	Z=1.26, p=0.2068
Heterogeneity:	Q=0.20 (df=1)	p=0.6554	I^2=0.0%		
Others					
FIDELIO-DKD	18 / 94	19 / 97	61.6	0.97 [0.47,1.99]	
FIGARO-DKD	16 / 62	9 / 59	38.4	1.93 [0.78,4.80]	
Total	34 / 156	28 / 156		1.27 [0.73,2.22]	Z=0.84, p=0.3981
Heterogeneity:	Q=1.35 (df=1)	p=0.2453	I^2=25.9%		
Subgroup Heterogeneity:	Q=3.16 (df=4)	p=0.5309	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

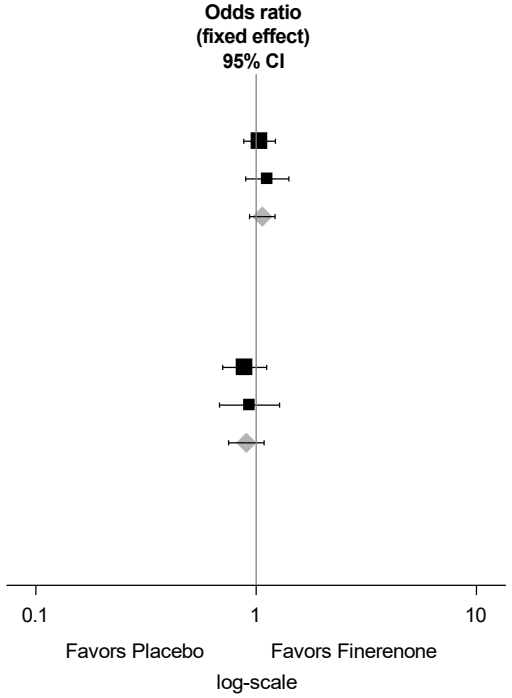
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	240 / 1215	249 / 1213	57.8	0.95 [0.78,1.16]	
FIGARO-DKD	189 / 865	173 / 851	42.2	1.10 [0.87,1.38]	
Total	429 / 2080	422 / 2064		1.01 [0.87,1.18]	Z=0.14, p=0.8886
Heterogeneity:	Q=0.80 (df=1)	p=0.3703	I^2=0.0%		
Absent					
FIDELIO-DKD	293 / 1407	291 / 1407	72.7	1.01 [0.84,1.21]	
FIGARO-DKD	110 / 494	114 / 511	27.3	1.00 [0.74,1.34]	
Total	403 / 1901	405 / 1918		1.01 [0.86,1.17]	Z=0.07, p=0.9435
Heterogeneity:	Q=0.00 (df=1)	p=0.9504	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9627	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

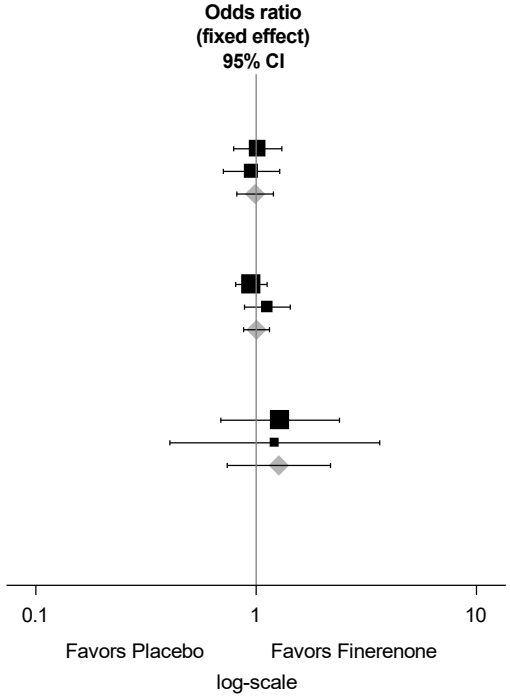
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	362 / 1737	345 / 1703	65.0	1.04 [0.88,1.22]	
FIGARO-DKD	199 / 924	183 / 932	35.0	1.12 [0.90,1.41]	
Total	561 / 2661	528 / 2635		1.07 [0.93,1.22]	Z=0.94, p=0.3470
Heterogeneity:	Q=0.32 (df=1)	p=0.5713	I^2=0.0%		
> 4.5					
FIDELIO-DKD	171 / 884	195 / 916	65.1	0.89 [0.70,1.12]	
FIGARO-DKD	100 / 435	104 / 429	34.9	0.93 [0.68,1.28]	
Total	271 / 1319	299 / 1345		0.90 [0.75,1.09]	Z=-1.08, p=0.2788
Heterogeneity:	Q=0.07 (df=1)	p=0.7987	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.04 (df=1)	p=0.1532	I^2=51.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

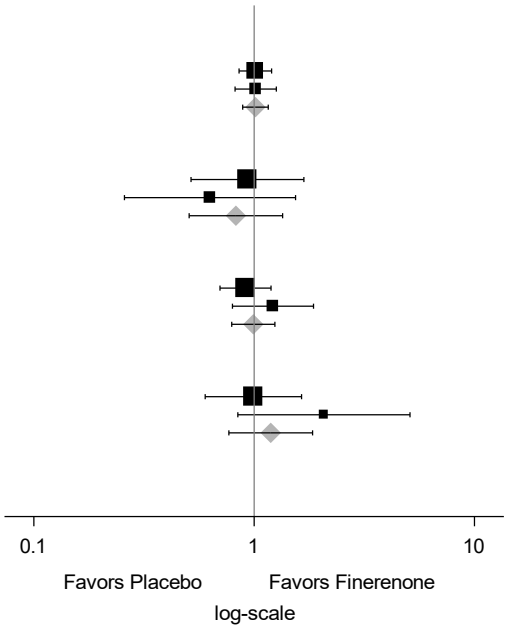
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	155 / 724	153 / 724	57.8	1.02 [0.79,1.31]	
FIGARO-DKD	113 / 494	118 / 497	42.2	0.95 [0.71,1.28]	
Total	268 / 1218	271 / 1221		0.99 [0.82,1.20]	Z=-0.11, p=0.9106
Heterogeneity:	Q=0.11 (df=1)	p=0.7421	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	350 / 1762	365 / 1766	68.0	0.95 [0.81,1.12]	
FIGARO-DKD	177 / 831	161 / 830	32.0	1.12 [0.89,1.43]	
Total	527 / 2593	526 / 2596		1.00 [0.88,1.15]	Z=0.06, p=0.9558
Heterogeneity:	Q=1.28 (df=1)	p=0.2586	I^2=21.7%		
>= 160					
FIDELIO-DKD	28 / 133	22 / 128	75.8	1.28 [0.69,2.39]	
FIGARO-DKD	9 / 34	8 / 35	24.2	1.21 [0.41,3.64]	
Total	37 / 167	30 / 163		1.27 [0.74,2.17]	Z=0.86, p=0.3892
Heterogeneity:	Q=0.01 (df=1)	p=0.9307	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=2)	p=0.6930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

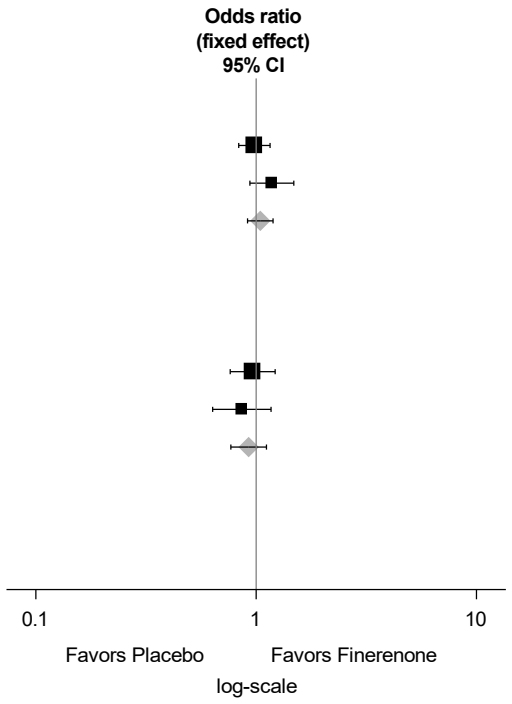
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	332 / 1637	334 / 1663	61.7	1.01 [0.85,1.20]	
FIGARO-DKD	212 / 1013	205 / 992	38.3	1.02 [0.82,1.26]	
Total	544 / 2650	539 / 2655		1.01 [0.89,1.16]	Z=0.20, p=0.8413
Heterogeneity:	Q=0.00 (df=1)	p=0.9788	I^2=0.0%		
Black					
FIDELIO-DKD	30 / 130	28 / 115	69.7	0.93 [0.52,1.68]	
FIGARO-DKD	9 / 43	21 / 71	30.3	0.63 [0.26,1.54]	
Total	39 / 173	49 / 186		0.83 [0.51,1.35]	Z=-0.77, p=0.4430
Heterogeneity:	Q=0.51 (df=1)	p=0.4739	I^2=0.0%		
Asian					
FIDELIO-DKD	130 / 678	140 / 679	71.6	0.91 [0.70,1.19]	
FIGARO-DKD	59 / 251	51 / 253	28.4	1.22 [0.80,1.86]	
Total	189 / 929	191 / 932		0.99 [0.79,1.24]	Z=-0.08, p=0.9374
Heterogeneity:	Q=1.26 (df=1)	p=0.2609	I^2=20.9%		
Others					
FIDELIO-DKD	41 / 177	38 / 163	76.1	0.99 [0.60,1.64]	
FIGARO-DKD	19 / 52	10 / 46	23.9	2.07 [0.84,5.10]	
Total	60 / 229	48 / 209		1.19 [0.77,1.84]	Z=0.77, p=0.4385
Heterogeneity:	Q=1.96 (df=1)	p=0.1611	I^2=49.1%		
Subgroup Heterogeneity:	Q=1.21 (df=3)	p=0.7498	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.9.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

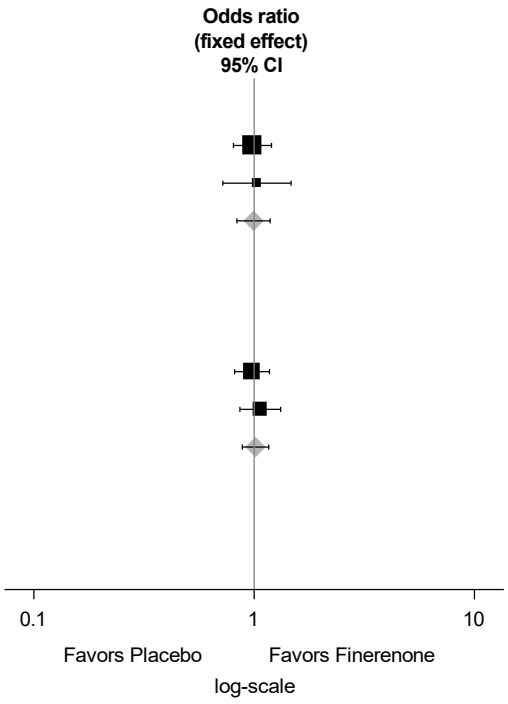
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	345 / 1800	365 / 1876	66.2	0.98 [0.83,1.16]	
FIGARO-DKD	192 / 917	172 / 937	33.8	1.18 [0.94,1.48]	
Total	537 / 2717	537 / 2813		1.04 [0.91,1.19]	Z=0.63, p=0.5270
Heterogeneity:	Q=1.61 (df=1)	p=0.2051	I^2=37.7%		
Female					
FIDELIO-DKD	188 / 822	175 / 744	62.8	0.96 [0.76,1.22]	
FIGARO-DKD	107 / 442	115 / 425	37.2	0.86 [0.63,1.17]	
Total	295 / 1264	290 / 1169		0.92 [0.77,1.11]	Z=-0.83, p=0.4077
Heterogeneity:	Q=0.33 (df=1)	p=0.5648	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.08 (df=1)	p=0.2977	I^2=7.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.9.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

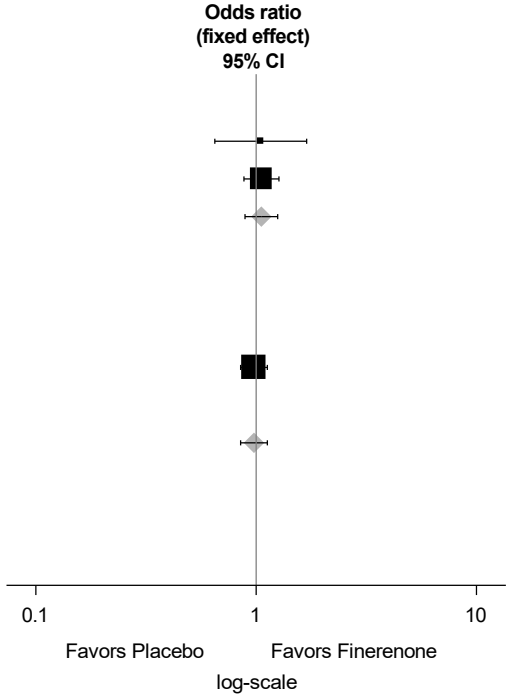
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	254 / 1106	251 / 1078	76.3	0.98 [0.81,1.20]	
FIGARO-DKD	80 / 337	78 / 336	23.7	1.03 [0.72,1.47]	
Total	334 / 1443	329 / 1414		0.99 [0.83,1.18]	Z=-0.08, p=0.9396
Heterogeneity:	Q=0.05 (df=1)	p=0.8211	I^2=0.0%		
>= 65					
FIDELIO-DKD	279 / 1516	289 / 1542	57.7	0.98 [0.81,1.17]	
FIGARO-DKD	219 / 1022	209 / 1026	42.3	1.07 [0.86,1.32]	
Total	498 / 2538	498 / 2568		1.01 [0.88,1.16]	Z=0.20, p=0.8414
Heterogeneity:	Q=0.36 (df=1)	p=0.5460	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8540	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.9.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

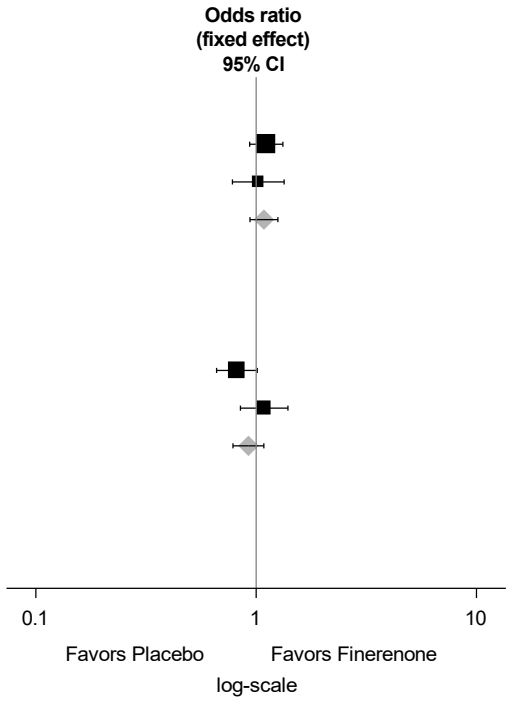
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	42 / 210	41 / 213	12.7	1.05 [0.65,1.69]	
FIGARO-DKD	299 / 1359	287 / 1362	87.3	1.06 [0.88,1.27]	
Total	341 / 1569	328 / 1575		1.06 [0.89,1.25]	Z=0.62, p=0.5350
Heterogeneity:	Q=0.00 (df=1)	p=0.9775	I^2=0.0%		
Very High					
FIDELIO-DKD	491 / 2412	499 / 2407	100.0	0.98 [0.85,1.12]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	491 / 2412	499 / 2407		0.98 [0.85,1.12]	Z=-0.32, p=0.7476
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4940	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.9.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Mental Component Summary of at least MID=9 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

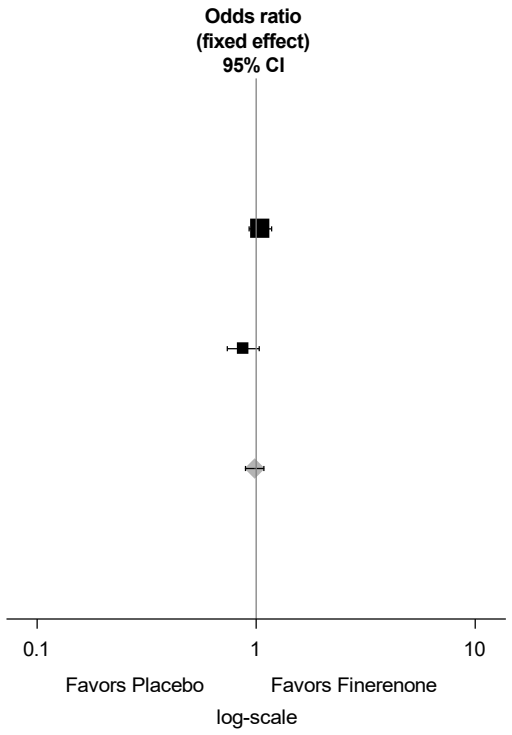
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	337 / 1559	308 / 1549	70.8	1.11 [0.93,1.32]	
FIGARO-DKD	135 / 639	131 / 631	29.2	1.02 [0.78,1.34]	
Total	472 / 2198	439 / 2180		1.08 [0.94,1.26]	Z=1.09, p=0.2762
Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	196 / 1063	232 / 1071	57.7	0.82 [0.66,1.01]	
FIGARO-DKD	164 / 720	156 / 731	42.3	1.09 [0.85,1.39]	
Total	360 / 1783	388 / 1802		0.92 [0.78,1.08]	Z=-0.99, p=0.3244
Heterogeneity:	Q=2.92 (df=1)	p=0.0873	I^2=65.8%		
Subgroup Heterogeneity:	Q=2.14 (df=1)	p=0.1439	I^2=53.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

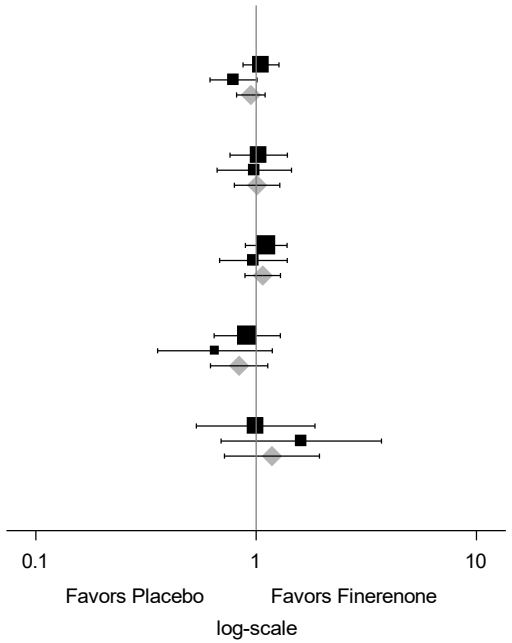
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	803 / 2622	778 / 2620	66.8	1.05 [0.93,1.18]	
FIGARO-DKD	361 / 1359	399 / 1362	33.2	0.87 [0.74,1.03]	
Total	1164 / 3981	1177 / 3982		0.98 [0.89,1.08]	Z=-0.32, p=0.7497
Heterogeneity:	Q=2.95 (df=1)	p=0.0861	I^2=66.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.10.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

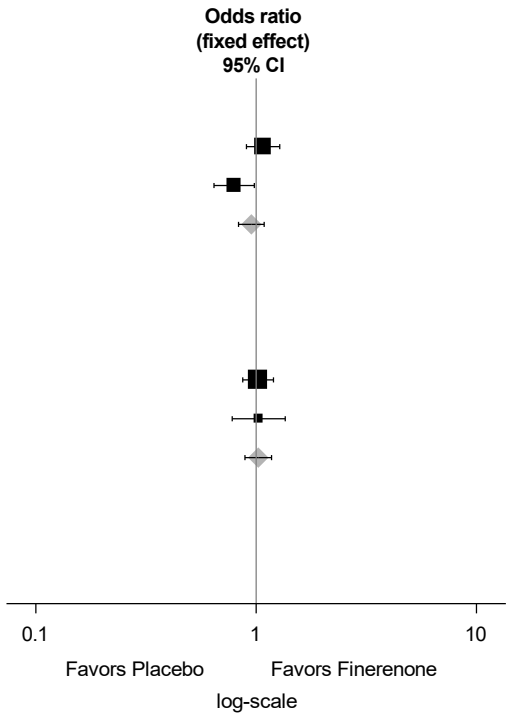
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	312 / 1078	297 / 1064	63.1	1.05 [0.87,1.27]	
FIGARO-DKD	162 / 640	192 / 639	36.9	0.79 [0.62,1.01]	
Total	474 / 1718	489 / 1703		0.95 [0.81,1.10]	Z=-0.73, p=0.4641
Heterogeneity:	Q=3.32 (df=1)	p=0.0684	I^2=69.9%		
North America					
FIDELIO-DKD	117 / 425	118 / 437	62.7	1.03 [0.76,1.39]	
FIGARO-DKD	67 / 267	69 / 271	37.3	0.98 [0.66,1.45]	
Total	184 / 692	187 / 708		1.01 [0.80,1.28]	Z=0.08, p=0.9381
Heterogeneity:	Q=0.03 (df=1)	p=0.8542	I^2=0.0%		
Asia					
FIDELIO-DKD	246 / 751	228 / 748	72.5	1.11 [0.89,1.38]	
FIGARO-DKD	87 / 288	90 / 292	27.5	0.97 [0.68,1.38]	
Total	333 / 1039	318 / 1040		1.07 [0.89,1.29]	Z=0.72, p=0.4702
Heterogeneity:	Q=0.40 (df=1)	p=0.5265	I^2=0.0%		
Latin America					
FIDELIO-DKD	100 / 274	106 / 274	75.0	0.91 [0.64,1.29]	
FIGARO-DKD	27 / 102	36 / 101	25.0	0.65 [0.36,1.18]	
Total	127 / 376	142 / 375		0.84 [0.62,1.13]	Z=-1.17, p=0.2433
Heterogeneity:	Q=0.91 (df=1)	p=0.3392	I^2=0.0%		
Others					
FIDELIO-DKD	28 / 94	29 / 97	64.6	0.99 [0.54,1.85]	
FIGARO-DKD	18 / 62	12 / 59	35.4	1.60 [0.69,3.70]	
Total	46 / 156	41 / 156		1.18 [0.72,1.94]	Z=0.65, p=0.5149
Heterogeneity:	Q=0.80 (df=1)	p=0.3702	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=4)	p=0.6007	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

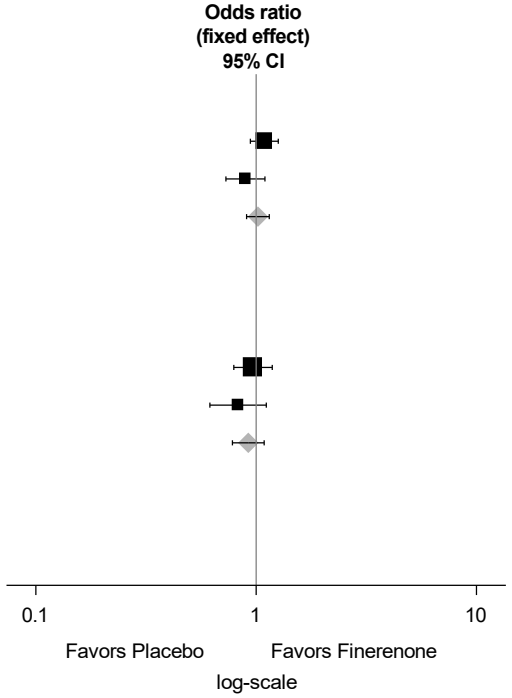
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	372 / 1215	353 / 1213	59.5	1.08 [0.90,1.28]	
FIGARO-DKD	224 / 865	260 / 851	40.5	0.79 [0.64,0.98]	
Total	596 / 2080	613 / 2064		0.95 [0.83,1.09]	Z=-0.74, p=0.4615
Heterogeneity:	Q=4.71 (df=1)	p=0.0299	I^2=78.8%		
Absent					
FIDELIO-DKD	431 / 1407	425 / 1407	74.8	1.02 [0.87,1.20]	
FIGARO-DKD	137 / 494	139 / 511	25.2	1.03 [0.78,1.35]	
Total	568 / 1901	564 / 1918		1.02 [0.89,1.17]	Z=0.31, p=0.7586
Heterogeneity:	Q=0.00 (df=1)	p=0.9682	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=1)	p=0.4639	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

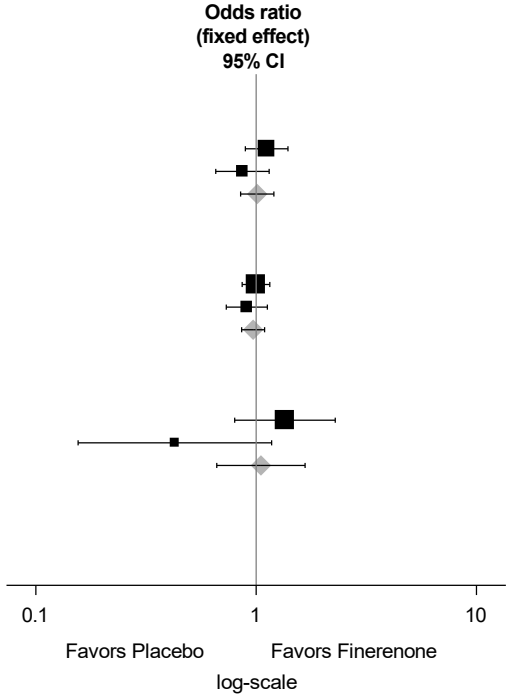
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	537 / 1737	496 / 1703	66.1	1.09 [0.94,1.26]	
FIGARO-DKD	244 / 924	267 / 932	33.9	0.89 [0.73,1.10]	
Total	781 / 2661	763 / 2635		1.02 [0.90,1.15]	Z=0.30, p=0.7625
Heterogeneity:	Q=2.39 (df=1)	p=0.1223	I^2=58.1%		
> 4.5					
FIDELIO-DKD	266 / 884	282 / 916	68.3	0.97 [0.79,1.18]	
FIGARO-DKD	117 / 435	132 / 429	31.7	0.83 [0.62,1.11]	
Total	383 / 1319	414 / 1345		0.92 [0.78,1.09]	Z=-0.97, p=0.3307
Heterogeneity:	Q=0.74 (df=1)	p=0.3912	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.94 (df=1)	p=0.3334	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

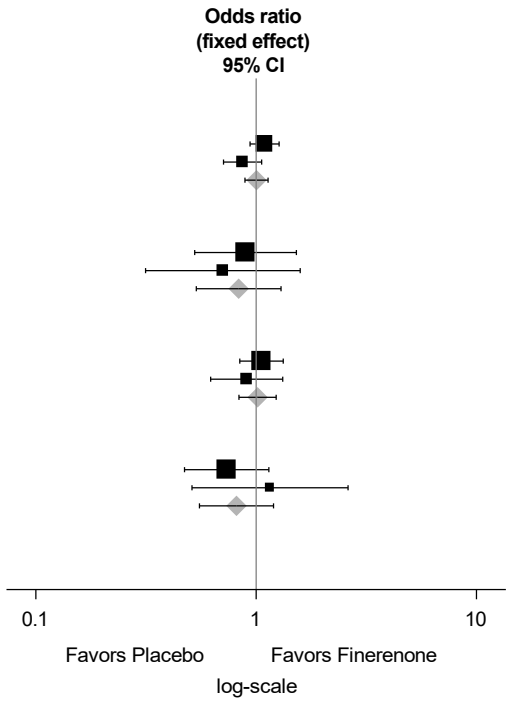
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	234 / 724	217 / 724	61.1	1.12 [0.89,1.39]	
FIGARO-DKD	129 / 494	144 / 497	38.9	0.87 [0.66,1.15]	
Total	363 / 1218	361 / 1221		1.01 [0.85,1.20]	Z=0.13, p=0.9002
Heterogeneity:	Q=1.93 (df=1)	p=0.1648	I^2=48.2%		
130 - < 160					
FIDELIO-DKD	523 / 1762	525 / 1766	68.9	1.00 [0.86,1.15]	
FIGARO-DKD	223 / 831	239 / 830	31.1	0.91 [0.73,1.12]	
Total	746 / 2593	764 / 2596		0.97 [0.86,1.09]	Z=-0.52, p=0.6014
Heterogeneity:	Q=0.52 (df=1)	p=0.4698	I^2=0.0%		
>= 160					
FIDELIO-DKD	46 / 133	36 / 128	78.7	1.35 [0.80,2.29]	
FIGARO-DKD	9 / 34	16 / 35	21.3	0.43 [0.16,1.18]	
Total	55 / 167	52 / 163		1.05 [0.66,1.67]	Z=0.21, p=0.8330
Heterogeneity:	Q=3.92 (df=1)	p=0.0478	I^2=74.5%		
Subgroup Heterogeneity:	Q=0.24 (df=2)	p=0.8874	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

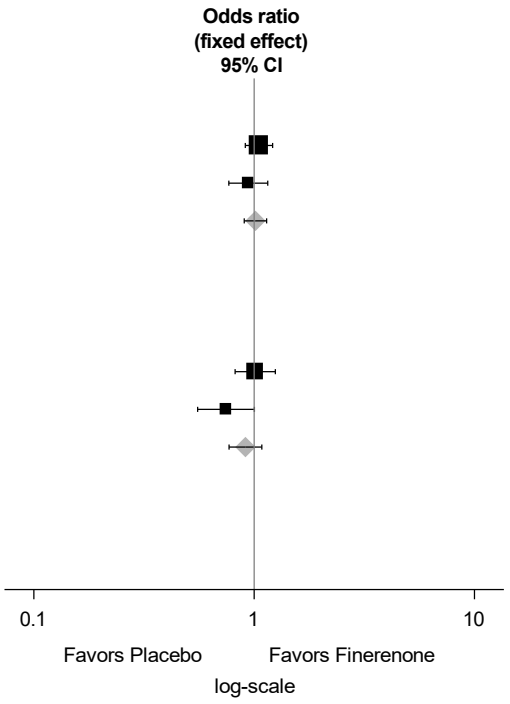
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	476 / 1637	454 / 1663	63.3	1.09 [0.94,1.27]	
FIGARO-DKD	251 / 1013	273 / 992	36.7	0.87 [0.71,1.06]	
Total	727 / 2650	727 / 2655		1.00 [0.89,1.13]	Z=0.06, p=0.9548
Heterogeneity:	Q=3.24 (df=1)	p=0.0721	I^2=69.1%		
Black					
FIDELIO-DKD	42 / 130	40 / 115	69.8	0.89 [0.53,1.52]	
FIGARO-DKD	13 / 43	27 / 71	30.2	0.71 [0.31,1.58]	
Total	55 / 173	67 / 186		0.83 [0.53,1.30]	Z=-0.81, p=0.4177
Heterogeneity:	Q=0.23 (df=1)	p=0.6313	I^2=0.0%		
Asian					
FIDELIO-DKD	225 / 678	217 / 679	73.3	1.06 [0.84,1.33]	
FIGARO-DKD	76 / 251	82 / 253	26.7	0.91 [0.62,1.32]	
Total	301 / 929	299 / 932		1.01 [0.84,1.23]	Z=0.15, p=0.8836
Heterogeneity:	Q=0.48 (df=1)	p=0.4897	I^2=0.0%		
Others					
FIDELIO-DKD	60 / 177	67 / 163	77.4	0.73 [0.47,1.14]	
FIGARO-DKD	21 / 52	17 / 46	22.6	1.16 [0.51,2.61]	
Total	81 / 229	84 / 209		0.81 [0.55,1.20]	Z=-1.04, p=0.2976
Heterogeneity:	Q=0.92 (df=1)	p=0.3384	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.66 (df=3)	p=0.6448	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.10.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

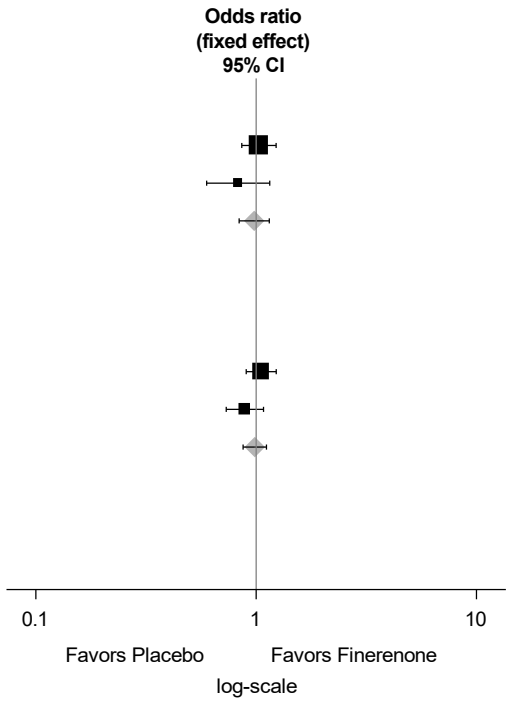
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	527 / 1800	530 / 1876	67.0	1.05 [0.91,1.21]	
FIGARO-DKD	249 / 917	266 / 937	33.0	0.94 [0.77,1.15]	
Total	776 / 2717	796 / 2813		1.01 [0.90,1.14]	Z=0.22, p=0.8252
Heterogeneity:	Q=0.78 (df=1)	p=0.3786	I^2=0.0%		
Female					
FIDELIO-DKD	276 / 822	248 / 744	66.6	1.01 [0.82,1.25]	
FIGARO-DKD	112 / 442	133 / 425	33.4	0.75 [0.55,1.00]	
Total	388 / 1264	381 / 1169		0.91 [0.77,1.08]	Z=-1.04, p=0.2962
Heterogeneity:	Q=2.71 (df=1)	p=0.1000	I^2=63.0%		
Subgroup Heterogeneity:	Q=0.97 (df=1)	p=0.3235	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.10.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

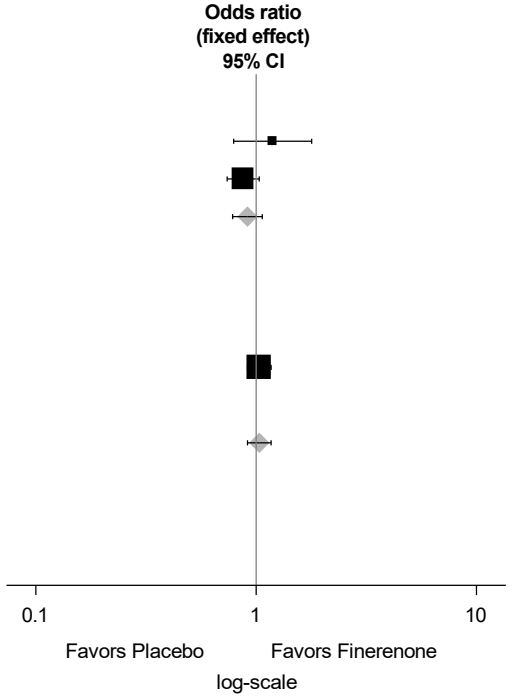
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	361 / 1106	345 / 1078	77.2	1.03 [0.86,1.23]	
FIGARO-DKD	95 / 337	108 / 336	22.8	0.83 [0.60,1.15]	
Total	456 / 1443	453 / 1414		0.98 [0.84,1.15]	Z=-0.26, p=0.7985
Heterogeneity:	Q=1.28 (df=1)	p=0.2573	I^2=22.1%		
>= 65					
FIDELIO-DKD	442 / 1516	433 / 1542	60.7	1.05 [0.90,1.23]	
FIGARO-DKD	266 / 1022	291 / 1026	39.3	0.89 [0.73,1.08]	
Total	708 / 2538	724 / 2568		0.99 [0.87,1.11]	Z=-0.23, p=0.8159
Heterogeneity:	Q=1.79 (df=1)	p=0.1812	I^2=44.1%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9529	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.10.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

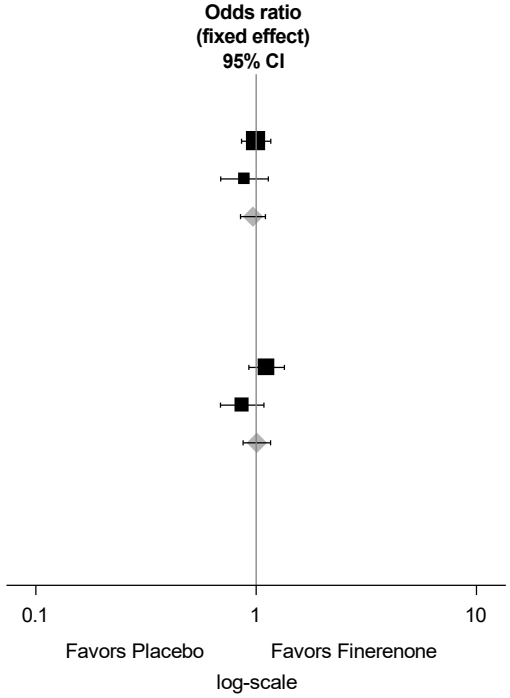
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	72 / 210	65 / 213	14.5	1.19 [0.79,1.79]	
FIGARO-DKD	361 / 1359	399 / 1362	85.5	0.87 [0.74,1.03]	
Total	433 / 1569	464 / 1575		0.91 [0.78,1.07]	Z=-1.15, p=0.2488
Heterogeneity:	Q=1.88 (df=1)	p=0.1709	I^2=46.7%		
Very High					
FIDELIO-DKD	731 / 2412	713 / 2407	100.0	1.03 [0.91,1.17]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	731 / 2412	713 / 2407		1.03 [0.91,1.17]	Z=0.52, p=0.6038
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.50 (df=1)	p=0.2203	I^2=33.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.10.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Burden of Kidney Disease of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

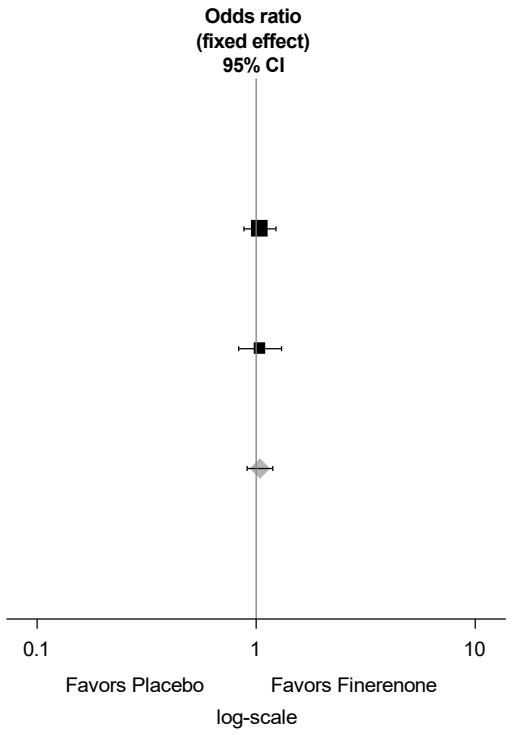
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	474 / 1559	471 / 1549	72.6	1.00 [0.86,1.17]	
FIGARO-DKD	163 / 639	176 / 631	27.4	0.89 [0.69,1.14]	
Total	637 / 2198	647 / 2180		0.97 [0.85,1.10]	Z=-0.50, p=0.6142
Heterogeneity:	Q=0.67 (df=1)	p=0.4139	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	329 / 1063	307 / 1071	59.9	1.12 [0.93,1.34]	
FIGARO-DKD	198 / 720	223 / 731	40.1	0.86 [0.69,1.08]	
Total	527 / 1783	530 / 1802		1.01 [0.87,1.16]	Z=0.09, p=0.9248
Heterogeneity:	Q=2.91 (df=1)	p=0.0879	I^2=65.7%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

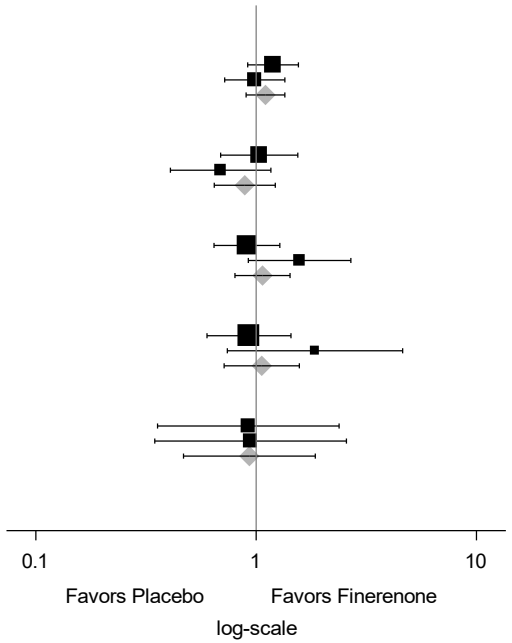
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	314 / 2622	303 / 2620	64.1	1.04 [0.88,1.23]	
FIGARO-DKD	177 / 1359	171 / 1362	35.9	1.04 [0.83,1.31]	
Total	491 / 3981	474 / 3982		1.04 [0.91,1.19]	Z=0.58, p=0.5639
Heterogeneity:	Q=0.00 (df=1)	p=0.9894	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.11.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Region
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

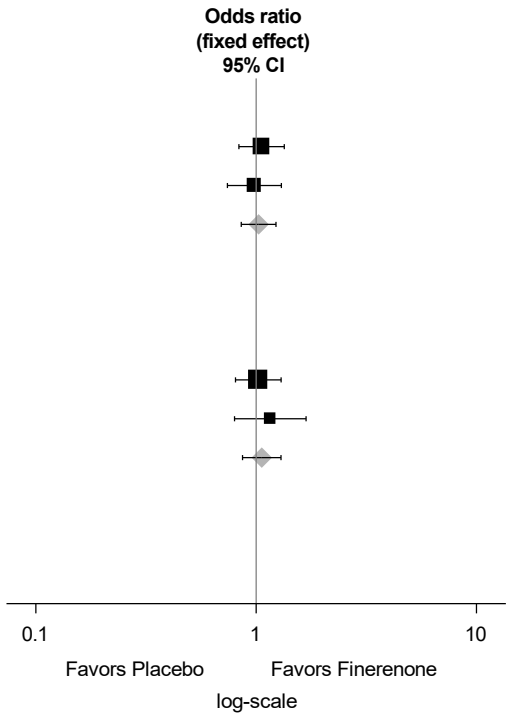
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	135 / 1078	114 / 1064	58.5	1.19 [0.92,1.56]	
FIGARO-DKD	90 / 640	91 / 639	41.5	0.99 [0.72,1.35]	
Total	225 / 1718	205 / 1703		1.10 [0.90,1.35]	Z=0.94, p=0.3469
Heterogeneity:	Q=0.83 (df=1)	p=0.3623	I^2=0.0%		
North America					
FIDELIO-DKD	54 / 425	54 / 437	62.9	1.03 [0.69,1.55]	
FIGARO-DKD	27 / 267	38 / 271	37.1	0.69 [0.41,1.17]	
Total	81 / 692	92 / 708		0.89 [0.65,1.22]	Z=-0.73, p=0.4643
Heterogeneity:	Q=1.42 (df=1)	p=0.2327	I^2=29.8%		
Asia					
FIDELIO-DKD	69 / 751	75 / 748	70.8	0.91 [0.64,1.28]	
FIGARO-DKD	37 / 288	25 / 292	29.2	1.57 [0.92,2.69]	
Total	106 / 1039	100 / 1040		1.07 [0.80,1.42]	Z=0.45, p=0.6522
Heterogeneity:	Q=2.87 (df=1)	p=0.0901	I^2=65.2%		
Latin America					
FIDELIO-DKD	47 / 274	50 / 274	81.3	0.93 [0.60,1.44]	
FIGARO-DKD	14 / 102	8 / 101	18.7	1.85 [0.74,4.62]	
Total	61 / 376	58 / 375		1.06 [0.72,1.57]	Z=0.29, p=0.7719
Heterogeneity:	Q=1.77 (df=1)	p=0.1830	I^2=43.6%		
Others					
FIDELIO-DKD	9 / 94	10 / 97	52.7	0.92 [0.36,2.38]	
FIGARO-DKD	9 / 62	9 / 59	47.3	0.94 [0.35,2.57]	
Total	18 / 156	19 / 156		0.93 [0.47,1.86]	Z=-0.20, p=0.8403
Heterogeneity:	Q=0.00 (df=1)	p=0.9730	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.40 (df=4)	p=0.8439	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

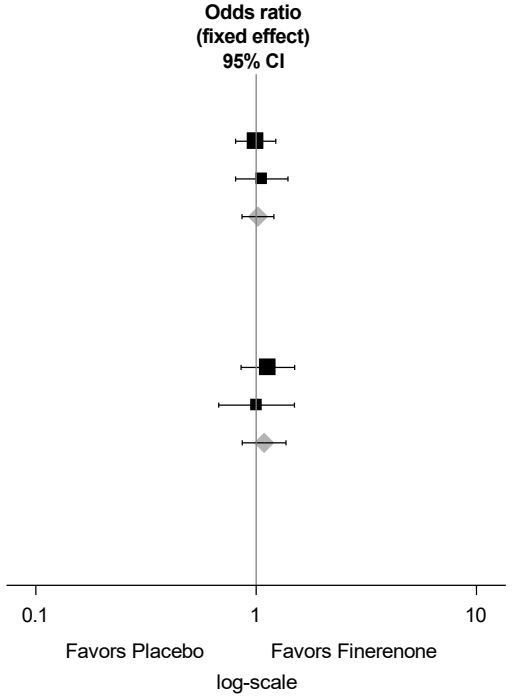
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	161 / 1215	153 / 1213	58.6	1.06 [0.83,1.34]	
FIGARO-DKD	111 / 865	111 / 851	41.4	0.98 [0.74,1.30]	
Total	272 / 2080	264 / 2064		1.03 [0.86,1.23]	Z=0.27, p=0.7837
Heterogeneity:	Q=0.16 (df=1)	p=0.6884	I^2=0.0%		
Absent					
FIDELIO-DKD	153 / 1407	150 / 1407	71.1	1.02 [0.81,1.30]	
FIGARO-DKD	66 / 494	60 / 511	28.9	1.16 [0.80,1.68]	
Total	219 / 1901	210 / 1918		1.06 [0.87,1.30]	Z=0.57, p=0.5683
Heterogeneity:	Q=0.31 (df=1)	p=0.5791	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8107	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

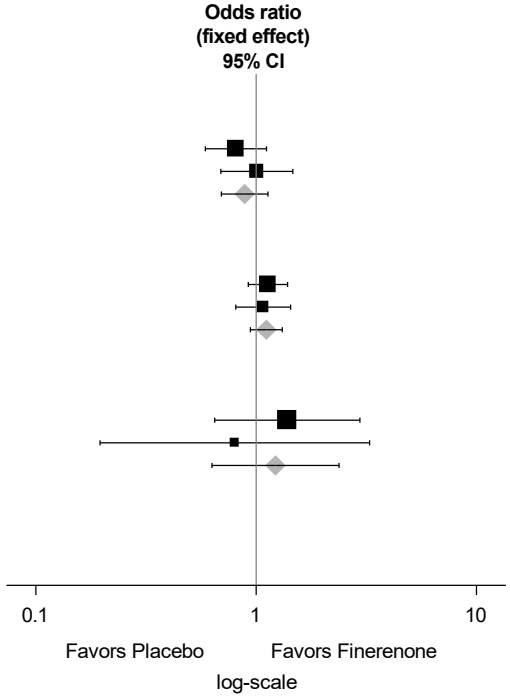
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	198 / 1737	195 / 1703	62.9	0.99 [0.81,1.23]	
FIGARO-DKD	120 / 924	115 / 932	37.1	1.06 [0.81,1.39]	
Total	318 / 2661	310 / 2635		1.02 [0.86,1.20]	Z=0.22, p=0.8274
Heterogeneity:	Q=0.13 (df=1)	p=0.7175	I^2=0.0%		
> 4.5					
FIDELIO-DKD	116 / 884	108 / 916	66.6	1.13 [0.85,1.50]	
FIGARO-DKD	57 / 435	56 / 429	33.4	1.00 [0.68,1.49]	
Total	173 / 1319	164 / 1345		1.09 [0.86,1.37]	Z=0.71, p=0.4771
Heterogeneity:	Q=0.23 (df=1)	p=0.6337	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6556	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

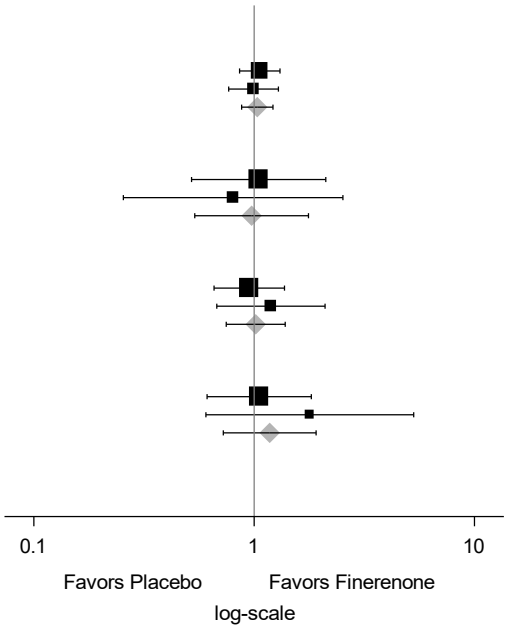
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	78 / 724	94 / 724	58.1	0.81 [0.59,1.11]	
FIGARO-DKD	62 / 494	62 / 497	41.9	1.01 [0.69,1.47]	
Total	140 / 1218	156 / 1221		0.89 [0.70,1.13]	Z=-0.97, p=0.3328
Heterogeneity:	Q=0.75 (df=1)	p=0.3856	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	218 / 1762	196 / 1766	66.1	1.13 [0.92,1.39]	
FIGARO-DKD	111 / 831	104 / 830	33.9	1.08 [0.81,1.43]	
Total	329 / 2593	300 / 2596		1.11 [0.94,1.31]	Z=1.25, p=0.2121
Heterogeneity:	Q=0.08 (df=1)	p=0.7826	I^2=0.0%		
>= 160					
FIDELIO-DKD	18 / 133	13 / 128	77.5	1.38 [0.65,2.96]	
FIGARO-DKD	4 / 34	5 / 35	22.5	0.80 [0.20,3.27]	
Total	22 / 167	18 / 163		1.22 [0.63,2.38]	Z=0.60, p=0.5512
Heterogeneity:	Q=0.45 (df=1)	p=0.5016	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.50 (df=2)	p=0.2866	I^2=20.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Race
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

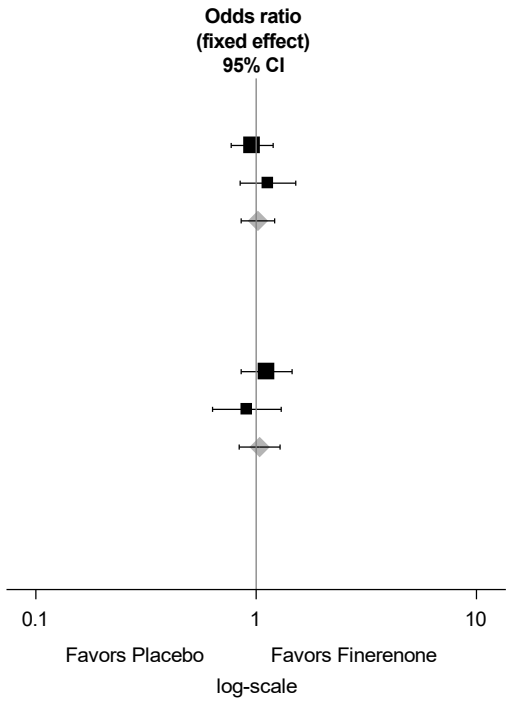
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	199 / 1637	192 / 1663	60.2	1.06 [0.86,1.31]	
FIGARO-DKD	132 / 1013	130 / 992	39.8	0.99 [0.77,1.29]	
Total	331 / 2650	322 / 2655		1.03 [0.88,1.22]	Z=0.39, p=0.6964
Heterogeneity:	Q=0.14 (df=1)	p=0.7034	I^2=0.0%		
Black					
FIDELIO-DKD	20 / 130	17 / 115	72.8	1.05 [0.52,2.11]	
FIGARO-DKD	5 / 43	10 / 71	27.2	0.80 [0.25,2.53]	
Total	25 / 173	27 / 186		0.97 [0.54,1.76]	Z=-0.09, p=0.9298
Heterogeneity:	Q=0.15 (df=1)	p=0.6973	I^2=0.0%		
Asian					
FIDELIO-DKD	61 / 678	64 / 679	70.3	0.95 [0.66,1.37]	
FIGARO-DKD	29 / 251	25 / 253	29.7	1.19 [0.68,2.10]	
Total	90 / 929	89 / 932		1.02 [0.75,1.38]	Z=0.10, p=0.9182
Heterogeneity:	Q=0.43 (df=1)	p=0.5111	I^2=0.0%		
Others					
FIDELIO-DKD	34 / 177	30 / 163	79.9	1.05 [0.61,1.82]	
FIGARO-DKD	11 / 52	6 / 46	20.1	1.79 [0.60,5.30]	
Total	45 / 229	36 / 209		1.18 [0.72,1.91]	Z=0.66, p=0.5121
Heterogeneity:	Q=0.73 (df=1)	p=0.3936	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.32 (df=3)	p=0.9561	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.11.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

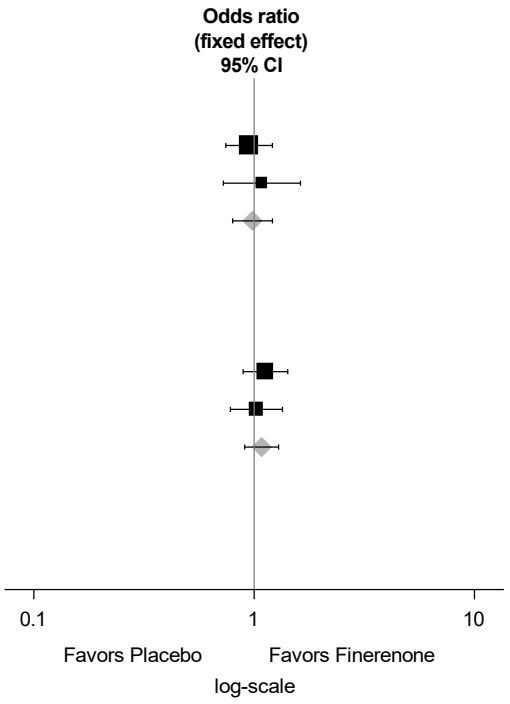
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	170 / 1800	184 / 1876	63.7	0.96 [0.77,1.19]	
FIGARO-DKD	107 / 917	98 / 937	36.3	1.13 [0.85,1.51]	
Total	277 / 2717	282 / 2813		1.02 [0.85,1.21]	Z=0.20, p=0.8398
Heterogeneity:	Q=0.79 (df=1)	p=0.3748	I^2=0.0%		
Female					
FIDELIO-DKD	144 / 822	119 / 744	64.5	1.12 [0.85,1.46]	
FIGARO-DKD	70 / 442	73 / 425	35.5	0.91 [0.63,1.30]	
Total	214 / 1264	192 / 1169		1.04 [0.84,1.28]	Z=0.33, p=0.7401
Heterogeneity:	Q=0.82 (df=1)	p=0.3648	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8978	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.11.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

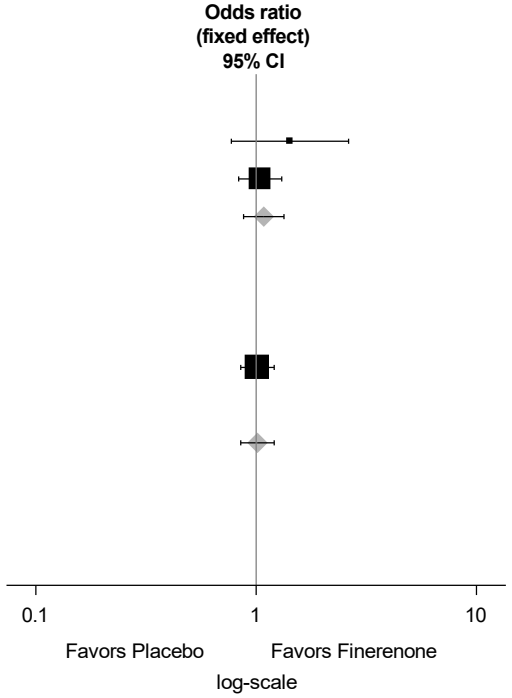
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	149 / 1106	152 / 1078	73.3	0.95 [0.74,1.21]	
FIGARO-DKD	59 / 337	55 / 336	26.7	1.08 [0.72,1.62]	
Total	208 / 1443	207 / 1414		0.98 [0.80,1.21]	Z=-0.16, p=0.8722
Heterogeneity:	Q=0.31 (df=1)	p=0.5775	I^2=0.0%		
>= 65					
FIDELIO-DKD	165 / 1516	151 / 1542	57.7	1.13 [0.89,1.42]	
FIGARO-DKD	118 / 1022	116 / 1026	42.3	1.02 [0.78,1.34]	
Total	283 / 2538	267 / 2568		1.08 [0.91,1.29]	Z=0.86, p=0.3875
Heterogeneity:	Q=0.26 (df=1)	p=0.6067	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=1)	p=0.4951	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.11.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

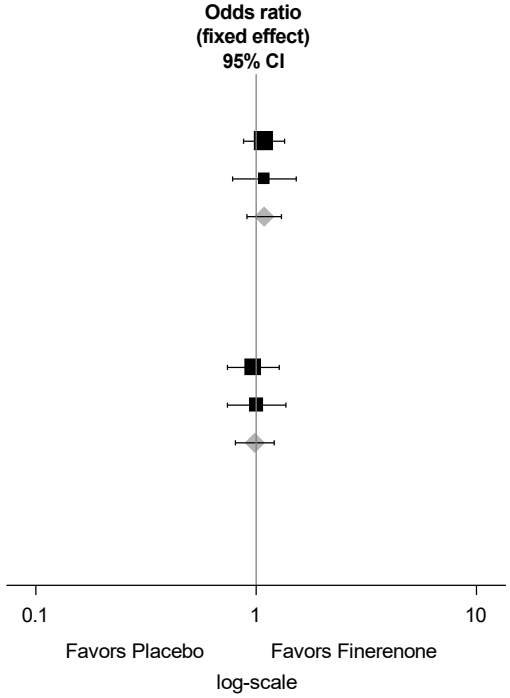
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	27 / 210	20 / 213	11.9	1.42 [0.77,2.63]	
FIGARO-DKD	177 / 1359	171 / 1362	88.1	1.04 [0.83,1.31]	
Total	204 / 1569	191 / 1575		1.08 [0.88,1.34]	Z=0.74, p=0.4605
Heterogeneity:	Q=0.87 (df=1)	p=0.3499	I^2=0.0%		
Very High					
FIDELIO-DKD	287 / 2412	283 / 2407	100.0	1.01 [0.85,1.21]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	287 / 2412	283 / 2407		1.01 [0.85,1.21]	Z=0.15, p=0.8792
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6374	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.11.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Symptoms and Problems of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

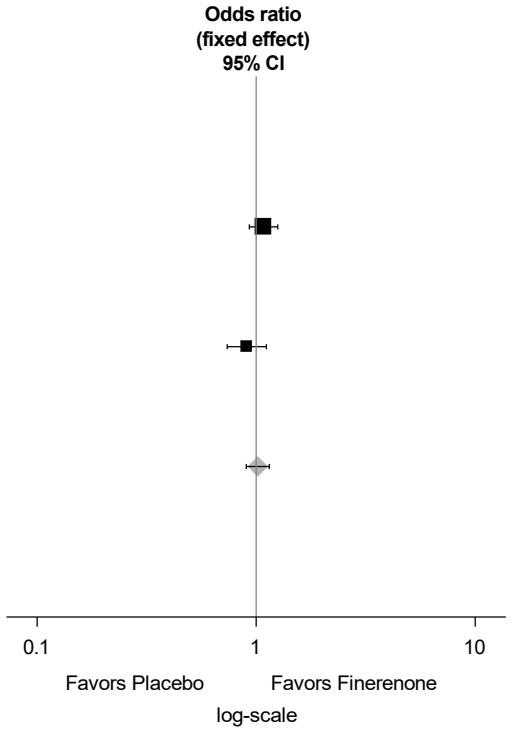
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	198 / 1559	183 / 1549	70.6	1.09 [0.88,1.35]	
FIGARO-DKD	83 / 639	76 / 631	29.4	1.09 [0.78,1.52]	
Total	281 / 2198	259 / 2180		1.09 [0.91,1.30]	Z=0.91, p=0.3636
Heterogeneity:	Q=0.00 (df=1)	p=0.9848	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	116 / 1063	120 / 1071	56.1	0.97 [0.74,1.27]	
FIGARO-DKD	94 / 720	95 / 731	43.9	1.01 [0.74,1.36]	
Total	210 / 1783	215 / 1802		0.99 [0.80,1.21]	Z=-0.14, p=0.8897
Heterogeneity:	Q=0.03 (df=1)	p=0.8668	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4792	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	422 / 2622	395 / 2620	65.5	1.08 [0.93,1.25]	
FIGARO-DKD	208 / 1359	226 / 1362	34.5	0.91 [0.74,1.11]	
Total	630 / 3981	621 / 3982		1.02 [0.90,1.15]	Z=0.27, p=0.7850
Heterogeneity:	Q=1.84 (df=1)	p=0.1749	I^2=45.7%		

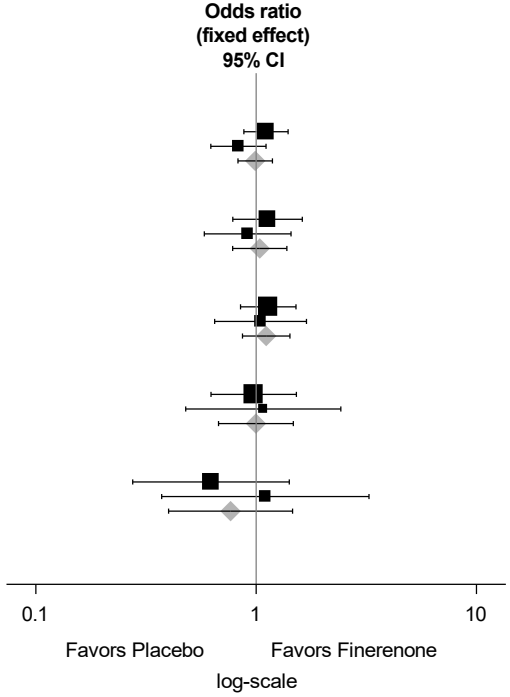


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group, region, eGFR category at screening, type of albuminuria at screening, CVD history and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A3.3.12.1: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Region

Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	180 / 1078	163 / 1064	60.9	1.11 [0.88,1.40]	
FIGARO-DKD	104 / 640	121 / 639	39.1	0.83 [0.62,1.11]	
Total	284 / 1718	284 / 1703		0.99 [0.83,1.19]	Z=-0.11, p=0.9115
Heterogeneity:	Q=2.33 (df=1)	p=0.1267	I^2=57.1%		
North America					
FIDELIO-DKD	72 / 425	67 / 437	60.9	1.13 [0.78,1.62]	
FIGARO-DKD	43 / 267	47 / 271	39.1	0.91 [0.58,1.44]	
Total	115 / 692	114 / 708		1.04 [0.78,1.38]	Z=0.26, p=0.7945
Heterogeneity:	Q=0.49 (df=1)	p=0.4828	I^2=0.0%		
Asia					
FIDELIO-DKD	113 / 751	101 / 748	73.3	1.13 [0.85,1.52]	
FIGARO-DKD	39 / 288	38 / 292	26.7	1.05 [0.65,1.69]	
Total	152 / 1039	139 / 1040		1.11 [0.87,1.42]	Z=0.83, p=0.4076
Heterogeneity:	Q=0.08 (df=1)	p=0.7785	I^2=0.0%		
Latin America					
FIDELIO-DKD	46 / 274	47 / 274	76.8	0.97 [0.62,1.52]	
FIGARO-DKD	14 / 102	13 / 101	23.2	1.08 [0.48,2.42]	
Total	60 / 376	60 / 375		1.00 [0.67,1.47]	Z=-0.01, p=0.9894
Heterogeneity:	Q=0.04 (df=1)	p=0.8322	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 94	17 / 97	63.7	0.62 [0.28,1.41]	
FIGARO-DKD	8 / 62	7 / 59	36.3	1.10 [0.37,3.25]	
Total	19 / 156	24 / 156		0.77 [0.40,1.46]	Z=-0.81, p=0.4185
Heterogeneity:	Q=0.67 (df=1)	p=0.4123	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.34 (df=4)	p=0.8547	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.

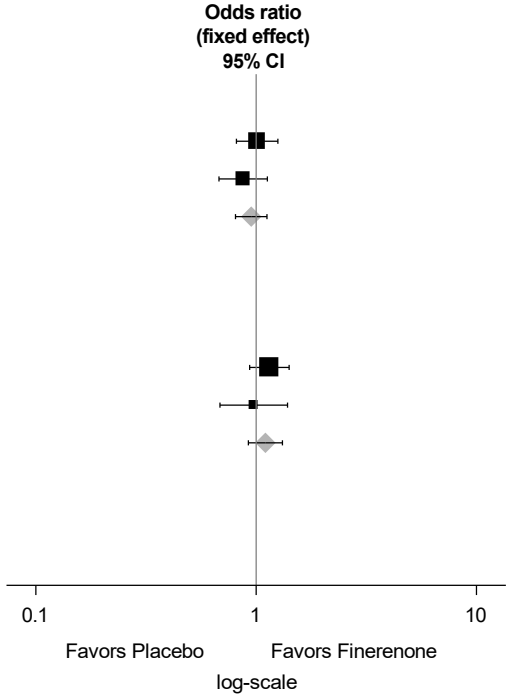
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.

Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12.2: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by History of CVD
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

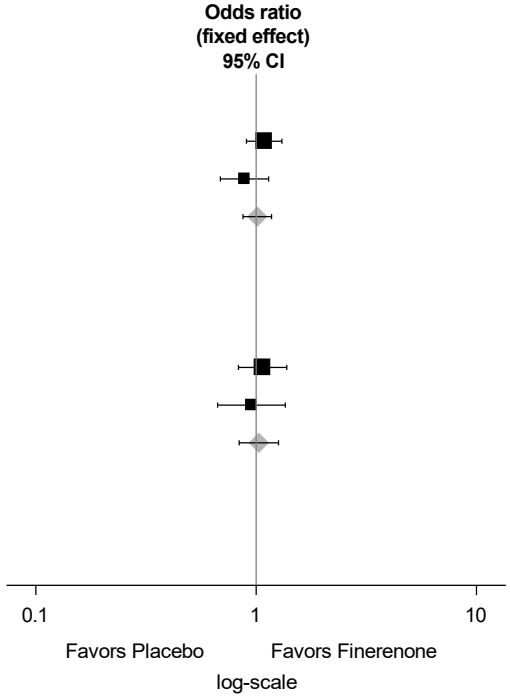
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	196 / 1215	194 / 1213	57.6	1.01 [0.81,1.25]	
FIGARO-DKD	138 / 865	152 / 851	42.4	0.87 [0.68,1.12]	
Total	334 / 2080	346 / 2064		0.95 [0.81,1.12]	Z=-0.62, p=0.5379
Heterogeneity:	Q=0.74 (df=1)	p=0.3895	I^2=0.0%		
Absent					
FIDELIO-DKD	226 / 1407	201 / 1407	74.6	1.15 [0.93,1.41]	
FIGARO-DKD	70 / 494	74 / 511	25.4	0.97 [0.68,1.39]	
Total	296 / 1901	275 / 1918		1.10 [0.92,1.32]	Z=1.06, p=0.2876
Heterogeneity:	Q=0.61 (df=1)	p=0.4331	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.44 (df=1)	p=0.2305	I^2=30.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12.3: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Serum Potassium (mmol/L) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

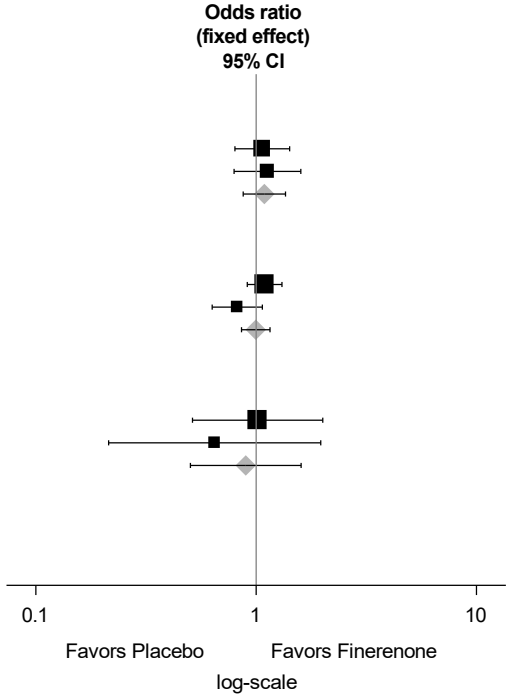
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	277 / 1737	253 / 1703	65.0	1.09 [0.90,1.31]	
FIGARO-DKD	135 / 924	151 / 932	35.0	0.88 [0.69,1.14]	
Total	412 / 2661	404 / 2635		1.01 [0.87,1.17]	Z=0.15, p=0.8792
Heterogeneity:	Q=1.66 (df=1)	p=0.1973	I^2=39.8%		
> 4.5					
FIDELIO-DKD	145 / 884	142 / 916	66.3	1.07 [0.83,1.38]	
FIGARO-DKD	73 / 435	75 / 429	33.7	0.95 [0.67,1.36]	
Total	218 / 1319	217 / 1345		1.03 [0.84,1.26]	Z=0.27, p=0.7902
Heterogeneity:	Q=0.28 (df=1)	p=0.5993	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8998	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12.4: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Systolic Blood Pressure (mmHg) Category at Baseline
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	114 / 724	108 / 724	59.8	1.07 [0.80,1.42]	
FIGARO-DKD	78 / 494	71 / 497	40.2	1.12 [0.79,1.59]	
Total	192 / 1218	179 / 1221		1.09 [0.87,1.36]	Z=0.76, p=0.4483
Heterogeneity:	Q=0.05 (df=1)	p=0.8147	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	288 / 1762	268 / 1766	67.7	1.09 [0.91,1.31]	
FIGARO-DKD	123 / 831	145 / 830	32.3	0.82 [0.63,1.07]	
Total	411 / 2593	413 / 2596		1.00 [0.86,1.16]	Z=-0.06, p=0.9536
Heterogeneity:	Q=3.09 (df=1)	p=0.0790	I^2=67.6%		
>= 160					
FIDELIO-DKD	20 / 133	19 / 128	72.6	1.02 [0.51,2.01]	
FIGARO-DKD	7 / 34	10 / 35	27.4	0.65 [0.21,1.96]	
Total	27 / 167	29 / 163		0.90 [0.50,1.60]	Z=-0.37, p=0.7123
Heterogeneity:	Q=0.46 (df=1)	p=0.4988	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=2)	p=0.7297	I^2=0.0%		

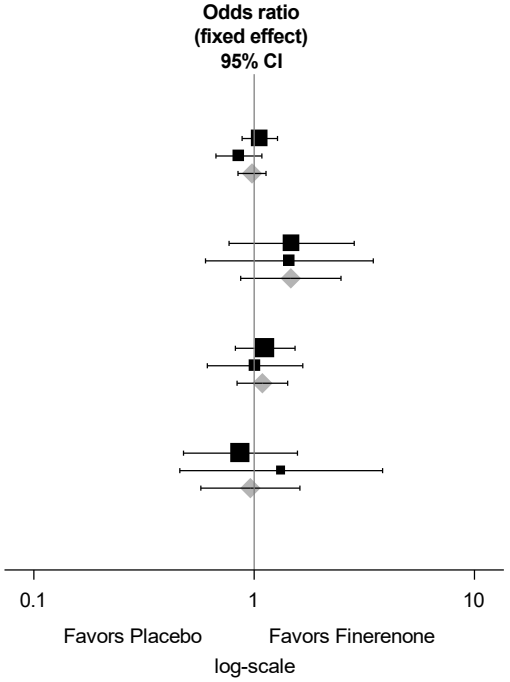


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12.5: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Race

Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	273 / 1637	264 / 1663	62.8	1.06 [0.88,1.28]	
FIGARO-DKD	150 / 1013	168 / 992	37.2	0.85 [0.67,1.08]	
Total	423 / 2650	432 / 2655		0.98 [0.84,1.13]	Z=-0.30, p=0.7623
Heterogeneity:	Q=2.00 (df=1)	p=0.1576	I^2=49.9%		
Black					
FIDELIO-DKD	28 / 130	18 / 115	64.2	1.48 [0.77,2.85]	
FIGARO-DKD	12 / 43	15 / 71	35.8	1.45 [0.60,3.47]	
Total	40 / 173	33 / 186		1.47 [0.87,2.48]	Z=1.43, p=0.1518
Heterogeneity:	Q=0.00 (df=1)	p=0.9666	I^2=0.0%		
Asian					
FIDELIO-DKD	96 / 678	87 / 679	71.9	1.12 [0.82,1.53]	
FIGARO-DKD	36 / 251	36 / 253	28.1	1.01 [0.61,1.66]	
Total	132 / 929	123 / 932		1.09 [0.84,1.42]	Z=0.63, p=0.5255
Heterogeneity:	Q=0.13 (df=1)	p=0.7235	I^2=0.0%		
Others					
FIDELIO-DKD	25 / 177	26 / 163	76.0	0.87 [0.48,1.57]	
FIGARO-DKD	10 / 52	7 / 46	24.0	1.33 [0.46,3.83]	
Total	35 / 229	33 / 209		0.96 [0.57,1.61]	Z=-0.15, p=0.8802
Heterogeneity:	Q=0.47 (df=1)	p=0.4925	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.46 (df=3)	p=0.4828	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.

Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.

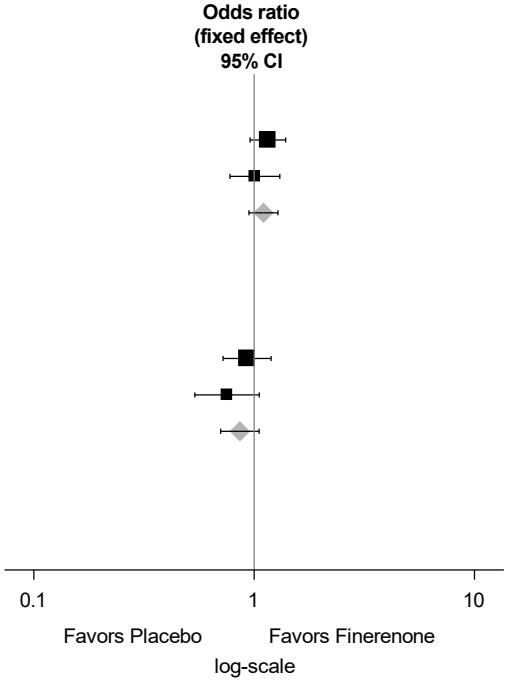
Analysis is based on all post-baseline assessments available for this parameter.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure A3.3.12.6: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Sex
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

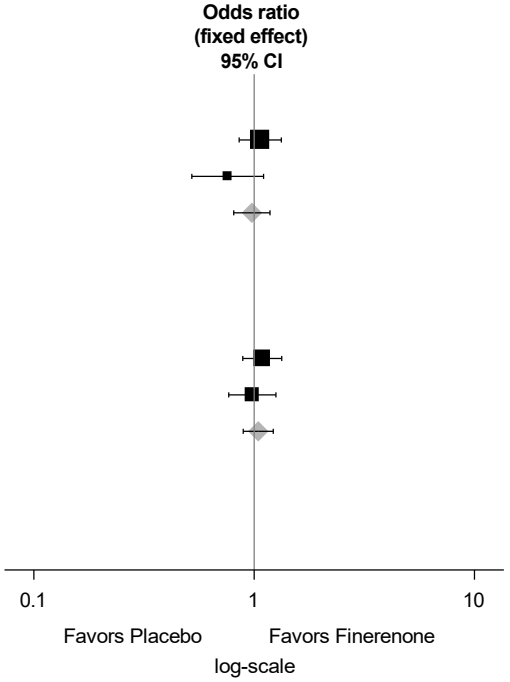
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	268 / 1800	247 / 1876	66.1	1.15 [0.96,1.39]	
FIGARO-DKD	131 / 917	133 / 937	33.9	1.01 [0.78,1.31]	
Total	399 / 2717	380 / 2813		1.10 [0.95,1.28]	Z=1.26, p=0.2091
Heterogeneity:	Q=0.69 (df=1)	p=0.4071	I^2=0.0%		
Female					
FIDELIO-DKD	154 / 822	148 / 744	64.2	0.93 [0.72,1.19]	
FIGARO-DKD	77 / 442	93 / 425	35.8	0.75 [0.54,1.05]	
Total	231 / 1264	241 / 1169		0.86 [0.70,1.05]	Z=-1.46, p=0.1456
Heterogeneity:	Q=0.95 (df=1)	p=0.3288	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.68 (df=1)	p=0.0551	I^2=72.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.12.7: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Age Group (years)
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

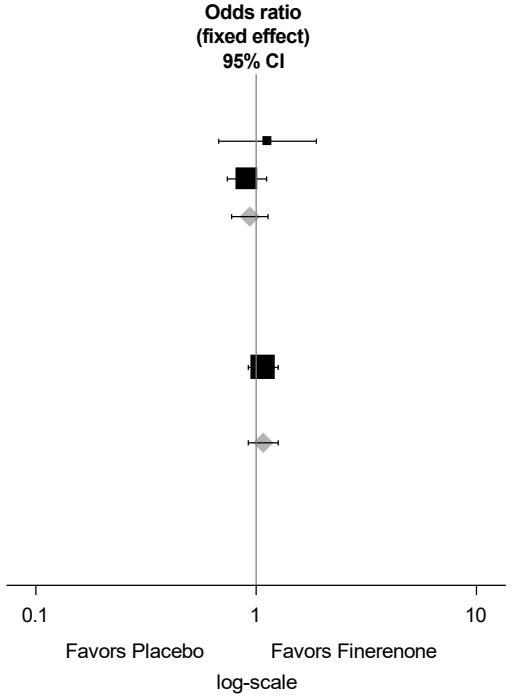
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	200 / 1106	185 / 1078	74.4	1.07 [0.85,1.33]	
FIGARO-DKD	62 / 337	77 / 336	25.6	0.76 [0.52,1.10]	
Total	262 / 1443	262 / 1414		0.98 [0.81,1.18]	Z=-0.25, p=0.8036
Heterogeneity:	Q=2.35 (df=1)	p=0.1253	I^2=57.4%		
>= 65					
FIDELIO-DKD	222 / 1516	210 / 1542	59.5	1.09 [0.89,1.33]	
FIGARO-DKD	146 / 1022	149 / 1026	40.5	0.98 [0.77,1.26]	
Total	368 / 2538	359 / 2568		1.04 [0.89,1.22]	Z=0.53, p=0.5957
Heterogeneity:	Q=0.40 (df=1)	p=0.5251	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5961	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A3.3.12.8: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by Type of Albuminuria at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

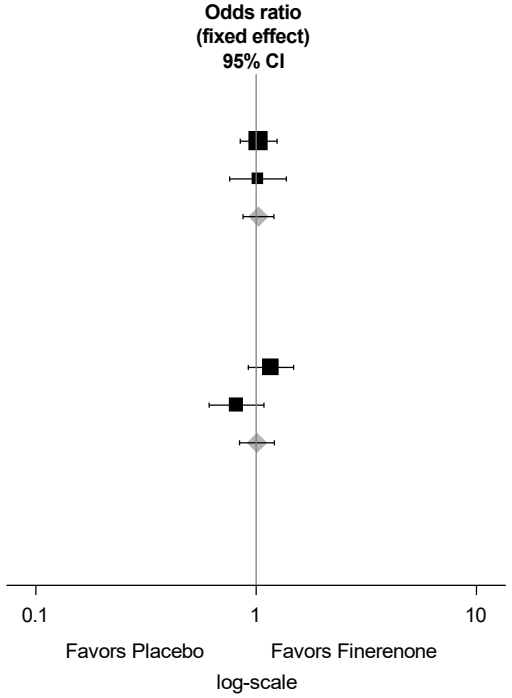
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	37 / 210	34 / 213	13.9	1.13 [0.68,1.88]	
FIGARO-DKD	208 / 1359	226 / 1362	86.1	0.91 [0.74,1.12]	
Total	245 / 1569	260 / 1575		0.94 [0.77,1.13]	Z=-0.68, p=0.4960
Heterogeneity:	Q=0.59 (df=1)	p=0.4442	I^2=0.0%		
Very High					
FIDELIO-DKD	385 / 2412	361 / 2407	100.0	1.08 [0.92,1.26]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	385 / 2412	361 / 2407		1.08 [0.92,1.26]	Z=0.92, p=0.3550
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.24 (df=1)	p=0.2658	I^2=19.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A3.3.12.9: KDQoL-36 - Forestplot for Odds Ratio of Proportion of Subjects with at least one Improvement of Effects of Kidney Disease on Daily Life of at least MID=15 by eGFR (mL/min/1.73m2) Category at Screening
Full Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	250 / 1559	243 / 1549	70.2	1.03 [0.85,1.24]	
FIGARO-DKD	107 / 639	104 / 631	29.8	1.02 [0.76,1.37]	
Total	357 / 2198	347 / 2180		1.02 [0.87,1.20]	Z=0.29, p=0.7707
Heterogeneity:	Q=0.00 (df=1)	p=0.9685	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	172 / 1063	152 / 1071	59.4	1.17 [0.92,1.48]	
FIGARO-DKD	101 / 720	122 / 731	40.6	0.81 [0.61,1.08]	
Total	273 / 1783	274 / 1802		1.01 [0.84,1.21]	Z=0.09, p=0.9295
Heterogeneity:	Q=3.60 (df=1)	p=0.0578	I^2=72.2%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8989	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, DF=degrees of freedom, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, KDQoL=Kidney Disease Quality of Life, MID=minimal important difference, N=number of subjects, OR=odds ratio, SoC=standard of care.
Note: For 'Total' the OR is estimated by a GLM with factors treatment group and study using a binomial distribution and logit as link function.
Analysis is based on all post-baseline assessments available for this parameter.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Any TEAE	3482(87.6%)	3492(88.0%)
Infections And Infestations	1803(45.4%)	1816(45.8%)
Nasopharyngitis	366(9.2%)	358(9.0%)
Urinary tract infection	274(6.9%)	286(7.2%)
Upper respiratory tract infection	263(6.6%)	244(6.2%)
Bronchitis	206(5.2%)	205(5.2%)
Pneumonia	176(4.4%)	252(6.4%)
Influenza	157(4.0%)	156(3.9%)
Cellulitis	112(2.8%)	88(2.2%)
Gastroenteritis	73(1.8%)	76(1.9%)
Respiratory tract infection	70(1.8%)	63(1.6%)
Conjunctivitis	67(1.7%)	53(1.3%)
Herpes zoster	57(1.4%)	55(1.4%)
Pharyngitis	53(1.3%)	53(1.3%)
Sinusitis	45(1.1%)	47(1.2%)
Cystitis	44(1.1%)	46(1.2%)
Localised infection	35(0.9%)	27(0.7%)
Erysipelas	32(0.8%)	32(0.8%)
Lower respiratory tract infection	29(0.7%)	37(0.9%)
Viral infection	27(0.7%)	33(0.8%)
Sepsis	27(0.7%)	28(0.7%)
Osteomyelitis	26(0.7%)	20(0.5%)
Periodontitis	25(0.6%)	37(0.9%)
Rhinitis	25(0.6%)	26(0.7%)
Wound infection	23(0.6%)	12(0.3%)
Onychomycosis	21(0.5%)	30(0.8%)
Gingivitis	21(0.5%)	20(0.5%)
COVID-19	20(0.5%)	24(0.6%)
Tooth abscess	20(0.5%)	13(0.3%)
Otitis externa	17(0.4%)	18(0.5%)
Pyelonephritis	17(0.4%)	16(0.4%)
Gastroenteritis viral	17(0.4%)	15(0.4%)
Paronychia	17(0.4%)	10(0.3%)
Tinea pedis	16(0.4%)	24(0.6%)
Skin infection	16(0.4%)	16(0.4%)
Helicobacter infection	16(0.4%)	13(0.3%)
Ear infection	16(0.4%)	12(0.3%)
Respiratory tract infection viral	15(0.4%)	19(0.5%)
Tooth infection	15(0.4%)	19(0.5%)
Fungal skin infection	15(0.4%)	13(0.3%)
Acute sinusitis	14(0.4%)	13(0.3%)
Otitis media	12(0.3%)	14(0.4%)
Abscess limb	12(0.3%)	9(0.2%)
Folliculitis	12(0.3%)	9(0.2%)
Pyelonephritis chronic	12(0.3%)	7(0.2%)
Diverticulitis	11(0.3%)	15(0.4%)
Tonsillitis	11(0.3%)	14(0.4%)
Infected skin ulcer	11(0.3%)	9(0.2%)
Postoperative wound infection	11(0.3%)	9(0.2%)
Viral upper respiratory tract infection	10(0.3%)	12(0.3%)
Urosepsis	10(0.3%)	10(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Subcutaneous abscess	10(0.3%)	8(0.2%)
Gangrene	10(0.3%)	6(0.2%)
Epididymitis	9(0.2%)	7(0.2%)
Dermatophytosis of nail	8(0.2%)	5(0.1%)
Hordeolum	8(0.2%)	4(0.1%)
Pyelonephritis acute	8(0.2%)	2(0.1%)
Acarodermatitis	7(0.2%)	7(0.2%)
Oral candidiasis	7(0.2%)	7(0.2%)
Laryngitis	7(0.2%)	6(0.2%)
Urinary tract infection bacterial	7(0.2%)	6(0.2%)
Soft tissue infection	7(0.2%)	2(0.1%)
Diabetic foot infection	6(0.2%)	13(0.3%)
Infection	6(0.2%)	10(0.3%)
Escherichia urinary tract infection	6(0.2%)	8(0.2%)
Tracheobronchitis	6(0.2%)	7(0.2%)
Pharyngotonsillitis	6(0.2%)	4(0.1%)
Pulmonary sepsis	6(0.2%)	3(0.1%)
Eye infection	5(0.1%)	9(0.2%)
Septic shock	5(0.1%)	9(0.2%)
Fungal infection	5(0.1%)	4(0.1%)
Asymptomatic bacteriuria	5(0.1%)	3(0.1%)
Bacteraemia	5(0.1%)	3(0.1%)
Oral herpes	5(0.1%)	2(0.1%)
Febrile infection	5(0.1%)	1(0.0%)
Vaginal infection	5(0.1%)	1(0.0%)
Arthritis bacterial	5(0.1%)	0
Infected dermal cyst	4(0.1%)	6(0.2%)
Chronic sinusitis	4(0.1%)	5(0.1%)
Labyrinthitis	4(0.1%)	5(0.1%)
Vulvovaginal candidiasis	4(0.1%)	5(0.1%)
Pulmonary tuberculosis	4(0.1%)	4(0.1%)
Abscess	4(0.1%)	3(0.1%)
Groin abscess	4(0.1%)	3(0.1%)
Herpes dermatitis	4(0.1%)	3(0.1%)
Oesophageal candidiasis	4(0.1%)	3(0.1%)
Pulpitis dental	4(0.1%)	3(0.1%)
COVID-19 pneumonia	4(0.1%)	2(0.1%)
Infected bite	4(0.1%)	2(0.1%)
Oral fungal infection	4(0.1%)	2(0.1%)
Hepatitis C	4(0.1%)	1(0.0%)
Furuncle	3(0.1%)	11(0.3%)
Tracheitis	3(0.1%)	5(0.1%)
Helicobacter gastritis	3(0.1%)	4(0.1%)
Orchitis	3(0.1%)	4(0.1%)
Otitis media acute	3(0.1%)	4(0.1%)
Tinea cruris	3(0.1%)	4(0.1%)
Anal abscess	3(0.1%)	3(0.1%)
Body tinea	3(0.1%)	3(0.1%)
Abdominal abscess	3(0.1%)	2(0.1%)
Groin infection	3(0.1%)	2(0.1%)
Herpes ophthalmic	3(0.1%)	2(0.1%)
Sialoadenitis	3(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Parotitis	3(0.1%)	1(0.0%)
Bacteriuria	3(0.1%)	0
Appendicitis	2(0.1%)	7(0.2%)
Tinea infection	2(0.1%)	7(0.2%)
Liver abscess	2(0.1%)	6(0.2%)
Pneumonia bacterial	2(0.1%)	6(0.2%)
Atypical pneumonia	2(0.1%)	5(0.1%)
Otitis media chronic	2(0.1%)	5(0.1%)
Candida infection	2(0.1%)	3(0.1%)
Bronchitis viral	2(0.1%)	2(0.1%)
Clostridium difficile infection	2(0.1%)	2(0.1%)
Conjunctivitis viral	2(0.1%)	2(0.1%)
Impetigo	2(0.1%)	2(0.1%)
Pyuria	2(0.1%)	2(0.1%)
Staphylococcal sepsis	2(0.1%)	2(0.1%)
Tuberculosis	2(0.1%)	2(0.1%)
Urethritis	2(0.1%)	2(0.1%)
Vulvovaginal mycotic infection	2(0.1%)	2(0.1%)
Abdominal wall abscess	2(0.1%)	1(0.0%)
Abscess neck	2(0.1%)	1(0.0%)
Enteritis infectious	2(0.1%)	1(0.0%)
Gastritis viral	2(0.1%)	1(0.0%)
Osteomyelitis chronic	2(0.1%)	1(0.0%)
Pharyngitis streptococcal	2(0.1%)	1(0.0%)
Staphylococcal infection	2(0.1%)	1(0.0%)
Urinary tract infection fungal	2(0.1%)	1(0.0%)
Viral diarrhoea	2(0.1%)	1(0.0%)
Appendicitis perforated	2(0.1%)	0
Aspergilloma	2(0.1%)	0
Diarrhoea infectious	2(0.1%)	0
Emphysematous pyelonephritis	2(0.1%)	0
Kidney infection	2(0.1%)	0
Peritonitis bacterial	2(0.1%)	0
Pneumonia streptococcal	2(0.1%)	0
Prostatic abscess	2(0.1%)	0
Pyelocystitis	2(0.1%)	0
Pyoderma	2(0.1%)	0
Tinea versicolour	2(0.1%)	0
Wound infection bacterial	2(0.1%)	0
Herpes simplex	1(0.0%)	4(0.1%)
Myringitis	1(0.0%)	4(0.1%)
Nail infection	1(0.0%)	4(0.1%)
Conjunctivitis bacterial	1(0.0%)	3(0.1%)
Ear infection fungal	1(0.0%)	3(0.1%)
Gastroenteritis salmonella	1(0.0%)	3(0.1%)
Large intestine infection	1(0.0%)	3(0.1%)
Mastoiditis	1(0.0%)	3(0.1%)
Post procedural infection	1(0.0%)	3(0.1%)
Carbuncle	1(0.0%)	2(0.1%)
Clostridium difficile colitis	1(0.0%)	2(0.1%)
Dengue fever	1(0.0%)	2(0.1%)
Endocarditis	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Genitourinary tract infection	1(0.0%)	2(0.1%)
Gingival abscess	1(0.0%)	2(0.1%)
Infective exacerbation of chronic obstructive airways disease	1(0.0%)	2(0.1%)
Pharyngitis bacterial	1(0.0%)	2(0.1%)
Pneumonia viral	1(0.0%)	2(0.1%)
Abscess oral	1(0.0%)	1(0.0%)
Bacterial sepsis	1(0.0%)	1(0.0%)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Cystitis bacterial	1(0.0%)	1(0.0%)
Dacryocystitis	1(0.0%)	1(0.0%)
Diabetic gangrene	1(0.0%)	1(0.0%)
Eyelid infection	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Fungal oesophagitis	1(0.0%)	1(0.0%)
Gastroenteritis norovirus	1(0.0%)	1(0.0%)
Incision site abscess	1(0.0%)	1(0.0%)
Infective spondylitis	1(0.0%)	1(0.0%)
Injection site infection	1(0.0%)	1(0.0%)
Latent tuberculosis	1(0.0%)	1(0.0%)
Lyme disease	1(0.0%)	1(0.0%)
Lymphangitis	1(0.0%)	1(0.0%)
Medical device site infection	1(0.0%)	1(0.0%)
Ophthalmic herpes simplex	1(0.0%)	1(0.0%)
Oral infection	1(0.0%)	1(0.0%)
Pericoronitis	1(0.0%)	1(0.0%)
Perineal abscess	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Respiratory syncytial virus infection	1(0.0%)	1(0.0%)
Viral pericarditis	1(0.0%)	1(0.0%)
Abdominal infection	1(0.0%)	0
Ascariasis	1(0.0%)	0
Bacterial vaginosis	1(0.0%)	0
Bladder diverticulitis	1(0.0%)	0
Bone abscess	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Bronchiolitis	1(0.0%)	0
Cellulitis staphylococcal	1(0.0%)	0
Chest wall abscess	1(0.0%)	0
Dermatitis infected	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Endophthalmitis	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
External ear cellulitis	1(0.0%)	0
Eye infection bacterial	1(0.0%)	0
Eye infection viral	1(0.0%)	0
Eyelid folliculitis	1(0.0%)	0
Gastroenteritis bacterial	1(0.0%)	0
Genital herpes	1(0.0%)	0
Genital infection	1(0.0%)	0
Genital infection fungal	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Helminthic infection	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hepatic infection	1(0.0%)	0
Herpes zoster infection neurological	1(0.0%)	0
Infected cyst	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Infectious pleural effusion	1(0.0%)	0
Infective myositis	1(0.0%)	0
Infective tenosynovitis	1(0.0%)	0
Infusion site infection	1(0.0%)	0
Keratitis bacterial	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Ludwig angina	1(0.0%)	0
Mastitis bacterial	1(0.0%)	0
Meningitis	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oropharyngitis fungal	1(0.0%)	0
Otitis externa fungal	1(0.0%)	0
Otosalpingitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pharyngeal abscess	1(0.0%)	0
Pilonidal cyst	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Prostate infection	1(0.0%)	0
Pseudomonas infection	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Scrotal cellulitis	1(0.0%)	0
Septic rash	1(0.0%)	0
Sinusitis bacterial	1(0.0%)	0
Skin candida	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Sputum purulent	1(0.0%)	0
Staphylococcal bacteraemia	1(0.0%)	0
Stitch abscess	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Suspected COVID-19	1(0.0%)	0
Tongue fungal infection	1(0.0%)	0
Tracheobronchitis bacterial	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Varicella zoster virus infection	1(0.0%)	0
Vestibular neuronitis	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral labyrinthitis	1(0.0%)	0
Viral pharyngitis	1(0.0%)	0
Vulvitis	1(0.0%)	0
Vulvovaginitis	1(0.0%)	0
Intervertebral discitis	0	4(0.1%)
Acute hepatitis B	0	3(0.1%)
Gastrointestinal infection	0	3(0.1%)
Infective exacerbation of bronchiectasis	0	3(0.1%)
Bacterial vulvovaginitis	0	2(0.1%)
Breast abscess	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Bronchitis bacterial	0	2(0.1%)
Erythema migrans	0	2(0.1%)
Fungal pharyngitis	0	2(0.1%)
Gastrointestinal viral infection	0	2(0.1%)
Genital infection female	0	2(0.1%)
Hepatitis B	0	2(0.1%)
Infected seroma	0	2(0.1%)
Medical device site joint infection	0	2(0.1%)
Nail bed infection	0	2(0.1%)
Ophthalmic herpes zoster	0	2(0.1%)
Penile infection	0	2(0.1%)
Periorbital cellulitis	0	2(0.1%)
Root canal infection	0	2(0.1%)
Scrotal abscess	0	2(0.1%)
Skin bacterial infection	0	2(0.1%)
Urinary tract infection enterococcal	0	2(0.1%)
Alveolar osteitis	0	1(0.0%)
American trypanosomiasis	0	1(0.0%)
Anorectal infection bacterial	0	1(0.0%)
Arteriosclerotic gangrene	0	1(0.0%)
Arthritis infective	0	1(0.0%)
Bacterial disease carrier	0	1(0.0%)
Bacterial rhinitis	0	1(0.0%)
Bacterial tracheitis	0	1(0.0%)
Bartholinitis	0	1(0.0%)
Beta haemolytic streptococcal infection	0	1(0.0%)
Blister infected	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Burn infection	0	1(0.0%)
Chronic hepatitis B	0	1(0.0%)
Chronic hepatitis C	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Cryptococcosis	0	1(0.0%)
Dental fistula	0	1(0.0%)
Dermatophytosis	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Dysentery	0	1(0.0%)
Eczema herpeticum	0	1(0.0%)
Eczema infected	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Enterococcal infection	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Escherichia sepsis	0	1(0.0%)
Eye abscess	0	1(0.0%)
Fungal balanitis	0	1(0.0%)
Genital candidiasis	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
HIV infection	0	1(0.0%)
Haemophilus infection	0	1(0.0%)
Herpes virus infection	0	1(0.0%)
Herpes zoster reactivation	0	1(0.0%)
Joint abscess	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Klebsiella bacteraemia	0	1(0.0%)
Klebsiella infection	0	1(0.0%)
Laryngitis viral	0	1(0.0%)
Lower respiratory tract infection viral	0	1(0.0%)
Mastitis	0	1(0.0%)
Nasal herpes	0	1(0.0%)
Necrotising fasciitis	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Omphalitis	0	1(0.0%)
Parasitic gastroenteritis	0	1(0.0%)
Peritonitis	0	1(0.0%)
Pertussis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Prostatitis Escherichia coli	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Pustule	0	1(0.0%)
Renal abscess	0	1(0.0%)
Retinitis	0	1(0.0%)
Rotavirus infection	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Streptococcal bacteraemia	0	1(0.0%)
Subacute endocarditis	0	1(0.0%)
Sweat gland infection	0	1(0.0%)
Tinea blanca	0	1(0.0%)
Trichomoniasis	0	1(0.0%)
Upper respiratory tract infection bacterial	0	1(0.0%)
Urinary tract candidiasis	0	1(0.0%)
Varicella	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	1503(37.8%)	1331(33.6%)
Hyperkalaemia	614(15.5%)	292(7.4%)
Hypoglycaemia	232(5.8%)	267(6.7%)
Hyperuricaemia	174(4.4%)	143(3.6%)
Gout	124(3.1%)	131(3.3%)
Hyperglycaemia	114(2.9%)	105(2.6%)
Diabetes mellitus inadequate control	90(2.3%)	99(2.5%)
Diabetes mellitus	83(2.1%)	110(2.8%)
Vitamin D deficiency	68(1.7%)	73(1.8%)
Dehydration	55(1.4%)	48(1.2%)
Type 2 diabetes mellitus	52(1.3%)	54(1.4%)
Decreased appetite	48(1.2%)	41(1.0%)
Hyponatraemia	48(1.2%)	35(0.9%)
Hypokalaemia	43(1.1%)	95(2.4%)
Metabolic acidosis	42(1.1%)	29(0.7%)
Hypertriglyceridaemia	36(0.9%)	35(0.9%)
Hyperlipidaemia	34(0.9%)	35(0.9%)
Dyslipidaemia	29(0.7%)	40(1.0%)
Hypomagnesaemia	23(0.6%)	19(0.5%)
Diabetic metabolic decompensation	22(0.6%)	36(0.9%)
Vitamin B12 deficiency	20(0.5%)	11(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Iron deficiency	19(0.5%)	32(0.8%)
Fluid overload	16(0.4%)	21(0.5%)
Hyperphosphataemia	14(0.4%)	14(0.4%)
Hypocalcaemia	13(0.3%)	20(0.5%)
Hypercalcaemia	13(0.3%)	6(0.2%)
Hypovolaemia	12(0.3%)	3(0.1%)
Obesity	11(0.3%)	12(0.3%)
Folate deficiency	11(0.3%)	6(0.2%)
Diabetic ketoacidosis	10(0.3%)	14(0.4%)
Acidosis	9(0.2%)	6(0.2%)
Hypercholesterolaemia	8(0.2%)	12(0.3%)
Metabolic disorder	6(0.2%)	6(0.2%)
Fluid retention	6(0.2%)	5(0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	4(0.1%)	8(0.2%)
Hypernatraemia	4(0.1%)	7(0.2%)
Hypervolaemia	4(0.1%)	3(0.1%)
Vitamin B complex deficiency	4(0.1%)	2(0.1%)
Overweight	4(0.1%)	1(0.0%)
Hypoproteinaemia	3(0.1%)	7(0.2%)
Hypoalbuminaemia	3(0.1%)	5(0.1%)
Ketosis	3(0.1%)	0
Malnutrition	2(0.1%)	3(0.1%)
Hypophosphataemia	2(0.1%)	1(0.0%)
Hypovitaminosis	2(0.1%)	1(0.0%)
Ketoacidosis	2(0.1%)	1(0.0%)
Diabetic complication	2(0.1%)	0
Hypoglycaemia unawareness	2(0.1%)	0
Polydipsia	2(0.1%)	0
Abnormal loss of weight	1(0.0%)	4(0.1%)
Hyperhomocysteinaemia	1(0.0%)	4(0.1%)
Magnesium deficiency	1(0.0%)	2(0.1%)
Metabolic syndrome	1(0.0%)	2(0.1%)
Cachexia	1(0.0%)	1(0.0%)
Lipid metabolism disorder	1(0.0%)	1(0.0%)
Acidosis hyperchloraemic	1(0.0%)	0
Calciphylaxis	1(0.0%)	0
Calcium metabolism disorder	1(0.0%)	0
Decreased insulin requirement	1(0.0%)	0
Food aversion	1(0.0%)	0
Hyperchloraemia	1(0.0%)	0
Hyperferritinaemia	1(0.0%)	0
Hyperlipasaemia	1(0.0%)	0
Hyperphagia	1(0.0%)	0
Hypervitaminosis D	1(0.0%)	0
Hypometabolism	1(0.0%)	0
Lactose intolerance	1(0.0%)	0
Mineral deficiency	1(0.0%)	0
Phosphorus metabolism disorder	1(0.0%)	0
Shock hypoglycaemic	1(0.0%)	0
Vitamin B1 deficiency	1(0.0%)	0
Hypochloraemia	0	3(0.1%)
Increased appetite	0	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hypermagnesaemia	0	2(0.1%)
Metabolic alkalosis	0	2(0.1%)
Tumour lysis syndrome	0	2(0.1%)
Acid-base balance disorder mixed	0	1(0.0%)
Calcium deficiency	0	1(0.0%)
Central obesity	0	1(0.0%)
Diabetic ketosis	0	1(0.0%)
Food intolerance	0	1(0.0%)
Hyperalbuminaemia	0	1(0.0%)
Hyperosmolar state	0	1(0.0%)
Hyperproteinaemia	0	1(0.0%)
Hypervitaminosis B12	0	1(0.0%)
Lactic acidosis	0	1(0.0%)
Pancreatogenous diabetes	0	1(0.0%)
Periarthritis calcarea	0	1(0.0%)
Protein deficiency	0	1(0.0%)
Pseudohyponatraemia	0	1(0.0%)
Weight loss poor	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	1170(29.4%)	1200(30.3%)
Arthralgia	308(7.8%)	294(7.4%)
Back pain	274(6.9%)	281(7.1%)
Pain in extremity	162(4.1%)	167(4.2%)
Muscle spasms	160(4.0%)	131(3.3%)
Osteoarthritis	121(3.0%)	135(3.4%)
Myalgia	80(2.0%)	61(1.5%)
Spinal osteoarthritis	46(1.2%)	63(1.6%)
Neck pain	44(1.1%)	51(1.3%)
Arthritis	42(1.1%)	34(0.9%)
Gouty arthritis	27(0.7%)	32(0.8%)
Osteoporosis	24(0.6%)	21(0.5%)
Flank pain	23(0.6%)	25(0.6%)
Rotator cuff syndrome	23(0.6%)	25(0.6%)
Tendonitis	23(0.6%)	23(0.6%)
Intervertebral disc protrusion	22(0.6%)	41(1.0%)
Bursitis	21(0.5%)	29(0.7%)
Muscular weakness	21(0.5%)	24(0.6%)
Trigger finger	20(0.5%)	18(0.5%)
Lumbar spinal stenosis	19(0.5%)	24(0.6%)
Periarthritis	18(0.5%)	18(0.5%)
Joint swelling	15(0.4%)	25(0.6%)
Tenosynovitis	14(0.4%)	8(0.2%)
Musculoskeletal chest pain	13(0.3%)	15(0.4%)
Musculoskeletal pain	13(0.3%)	13(0.3%)
Exostosis	13(0.3%)	10(0.3%)
Intervertebral disc disorder	13(0.3%)	9(0.2%)
Plantar fasciitis	12(0.3%)	14(0.4%)
Spinal pain	10(0.3%)	12(0.3%)
Rhabdomyolysis	10(0.3%)	8(0.2%)
Tendon disorder	10(0.3%)	8(0.2%)
Musculoskeletal stiffness	10(0.3%)	7(0.2%)
Spondylolisthesis	8(0.2%)	4(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Spinal stenosis	7(0.2%)	13(0.3%)
Intervertebral disc degeneration	7(0.2%)	7(0.2%)
Synovial cyst	7(0.2%)	6(0.2%)
Arthropathy	7(0.2%)	2(0.1%)
Foot deformity	6(0.2%)	5(0.1%)
Scoliosis	6(0.2%)	3(0.1%)
Polymyalgia rheumatica	5(0.1%)	7(0.2%)
Osteopenia	5(0.1%)	6(0.2%)
Tenosynovitis stenosans	5(0.1%)	6(0.2%)
Dupuytren's contracture	5(0.1%)	5(0.1%)
Rheumatoid arthritis	5(0.1%)	2(0.1%)
Bone pain	4(0.1%)	6(0.2%)
Cervical spinal stenosis	4(0.1%)	4(0.1%)
Chondrocalcinosis pyrophosphate	4(0.1%)	4(0.1%)
Joint effusion	4(0.1%)	4(0.1%)
Limb mass	4(0.1%)	3(0.1%)
Limb discomfort	4(0.1%)	2(0.1%)
Muscle fatigue	4(0.1%)	2(0.1%)
Polyarthritis	4(0.1%)	2(0.1%)
Facet joint syndrome	4(0.1%)	0
Groin pain	3(0.1%)	9(0.2%)
Neuropathic arthropathy	3(0.1%)	6(0.2%)
Costochondritis	3(0.1%)	5(0.1%)
Mobility decreased	3(0.1%)	3(0.1%)
Kyphosis	3(0.1%)	1(0.0%)
Pain in jaw	3(0.1%)	0
Osteitis	2(0.1%)	8(0.2%)
Musculoskeletal discomfort	2(0.1%)	4(0.1%)
Spondylitis	2(0.1%)	4(0.1%)
Chondrocalcinosis	2(0.1%)	3(0.1%)
Coccydynia	2(0.1%)	3(0.1%)
Joint stiffness	2(0.1%)	3(0.1%)
Osteolysis	2(0.1%)	3(0.1%)
Myalgia intercostal	2(0.1%)	2(0.1%)
Myopathy	2(0.1%)	2(0.1%)
Tendon pain	2(0.1%)	2(0.1%)
Back disorder	2(0.1%)	1(0.0%)
Fracture pain	2(0.1%)	1(0.0%)
Meniscal degeneration	2(0.1%)	1(0.0%)
Musculoskeletal disorder	2(0.1%)	1(0.0%)
Myofascial pain syndrome	2(0.1%)	1(0.0%)
Osteosclerosis	2(0.1%)	1(0.0%)
Bone swelling	2(0.1%)	0
Clubbing	2(0.1%)	0
Periostitis	2(0.1%)	0
Sacroiliitis	2(0.1%)	0
Muscle contracture	1(0.0%)	7(0.2%)
Vertebral foraminal stenosis	1(0.0%)	4(0.1%)
Joint range of motion decreased	1(0.0%)	3(0.1%)
Osteochondrosis	1(0.0%)	3(0.1%)
Fibromyalgia	1(0.0%)	2(0.1%)
Joint contracture	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Muscle atrophy	1(0.0%)	2(0.1%)
Arthritis reactive	1(0.0%)	1(0.0%)
Chronic kidney disease-mineral and bone disorder	1(0.0%)	1(0.0%)
Fasciitis	1(0.0%)	1(0.0%)
Fistula	1(0.0%)	1(0.0%)
Gouty tophus	1(0.0%)	1(0.0%)
Immobilisation syndrome	1(0.0%)	1(0.0%)
Muscle twitching	1(0.0%)	1(0.0%)
Osteochondritis	1(0.0%)	1(0.0%)
Osteonecrosis	1(0.0%)	1(0.0%)
Rheumatic disorder	1(0.0%)	1(0.0%)
Synovitis	1(0.0%)	1(0.0%)
Tendon calcification	1(0.0%)	1(0.0%)
Torticollis	1(0.0%)	1(0.0%)
Vertebral osteophyte	1(0.0%)	1(0.0%)
Chest wall mass	1(0.0%)	0
Connective tissue inflammation	1(0.0%)	0
Enthesopathy	1(0.0%)	0
Finger deformity	1(0.0%)	0
Haemarthrosis	1(0.0%)	0
Haematoma muscle	1(0.0%)	0
Hypercreatinaemia	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Joint noise	1(0.0%)	0
Ligament pain	1(0.0%)	0
Ligamentitis	1(0.0%)	0
Mandibular mass	1(0.0%)	0
Metatarsalgia	1(0.0%)	0
Muscle discomfort	1(0.0%)	0
Muscle rigidity	1(0.0%)	0
Myositis	1(0.0%)	0
Neuropathic muscular atrophy	1(0.0%)	0
Palindromic rheumatism	1(0.0%)	0
Soft tissue swelling	1(0.0%)	0
Spinal flattening	1(0.0%)	0
Vertebral lateral recess stenosis	1(0.0%)	0
Bone formation increased	0	3(0.1%)
Osteoarthropathy	0	3(0.1%)
Spondyloarthropathy	0	3(0.1%)
Crystal arthropathy	0	2(0.1%)
Muscle haemorrhage	0	2(0.1%)
Psoriatic arthropathy	0	2(0.1%)
Sjogren's syndrome	0	2(0.1%)
Spinal instability	0	2(0.1%)
Spinal ligament ossification	0	2(0.1%)
Systemic lupus erythematosus	0	2(0.1%)
Temporomandibular joint syndrome	0	2(0.1%)
Amyotrophy	0	1(0.0%)
Articular calcification	0	1(0.0%)
Axillary mass	0	1(0.0%)
Bone callus excessive	0	1(0.0%)
Bursa disorder	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Chondritis	0	1(0.0%)
Chondropathy	0	1(0.0%)
Connective tissue disorder	0	1(0.0%)
Diastasis recti abdominis	0	1(0.0%)
Intervertebral disc calcification	0	1(0.0%)
Jaw cyst	0	1(0.0%)
Ligament calcification	0	1(0.0%)
Muscle disorder	0	1(0.0%)
Muscle swelling	0	1(0.0%)
Nodal osteoarthritis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Patellofemoral pain syndrome	0	1(0.0%)
Rheumatoid nodule	0	1(0.0%)
Soft tissue mass	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal disorder	0	1(0.0%)
Spinal fusion acquired	0	1(0.0%)
Systemic scleroderma	0	1(0.0%)
Trismus	0	1(0.0%)
Vertebral lesion	0	1(0.0%)
Gastrointestinal Disorders	1116(28.1%)	1127(28.4%)
Diarrhoea	268(6.7%)	278(7.0%)
Constipation	212(5.3%)	234(5.9%)
Nausea	133(3.3%)	132(3.3%)
Vomiting	106(2.7%)	95(2.4%)
Gastrooesophageal reflux disease	77(1.9%)	85(2.1%)
Gastritis	69(1.7%)	54(1.4%)
Abdominal pain upper	65(1.6%)	71(1.8%)
Abdominal pain	63(1.6%)	80(2.0%)
Haemorrhoids	61(1.5%)	45(1.1%)
Large intestine polyp	52(1.3%)	72(1.8%)
Dyspepsia	48(1.2%)	52(1.3%)
Toothache	30(0.8%)	35(0.9%)
Chronic gastritis	30(0.8%)	25(0.6%)
Diverticulum intestinal	25(0.6%)	21(0.5%)
Dental caries	23(0.6%)	17(0.4%)
Abdominal distension	22(0.6%)	15(0.4%)
Gastrointestinal haemorrhage	19(0.5%)	17(0.4%)
Gastritis erosive	18(0.5%)	14(0.4%)
Hiatus hernia	16(0.4%)	28(0.7%)
Abdominal discomfort	16(0.4%)	21(0.5%)
Gastric ulcer	15(0.4%)	13(0.3%)
Rectal haemorrhage	15(0.4%)	11(0.3%)
Gastric polyps	14(0.4%)	11(0.3%)
Umbilical hernia	13(0.3%)	15(0.4%)
Haematochezia	13(0.3%)	11(0.3%)
Periodontal disease	13(0.3%)	10(0.3%)
Dry mouth	12(0.3%)	11(0.3%)
Colitis	12(0.3%)	8(0.2%)
Dysphagia	11(0.3%)	15(0.4%)
Abdominal pain lower	11(0.3%)	14(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Inguinal hernia	10(0.3%)	20(0.5%)
Diverticulum	10(0.3%)	18(0.5%)
Flatulence	10(0.3%)	11(0.3%)
Lower gastrointestinal haemorrhage	10(0.3%)	4(0.1%)
Irritable bowel syndrome	9(0.2%)	14(0.4%)
Duodenal ulcer	9(0.2%)	12(0.3%)
Pancreatitis acute	9(0.2%)	11(0.3%)
Enteritis	8(0.2%)	4(0.1%)
Upper gastrointestinal haemorrhage	7(0.2%)	9(0.2%)
Ascites	7(0.2%)	5(0.1%)
Melaena	7(0.2%)	4(0.1%)
Haematemesis	7(0.2%)	2(0.1%)
Duodenitis	6(0.2%)	11(0.3%)
Peptic ulcer	6(0.2%)	10(0.3%)
Pancreatitis chronic	6(0.2%)	8(0.2%)
Oesophagitis	6(0.2%)	6(0.2%)
Pancreatic cyst	6(0.2%)	6(0.2%)
Mouth ulceration	6(0.2%)	4(0.1%)
Enterocolitis	6(0.2%)	3(0.1%)
Haemorrhoidal haemorrhage	6(0.2%)	2(0.1%)
Gastrointestinal disorder	5(0.1%)	6(0.2%)
Tooth disorder	5(0.1%)	6(0.2%)
Intestinal obstruction	5(0.1%)	5(0.1%)
Pancreatitis	5(0.1%)	4(0.1%)
Gingival pain	4(0.1%)	5(0.1%)
Anal fissure	4(0.1%)	4(0.1%)
Food poisoning	4(0.1%)	4(0.1%)
Epigastric discomfort	4(0.1%)	3(0.1%)
Anal incontinence	4(0.1%)	2(0.1%)
Ileus	4(0.1%)	1(0.0%)
Proctalgia	4(0.1%)	0
Abdominal hernia	3(0.1%)	6(0.2%)
Rectal polyp	3(0.1%)	6(0.2%)
Barrett's oesophagus	3(0.1%)	4(0.1%)
Faecaloma	3(0.1%)	4(0.1%)
Gingival swelling	3(0.1%)	4(0.1%)
Angular cheilitis	3(0.1%)	2(0.1%)
Duodenal polyp	3(0.1%)	2(0.1%)
Small intestinal obstruction	3(0.1%)	2(0.1%)
Gastroduodenal ulcer	3(0.1%)	1(0.0%)
Incarcerated umbilical hernia	3(0.1%)	1(0.0%)
Abdominal symptom	3(0.1%)	0
Gastric haemorrhage	3(0.1%)	0
Colon dysplasia	2(0.1%)	5(0.1%)
Change of bowel habit	2(0.1%)	4(0.1%)
Varices oesophageal	2(0.1%)	4(0.1%)
Abnormal faeces	2(0.1%)	2(0.1%)
Colitis microscopic	2(0.1%)	2(0.1%)
Eructation	2(0.1%)	2(0.1%)
Gastrointestinal angiodysplasia	2(0.1%)	2(0.1%)
Intestinal metaplasia	2(0.1%)	2(0.1%)
Odynophagia	2(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Oral pain	2(0.1%)	2(0.1%)
Anal fistula	2(0.1%)	1(0.0%)
Diarrhoea haemorrhagic	2(0.1%)	1(0.0%)
Diverticulum intestinal haemorrhagic	2(0.1%)	1(0.0%)
Gastric disorder	2(0.1%)	1(0.0%)
Gingival bleeding	2(0.1%)	1(0.0%)
Pancreatic disorder	2(0.1%)	1(0.0%)
Aphthous ulcer	2(0.1%)	0
Defaecation urgency	2(0.1%)	0
Functional gastrointestinal disorder	2(0.1%)	0
Gastric ulcer haemorrhage	2(0.1%)	0
Glossitis	2(0.1%)	0
Intestinal haemorrhage	2(0.1%)	0
Mouth cyst	2(0.1%)	0
Parotid gland enlargement	2(0.1%)	0
Proctitis	2(0.1%)	0
Reflux gastritis	2(0.1%)	0
Small intestinal haemorrhage	2(0.1%)	0
Swollen tongue	2(0.1%)	0
Stomatitis	1(0.0%)	9(0.2%)
Gastrointestinal motility disorder	1(0.0%)	4(0.1%)
Intestinal polyp	1(0.0%)	4(0.1%)
Anal haemorrhage	1(0.0%)	3(0.1%)
Colitis ischaemic	1(0.0%)	3(0.1%)
Duodenal ulcer haemorrhage	1(0.0%)	3(0.1%)
Frequent bowel movements	1(0.0%)	3(0.1%)
Pancreatolithiasis	1(0.0%)	3(0.1%)
Acquired oesophageal web	1(0.0%)	2(0.1%)
Faeces discoloured	1(0.0%)	2(0.1%)
Intestinal mass	1(0.0%)	2(0.1%)
Lip swelling	1(0.0%)	2(0.1%)
Lumbar hernia	1(0.0%)	2(0.1%)
Rectal prolapse	1(0.0%)	2(0.1%)
Salivary gland calculus	1(0.0%)	2(0.1%)
Abdominal adhesions	1(0.0%)	1(0.0%)
Abdominal mass	1(0.0%)	1(0.0%)
Anal pruritus	1(0.0%)	1(0.0%)
Diaphragmatic hernia	1(0.0%)	1(0.0%)
Faeces soft	1(0.0%)	1(0.0%)
Gastric mucosal lesion	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Gastritis haemorrhagic	1(0.0%)	1(0.0%)
Gastrointestinal dysplasia	1(0.0%)	1(0.0%)
Ileal ulcer	1(0.0%)	1(0.0%)
Intestinal ischaemia	1(0.0%)	1(0.0%)
Oesophageal obstruction	1(0.0%)	1(0.0%)
Pancreatic duct stenosis	1(0.0%)	1(0.0%)
Peptic ulcer haemorrhage	1(0.0%)	1(0.0%)
Abdominal rigidity	1(0.0%)	0
Aerophagia	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Anorectal swelling	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Apical granuloma	1(0.0%)	0
Aptyalism	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0
Coeliac artery stenosis	1(0.0%)	0
Defaecation disorder	1(0.0%)	0
Dental alveolar anomaly	1(0.0%)	0
Dental attrition	1(0.0%)	0
Dental cyst	1(0.0%)	0
Diabetic gastroparesis	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Dyschezia	1(0.0%)	0
Gastric dilatation	1(0.0%)	0
Gastric xanthoma	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal polyp	1(0.0%)	0
Gastrointestinal ulcer	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Glossodynia	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids thrombosed	1(0.0%)	0
Hyperaesthesia teeth	1(0.0%)	0
Hypoaesthesia oral	1(0.0%)	0
Infrequent bowel movements	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Intra-abdominal fluid collection	1(0.0%)	0
Large intestinal stenosis	1(0.0%)	0
Lip disorder	1(0.0%)	0
Lip pruritus	1(0.0%)	0
Mechanical ileus	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal ulcer	1(0.0%)	0
Oesophageal ulcer haemorrhage	1(0.0%)	0
Oesophagitis ulcerative	1(0.0%)	0
Pancreatic steatosis	1(0.0%)	0
Paraesthesia oral	1(0.0%)	0
Peritoneal adhesions	1(0.0%)	0
Portal hypertensive gastropathy	1(0.0%)	0
Precancerous lesion of digestive tract	1(0.0%)	0
Pyloric sphincter insufficiency	1(0.0%)	0
Rectal ulcer	1(0.0%)	0
Retching	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Salivary gland mass	1(0.0%)	0
Salivary hypersecretion	1(0.0%)	0
Splenic artery aneurysm	1(0.0%)	0
Tongue haemorrhage	1(0.0%)	0
Tongue ulceration	1(0.0%)	0
Gastric mucosa erythema	0	3(0.1%)
Impaired gastric emptying	0	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Abdominal wall haematoma	0	2(0.1%)
Bowel movement irregularity	0	2(0.1%)
Colitis ulcerative	0	2(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Erosive duodenitis	0	2(0.1%)
Erosive oesophagitis	0	2(0.1%)
Faeces hard	0	2(0.1%)
Gastrointestinal tract mucosal pigmentation	0	2(0.1%)
Hernial eventration	0	2(0.1%)
Mesenteric panniculitis	0	2(0.1%)
Pancreatic failure	0	2(0.1%)
Subileus	0	2(0.1%)
Abdominal strangulated hernia	0	1(0.0%)
Abdominal tenderness	0	1(0.0%)
Chapped lips	0	1(0.0%)
Diabetic gastroenteropathy	0	1(0.0%)
Enterovesical fistula	0	1(0.0%)
Gastric antral vascular ectasia	0	1(0.0%)
Gastric dysplasia	0	1(0.0%)
Gastric mucosal hypertrophy	0	1(0.0%)
Gastrointestinal hypomotility	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal mucosa hyperaemia	0	1(0.0%)
Gastrointestinal obstruction	0	1(0.0%)
Gastrointestinal oedema	0	1(0.0%)
Gastrointestinal pain	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Gastrooesophageal sphincter insufficiency	0	1(0.0%)
Gingival hypertrophy	0	1(0.0%)
Hyperchlorhydria	0	1(0.0%)
Lip blister	0	1(0.0%)
Lip ulceration	0	1(0.0%)
Malabsorption	0	1(0.0%)
Mesenteric artery stenosis	0	1(0.0%)
Mouth haemorrhage	0	1(0.0%)
Noninfective gingivitis	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Oesophageal disorder	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Oesophageal mass	0	1(0.0%)
Oesophageal polyp	0	1(0.0%)
Oesophageal stenosis	0	1(0.0%)
Oral discomfort	0	1(0.0%)
Oral disorder	0	1(0.0%)
Palatal polyp	0	1(0.0%)
Pancreatic mass	0	1(0.0%)
Periodontal inflammation	0	1(0.0%)
Pneumoperitoneum	0	1(0.0%)
Rectal dysplasia	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland cyst	0	1(0.0%)
Small intestinal perforation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Strangulated umbilical hernia	0	1(0.0%)
Terminal ileitis	0	1(0.0%)
Tooth deposit	0	1(0.0%)
Uvulitis	0	1(0.0%)
Investigations	939(23.6%)	941(23.7%)
Glomerular filtration rate decreased	233(5.9%)	175(4.4%)
Blood creatinine increased	138(3.5%)	115(2.9%)
Blood potassium increased	115(2.9%)	58(1.5%)
Blood creatine phosphokinase increased	92(2.3%)	122(3.1%)
C-reactive protein increased	81(2.0%)	93(2.3%)
Blood pressure increased	72(1.8%)	92(2.3%)
Glycosylated haemoglobin increased	53(1.3%)	39(1.0%)
Gamma-glutamyltransferase increased	44(1.1%)	34(0.9%)
Blood urea increased	34(0.9%)	16(0.4%)
Weight decreased	33(0.8%)	47(1.2%)
Blood glucose increased	33(0.8%)	32(0.8%)
Blood uric acid increased	28(0.7%)	29(0.7%)
Blood triglycerides increased	19(0.5%)	19(0.5%)
Haemoglobin decreased	18(0.5%)	21(0.5%)
Weight increased	17(0.4%)	26(0.7%)
Alanine aminotransferase increased	16(0.4%)	19(0.5%)
Blood pressure decreased	15(0.4%)	11(0.3%)
Aspartate aminotransferase increased	14(0.4%)	10(0.3%)
Prostatic specific antigen increased	13(0.3%)	11(0.3%)
Blood alkaline phosphatase increased	11(0.3%)	9(0.2%)
Occult blood positive	10(0.3%)	8(0.2%)
Heart rate increased	10(0.3%)	7(0.2%)
Blood potassium decreased	10(0.3%)	6(0.2%)
Liver function test increased	9(0.2%)	8(0.2%)
White blood cell count increased	9(0.2%)	3(0.1%)
Helicobacter test positive	8(0.2%)	4(0.1%)
Cardiac murmur	7(0.2%)	8(0.2%)
Electrocardiogram QT prolonged	6(0.2%)	6(0.2%)
Blood glucose decreased	6(0.2%)	3(0.1%)
Blood sodium decreased	6(0.2%)	2(0.1%)
Hepatic enzyme increased	5(0.1%)	18(0.5%)
Colonoscopy	5(0.1%)	6(0.2%)
Blood lactate dehydrogenase increased	5(0.1%)	5(0.1%)
Blood bicarbonate decreased	5(0.1%)	4(0.1%)
Blood cholesterol increased	5(0.1%)	2(0.1%)
Blood glucose fluctuation	5(0.1%)	2(0.1%)
Blood urine present	5(0.1%)	2(0.1%)
Troponin increased	4(0.1%)	14(0.4%)
Angiocardiogram	4(0.1%)	5(0.1%)
Vitamin D decreased	4(0.1%)	5(0.1%)
Platelet count decreased	4(0.1%)	3(0.1%)
Low density lipoprotein increased	4(0.1%)	1(0.0%)
Ejection fraction decreased	3(0.1%)	4(0.1%)
Influenza A virus test positive	3(0.1%)	4(0.1%)
Low density lipoprotein decreased	3(0.1%)	4(0.1%)
Troponin T increased	3(0.1%)	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Blood cholesterol decreased	3(0.1%)	2(0.1%)
Blood calcium increased	3(0.1%)	1(0.0%)
Blood iron decreased	3(0.1%)	1(0.0%)
Blood parathyroid hormone increased	3(0.1%)	1(0.0%)
Urine output decreased	3(0.1%)	1(0.0%)
Biopsy prostate	3(0.1%)	0
Catheterisation cardiac	3(0.1%)	0
N-terminal prohormone brain natriuretic peptide increased	2(0.1%)	14(0.4%)
Blood magnesium decreased	2(0.1%)	6(0.2%)
Electrocardiogram T wave inversion	2(0.1%)	6(0.2%)
Intraocular pressure increased	2(0.1%)	6(0.2%)
Amylase increased	2(0.1%)	3(0.1%)
Blood pressure diastolic decreased	2(0.1%)	3(0.1%)
Haematocrit decreased	2(0.1%)	3(0.1%)
Lipase increased	2(0.1%)	3(0.1%)
Biopsy kidney	2(0.1%)	2(0.1%)
Blood albumin decreased	2(0.1%)	2(0.1%)
Red blood cell count decreased	2(0.1%)	2(0.1%)
Vitamin B12 decreased	2(0.1%)	2(0.1%)
Bacterial test positive	2(0.1%)	1(0.0%)
Electrocardiogram abnormal	2(0.1%)	1(0.0%)
Electrocardiogram repolarisation abnormality	2(0.1%)	1(0.0%)
Glycosylated haemoglobin abnormal	2(0.1%)	1(0.0%)
International normalised ratio increased	2(0.1%)	1(0.0%)
Liver function test abnormal	2(0.1%)	1(0.0%)
Scan myocardial perfusion abnormal	2(0.1%)	1(0.0%)
Biopsy artery	2(0.1%)	0
Endoscopy	2(0.1%)	0
Pulmonary arterial pressure increased	2(0.1%)	0
Waist circumference increased	2(0.1%)	0
White blood cell count decreased	2(0.1%)	0
Urine albumin/creatinine ratio increased	1(0.0%)	7(0.2%)
Transaminases increased	1(0.0%)	6(0.2%)
Heart rate decreased	1(0.0%)	5(0.1%)
Anticoagulation drug level above therapeutic	1(0.0%)	4(0.1%)
Arthroscopy	1(0.0%)	3(0.1%)
Brain natriuretic peptide increased	1(0.0%)	3(0.1%)
Electrocardiogram ST segment depression	1(0.0%)	3(0.1%)
Inflammatory marker increased	1(0.0%)	3(0.1%)
Protein urine present	1(0.0%)	3(0.1%)
Biopsy skin	1(0.0%)	2(0.1%)
Blood calcium decreased	1(0.0%)	2(0.1%)
Blood folate decreased	1(0.0%)	2(0.1%)
Blood thyroid stimulating hormone increased	1(0.0%)	2(0.1%)
Bone density decreased	1(0.0%)	2(0.1%)
ECG signs of myocardial ischaemia	1(0.0%)	2(0.1%)
Blood lactic acid increased	1(0.0%)	1(0.0%)
Blood pressure systolic increased	1(0.0%)	1(0.0%)
Clostridium test positive	1(0.0%)	1(0.0%)
Electrocardiogram QRS complex abnormal	1(0.0%)	1(0.0%)
Electrocardiogram T wave amplitude decreased	1(0.0%)	1(0.0%)
Glomerular filtration rate increased	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Haematology test abnormal	1(0.0%)	1(0.0%)
Lipids increased	1(0.0%)	1(0.0%)
Mean cell volume increased	1(0.0%)	1(0.0%)
Oxygen consumption increased	1(0.0%)	1(0.0%)
Albumin urine present	1(0.0%)	0
Angiogram peripheral	1(0.0%)	0
Antinuclear antibody positive	1(0.0%)	0
Arteriogram	1(0.0%)	0
Aspiration pleural cavity	1(0.0%)	0
Biopsy bladder	1(0.0%)	0
Blood albumin abnormal	1(0.0%)	0
Blood albumin increased	1(0.0%)	0
Blood alkaline phosphatase abnormal	1(0.0%)	0
Blood chloride decreased	1(0.0%)	0
Blood creatine phosphokinase MB increased	1(0.0%)	0
Blood growth hormone decreased	1(0.0%)	0
Blood osmolarity decreased	1(0.0%)	0
Blood phosphorus decreased	1(0.0%)	0
Blood pressure orthostatic decreased	1(0.0%)	0
Blood testosterone decreased	1(0.0%)	0
Breath sounds abnormal	1(0.0%)	0
C-reactive protein abnormal	1(0.0%)	0
Cancer staging	1(0.0%)	0
Carbohydrate antigen 125 increased	1(0.0%)	0
Cardiac function test abnormal	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0
Cardiac stress test abnormal	1(0.0%)	0
Colonoscopy normal	1(0.0%)	0
Cystoscopy	1(0.0%)	0
Electrocardiogram P wave abnormal	1(0.0%)	0
Electrocardiogram Q wave abnormal	1(0.0%)	0
Electrocardiogram ST-T segment depression	1(0.0%)	0
Haematocrit increased	1(0.0%)	0
Haemoglobin increased	1(0.0%)	0
Human chorionic gonadotropin increased	1(0.0%)	0
Intestinal transit time decreased	1(0.0%)	0
Klebsiella test positive	1(0.0%)	0
Legionella test positive	1(0.0%)	0
Lipids abnormal	1(0.0%)	0
Mean cell haemoglobin concentration decreased	1(0.0%)	0
Myoglobin blood increased	1(0.0%)	0
Nitrite urine present	1(0.0%)	0
Optic nerve cup/disc ratio increased	1(0.0%)	0
Protein S decreased	1(0.0%)	0
Protein total increased	1(0.0%)	0
Prothrombin time prolonged	1(0.0%)	0
Pulmonary imaging procedure abnormal	1(0.0%)	0
Pulse abnormal	1(0.0%)	0
Red blood cell sedimentation rate decreased	1(0.0%)	0
Serratia test positive	1(0.0%)	0
Serum ferritin increased	1(0.0%)	0
Sputum abnormal	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Transaminases abnormal	1(0.0%)	0
Transferrin saturation decreased	1(0.0%)	0
Tumour marker increased	1(0.0%)	0
Polymerase chain reaction positive	0	4(0.1%)
Serum ferritin decreased	0	4(0.1%)
Carcinoembryonic antigen increased	0	3(0.1%)
Electrocardiogram T wave abnormal	0	3(0.1%)
Quality of life decreased	0	3(0.1%)
Blood phosphorus increased	0	2(0.1%)
Carotid bruit	0	2(0.1%)
Electrocardiogram ST segment abnormal	0	2(0.1%)
Fibrin D dimer increased	0	2(0.1%)
High density lipoprotein decreased	0	2(0.1%)
Peripheral arteriogram	0	2(0.1%)
QRS axis abnormal	0	2(0.1%)
Red blood cell sedimentation rate increased	0	2(0.1%)
SARS-CoV-2 test positive	0	2(0.1%)
Ultrasound Doppler abnormal	0	2(0.1%)
Ultrasound kidney abnormal	0	2(0.1%)
Urinary occult blood positive	0	2(0.1%)
Angiogram cerebral	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Anticoagulation drug level increased	0	1(0.0%)
Biopsy breast	0	1(0.0%)
Blood bilirubin increased	0	1(0.0%)
Blood chromogranin A increased	0	1(0.0%)
Blood magnesium increased	0	1(0.0%)
Brain scan abnormal	0	1(0.0%)
Carbohydrate antigen 19-9 increased	0	1(0.0%)
Carbohydrate antigen 50 increased	0	1(0.0%)
Cardiac index decreased	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)
Chest X-ray abnormal	0	1(0.0%)
Coagulation time prolonged	0	1(0.0%)
Computerised tomogram abdomen	0	1(0.0%)
Cytogenetic analysis abnormal	0	1(0.0%)
Electrocardiogram ST segment elevation	0	1(0.0%)
Electrocardiogram ST-T segment abnormal	0	1(0.0%)
Electroencephalogram abnormal	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Eosinophil count increased	0	1(0.0%)
Face and mouth X-ray abnormal	0	1(0.0%)
Gastric pH decreased	0	1(0.0%)
Heart rate irregular	0	1(0.0%)
Herpes simplex test positive	0	1(0.0%)
Human rhinovirus test positive	0	1(0.0%)
Imaging procedure abnormal	0	1(0.0%)
Influenza B virus test positive	0	1(0.0%)
Left ventricular end-diastolic pressure increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Magnetic resonance imaging brain abnormal	0	1(0.0%)
Mean cell volume decreased	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Myocardial necrosis marker increased	0	1(0.0%)
Oral soft tissue biopsy	0	1(0.0%)
Platelet count increased	0	1(0.0%)
Proteus test positive	0	1(0.0%)
Red blood cells urine positive	0	1(0.0%)
Renal function test abnormal	0	1(0.0%)
Scan adrenal gland abnormal	0	1(0.0%)
Thyroid hormones increased	0	1(0.0%)
Treponema test positive	0	1(0.0%)
Troponin I increased	0	1(0.0%)
Ultrasound thyroid abnormal	0	1(0.0%)
Urine analysis abnormal	0	1(0.0%)
Urine output increased	0	1(0.0%)
Vascular resistance systemic increased	0	1(0.0%)
Vitamin B12 increased	0	1(0.0%)
White blood cell analysis abnormal	0	1(0.0%)
Nervous System Disorders	851(21.4%)	921(23.2%)
Dizziness	232(5.8%)	239(6.0%)
Headache	121(3.0%)	130(3.3%)
Diabetic neuropathy	73(1.8%)	71(1.8%)
Syncope	54(1.4%)	85(2.1%)
Hypoaesthesia	49(1.2%)	47(1.2%)
Sciatica	40(1.0%)	42(1.1%)
Neuropathy peripheral	32(0.8%)	28(0.7%)
Carpal tunnel syndrome	29(0.7%)	27(0.7%)
Carotid artery stenosis	22(0.6%)	25(0.6%)
Carotid arteriosclerosis	22(0.6%)	21(0.5%)
Paraesthesia	21(0.5%)	30(0.8%)
Cognitive disorder	17(0.4%)	19(0.5%)
Presyncope	17(0.4%)	9(0.2%)
Loss of consciousness	17(0.4%)	3(0.1%)
Tremor	16(0.4%)	20(0.5%)
Dizziness postural	15(0.4%)	13(0.3%)
Lethargy	14(0.4%)	8(0.2%)
Polyneuropathy	13(0.3%)	15(0.4%)
Transient ischaemic attack	13(0.3%)	13(0.3%)
Facial paralysis	12(0.3%)	17(0.4%)
Neuralgia	11(0.3%)	17(0.4%)
Memory impairment	11(0.3%)	15(0.4%)
Restless legs syndrome	11(0.3%)	6(0.2%)
Dementia	10(0.3%)	14(0.4%)
Cerebrovascular disorder	9(0.2%)	9(0.2%)
Seizure	9(0.2%)	9(0.2%)
Cerebral infarction	8(0.2%)	9(0.2%)
Cerebral atrophy	8(0.2%)	7(0.2%)
Amnesia	7(0.2%)	17(0.4%)
Somnolence	7(0.2%)	17(0.4%)
Lacunar infarction	7(0.2%)	7(0.2%)
Cervicobrachial syndrome	7(0.2%)	6(0.2%)
Tension headache	7(0.2%)	2(0.1%)
Parkinson's disease	6(0.2%)	7(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Radiculopathy	6(0.2%)	7(0.2%)
Migraine	6(0.2%)	6(0.2%)
Hemiparesis	6(0.2%)	5(0.1%)
Dysarthria	6(0.2%)	4(0.1%)
Cerebral ischaemia	5(0.1%)	9(0.2%)
Cerebral arteriosclerosis	5(0.1%)	7(0.2%)
Dysgeusia	5(0.1%)	7(0.2%)
Cervical radiculopathy	5(0.1%)	3(0.1%)
Parkinsonism	5(0.1%)	3(0.1%)
Encephalopathy	4(0.1%)	10(0.3%)
Subarachnoid haemorrhage	4(0.1%)	5(0.1%)
Aphasia	4(0.1%)	4(0.1%)
Dementia Alzheimer's type	4(0.1%)	4(0.1%)
Epilepsy	4(0.1%)	4(0.1%)
Peripheral sensorimotor neuropathy	4(0.1%)	4(0.1%)
Nerve compression	4(0.1%)	3(0.1%)
Cerebral haemorrhage	4(0.1%)	0
Balance disorder	3(0.1%)	9(0.2%)
Lumbar radiculopathy	3(0.1%)	3(0.1%)
Post herpetic neuralgia	3(0.1%)	3(0.1%)
Hemianaesthesia	3(0.1%)	2(0.1%)
Normal pressure hydrocephalus	3(0.1%)	2(0.1%)
Altered state of consciousness	3(0.1%)	1(0.0%)
Cerebral microangiopathy	3(0.1%)	1(0.0%)
Cerebral small vessel ischaemic disease	3(0.1%)	1(0.0%)
Poor quality sleep	3(0.1%)	1(0.0%)
Visual field defect	3(0.1%)	1(0.0%)
Vocal cord paralysis	3(0.1%)	1(0.0%)
Autonomic neuropathy	3(0.1%)	0
Vascular encephalopathy	2(0.1%)	6(0.2%)
Sensory disturbance	2(0.1%)	5(0.1%)
Burning sensation	2(0.1%)	3(0.1%)
Carotid artery disease	2(0.1%)	3(0.1%)
Facial paresis	2(0.1%)	3(0.1%)
IIIrd nerve paralysis	2(0.1%)	3(0.1%)
Myelopathy	2(0.1%)	3(0.1%)
Leukoencephalopathy	2(0.1%)	2(0.1%)
Orthostatic intolerance	2(0.1%)	2(0.1%)
Ageusia	2(0.1%)	1(0.0%)
Myoclonus	2(0.1%)	1(0.0%)
Partial seizures	2(0.1%)	1(0.0%)
Hepatic encephalopathy	2(0.1%)	0
Hyporeflexia	2(0.1%)	0
IVth nerve paralysis	2(0.1%)	0
Motor dysfunction	2(0.1%)	0
Parosmia	2(0.1%)	0
Vascular headache	2(0.1%)	0
Vascular parkinsonism	2(0.1%)	0
White matter lesion	2(0.1%)	0
Essential tremor	1(0.0%)	6(0.2%)
Intracranial aneurysm	1(0.0%)	4(0.1%)
Metabolic encephalopathy	1(0.0%)	4(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Peripheral sensory neuropathy	1(0.0%)	4(0.1%)
Anosmia	1(0.0%)	2(0.1%)
Cerebrovascular accident	1(0.0%)	2(0.1%)
Cubital tunnel syndrome	1(0.0%)	2(0.1%)
Hydrocephalus	1(0.0%)	2(0.1%)
Hypersomnia	1(0.0%)	2(0.1%)
Intercostal neuralgia	1(0.0%)	2(0.1%)
Phantom limb syndrome	1(0.0%)	2(0.1%)
Senile dementia	1(0.0%)	2(0.1%)
Trigeminal neuralgia	1(0.0%)	2(0.1%)
Vertebral artery stenosis	1(0.0%)	2(0.1%)
Vertebrobasilar insufficiency	1(0.0%)	2(0.1%)
Cerebellar infarction	1(0.0%)	1(0.0%)
Cerebellar stroke	1(0.0%)	1(0.0%)
Cerebrovascular insufficiency	1(0.0%)	1(0.0%)
Decreased vibratory sense	1(0.0%)	1(0.0%)
Dementia with Lewy bodies	1(0.0%)	1(0.0%)
Dizziness exertional	1(0.0%)	1(0.0%)
Focal dyscognitive seizures	1(0.0%)	1(0.0%)
Hemiparaesthesia	1(0.0%)	1(0.0%)
Hypogeusia	1(0.0%)	1(0.0%)
Ischaemic stroke	1(0.0%)	1(0.0%)
Mixed dementia	1(0.0%)	1(0.0%)
Muscle contractions involuntary	1(0.0%)	1(0.0%)
Nervous system disorder	1(0.0%)	1(0.0%)
Neuritis	1(0.0%)	1(0.0%)
Peroneal nerve palsy	1(0.0%)	1(0.0%)
Subdural effusion	1(0.0%)	1(0.0%)
Vertebral artery occlusion	1(0.0%)	1(0.0%)
Amputation stump pain	1(0.0%)	0
Angiopathic neuropathy	1(0.0%)	0
Ataxia	1(0.0%)	0
Basilar artery occlusion	1(0.0%)	0
Basilar artery stenosis	1(0.0%)	0
Bulbar palsy	1(0.0%)	0
Cerebral artery occlusion	1(0.0%)	0
Cerebral hypoperfusion	1(0.0%)	0
Cerebral microhaemorrhage	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Cerebrospinal fluid leakage	1(0.0%)	0
Cerebrovascular stenosis	1(0.0%)	0
Cervicogenic headache	1(0.0%)	0
Drop attacks	1(0.0%)	0
Dyskinesia	1(0.0%)	0
Dysmetria	1(0.0%)	0
Frontotemporal dementia	1(0.0%)	0
Generalised tonic-clonic seizure	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianopia homonymous	1(0.0%)	0
Intention tremor	1(0.0%)	0
Meralgia paraesthetica	1(0.0%)	0
Migraine without aura	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Monoplegia	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Neuromuscular blockade	1(0.0%)	0
Peripheral motor neuropathy	1(0.0%)	0
Peripheral nerve lesion	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Post-traumatic headache	1(0.0%)	0
Resting tremor	1(0.0%)	0
Sinus headache	1(0.0%)	0
Slow speech	1(0.0%)	0
Speech disorder	1(0.0%)	0
Spinal claudication	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Unresponsive to stimuli	1(0.0%)	0
VIth nerve paralysis	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
Cerebral artery stenosis	0	5(0.1%)
Lumbosacral radiculopathy	0	4(0.1%)
Neurodegenerative disorder	0	3(0.1%)
Vascular dementia	0	3(0.1%)
Axonal neuropathy	0	2(0.1%)
Carotid artery occlusion	0	2(0.1%)
Central nervous system lesion	0	2(0.1%)
Disturbance in attention	0	2(0.1%)
Facial nerve disorder	0	2(0.1%)
Hemiplegia	0	2(0.1%)
Hypoxic-ischaemic encephalopathy	0	2(0.1%)
Postural tremor	0	2(0.1%)
Radicular pain	0	2(0.1%)
Alcohol induced persisting dementia	0	1(0.0%)
Amnestic disorder	0	1(0.0%)
Anaesthesia	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Basal ganglia haemorrhage	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brain stem infarction	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery aneurysm	0	1(0.0%)
Carotid artery thrombosis	0	1(0.0%)
Cerebellar atrophy	0	1(0.0%)
Cerebral circulatory failure	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebrovascular pseudoaneurysm	0	1(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Diabetic hyperosmolar coma	0	1(0.0%)
Dysstasia	0	1(0.0%)
Epidural lipomatosis	0	1(0.0%)
Facial neuralgia	0	1(0.0%)
Facial spasm	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Gliosis	0	1(0.0%)
Head titubation	0	1(0.0%)
Hemianopia	0	1(0.0%)
Hyperglycaemic unconsciousness	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypoglycaemic unconsciousness	0	1(0.0%)
Hypotonia	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Mental impairment	0	1(0.0%)
Migraine with aura	0	1(0.0%)
Mononeuropathy	0	1(0.0%)
Mononeuropathy multiplex	0	1(0.0%)
Multiple sclerosis relapse	0	1(0.0%)
Multiple system atrophy	0	1(0.0%)
Muscle tone disorder	0	1(0.0%)
Myasthenia gravis	0	1(0.0%)
Myelomalacia	0	1(0.0%)
Neurological symptom	0	1(0.0%)
Nystagmus	0	1(0.0%)
Occipital neuralgia	0	1(0.0%)
Optic neuritis	0	1(0.0%)
Paraparesis	0	1(0.0%)
Paraplegia	0	1(0.0%)
Peripheral nerve paresis	0	1(0.0%)
Piriformis syndrome	0	1(0.0%)
Posthaemorrhagic hydrocephalus	0	1(0.0%)
Precerebral arteriosclerosis	0	1(0.0%)
Pronator teres syndrome	0	1(0.0%)
Radiculitis brachial	0	1(0.0%)
Sciatic nerve neuropathy	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Spinal cord haematoma	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Subdural hygroma	0	1(0.0%)
Tarsal tunnel syndrome	0	1(0.0%)
Taste disorder	0	1(0.0%)
Thalamic infarction	0	1(0.0%)
Thalamus haemorrhage	0	1(0.0%)
Toxic neuropathy	0	1(0.0%)
Vertebral artery arteriosclerosis	0	1(0.0%)
Vascular Disorders	754(19.0%)	740(18.7%)
Hypertension	260(6.5%)	355(9.0%)
Hypotension	200(5.0%)	139(3.5%)
Peripheral arterial occlusive disease	63(1.6%)	57(1.4%)
Hypertensive crisis	40(1.0%)	39(1.0%)
Orthostatic hypotension	35(0.9%)	27(0.7%)
Intermittent claudication	25(0.6%)	22(0.6%)
Peripheral venous disease	22(0.6%)	17(0.4%)
Aortic stenosis	19(0.5%)	14(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Varicose vein	17(0.4%)	12(0.3%)
Aortic arteriosclerosis	14(0.4%)	16(0.4%)
Haematoma	13(0.3%)	12(0.3%)
Peripheral vascular disorder	12(0.3%)	17(0.4%)
Deep vein thrombosis	12(0.3%)	10(0.3%)
Peripheral artery occlusion	12(0.3%)	5(0.1%)
Aortic aneurysm	10(0.3%)	14(0.4%)
Peripheral artery stenosis	10(0.3%)	10(0.3%)
Diabetic vascular disorder	9(0.2%)	9(0.2%)
Extremity necrosis	9(0.2%)	2(0.1%)
Hypertensive urgency	8(0.2%)	8(0.2%)
Arteriosclerosis	7(0.2%)	8(0.2%)
Peripheral ischaemia	7(0.2%)	8(0.2%)
Blood pressure inadequately controlled	6(0.2%)	8(0.2%)
Lymphoedema	5(0.1%)	7(0.2%)
Thrombophlebitis	5(0.1%)	4(0.1%)
Circulatory collapse	4(0.1%)	3(0.1%)
Brachiocephalic arteriosclerosis	4(0.1%)	1(0.0%)
Hypertensive emergency	3(0.1%)	7(0.2%)
Aortic dilatation	3(0.1%)	6(0.2%)
Blood pressure fluctuation	3(0.1%)	5(0.1%)
Thrombosis	3(0.1%)	2(0.1%)
Lymphostasis	3(0.1%)	1(0.0%)
Thrombophlebitis superficial	3(0.1%)	1(0.0%)
Labile blood pressure	3(0.1%)	0
Peripheral artery aneurysm	3(0.1%)	0
Hot flush	2(0.1%)	7(0.2%)
Phlebitis	2(0.1%)	6(0.2%)
Peripheral coldness	2(0.1%)	3(0.1%)
Arterial occlusive disease	2(0.1%)	1(0.0%)
Iliac artery stenosis	2(0.1%)	1(0.0%)
Aortic dissection	2(0.1%)	0
Cyanosis	2(0.1%)	0
Peripheral embolism	2(0.1%)	0
Phlebitis superficial	2(0.1%)	0
Post thrombotic syndrome	2(0.1%)	0
Raynaud's phenomenon	2(0.1%)	0
Arterial stenosis	1(0.0%)	2(0.1%)
Microangiopathy	1(0.0%)	2(0.1%)
Subclavian artery stenosis	1(0.0%)	2(0.1%)
Aortic occlusion	1(0.0%)	1(0.0%)
Arteriosclerosis Moenckeberg-type	1(0.0%)	1(0.0%)
Arteriovenous fistula	1(0.0%)	1(0.0%)
Diabetic macroangiopathy	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Ischaemia	1(0.0%)	1(0.0%)
Labile hypertension	1(0.0%)	1(0.0%)
Peripheral artery thrombosis	1(0.0%)	1(0.0%)
Vasculitis	1(0.0%)	1(0.0%)
Vein disorder	1(0.0%)	1(0.0%)
Venous thrombosis limb	1(0.0%)	1(0.0%)
Angiodysplasia	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Artery dissection	1(0.0%)	0
Dialysis hypotension	1(0.0%)	0
Diastolic hypotension	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Iliac artery occlusion	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Lymphocele	1(0.0%)	0
Macroangiopathy	1(0.0%)	0
Penetrating aortic ulcer	1(0.0%)	0
Subclavian artery dissection	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Vascular wall hypertrophy	1(0.0%)	0
Venous occlusion	1(0.0%)	0
Essential hypertension	0	3(0.1%)
Hypertensive angiopathy	0	3(0.1%)
Accelerated hypertension	0	2(0.1%)
Aortic disorder	0	2(0.1%)
Aortic thrombosis	0	2(0.1%)
Arteritis	0	2(0.1%)
Hyperaemia	0	2(0.1%)
Malignant hypertension	0	2(0.1%)
Poor peripheral circulation	0	2(0.1%)
Angiosclerosis	0	1(0.0%)
Arterial disorder	0	1(0.0%)
Arterial thrombosis	0	1(0.0%)
Brachiocephalic artery stenosis	0	1(0.0%)
Embolism venous	0	1(0.0%)
Inferior vena cava syndrome	0	1(0.0%)
Internal haemorrhage	0	1(0.0%)
Neovascularisation	0	1(0.0%)
Orthostatic hypertension	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Renovascular hypertension	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Systolic hypertension	0	1(0.0%)
Thromboangiitis obliterans	0	1(0.0%)
Vein rupture	0	1(0.0%)
Renal And Urinary Disorders	748(18.8%)	764(19.3%)
Acute kidney injury	181(4.6%)	196(4.9%)
Renal impairment	138(3.5%)	127(3.2%)
Chronic kidney disease	60(1.5%)	68(1.7%)
Renal cyst	60(1.5%)	62(1.6%)
Nephrolithiasis	51(1.3%)	58(1.5%)
Haematuria	48(1.2%)	56(1.4%)
Urinary incontinence	38(1.0%)	27(0.7%)
Renal failure	37(0.9%)	28(0.7%)
Diabetic nephropathy	37(0.9%)	22(0.6%)
Urinary retention	36(0.9%)	31(0.8%)
Dysuria	27(0.7%)	32(0.8%)
Pollakiuria	18(0.5%)	29(0.7%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Nocturia	15(0.4%)	22(0.6%)
Proteinuria	11(0.3%)	19(0.5%)
Renal colic	9(0.2%)	7(0.2%)
Micturition urgency	9(0.2%)	5(0.1%)
Nephropathy	8(0.2%)	11(0.3%)
Ureterolithiasis	8(0.2%)	11(0.3%)
Polyuria	8(0.2%)	6(0.2%)
Hydronephrosis	7(0.2%)	18(0.5%)
Nephrotic syndrome	6(0.2%)	15(0.4%)
Hypertonic bladder	6(0.2%)	10(0.3%)
Urge incontinence	6(0.2%)	6(0.2%)
Urinary tract obstruction	6(0.2%)	4(0.1%)
Calculus urinary	5(0.1%)	8(0.2%)
End stage renal disease	5(0.1%)	6(0.2%)
Azotaemia	5(0.1%)	3(0.1%)
Urine flow decreased	5(0.1%)	2(0.1%)
Lower urinary tract symptoms	4(0.1%)	8(0.2%)
Albuminuria	4(0.1%)	4(0.1%)
Neurogenic bladder	4(0.1%)	4(0.1%)
Oliguria	4(0.1%)	1(0.0%)
Calculus bladder	3(0.1%)	4(0.1%)
Acquired cystic kidney disease	3(0.1%)	3(0.1%)
Renal artery stenosis	3(0.1%)	3(0.1%)
Urinary tract disorder	3(0.1%)	2(0.1%)
Nephropathy toxic	3(0.1%)	1(0.0%)
Stress urinary incontinence	3(0.1%)	1(0.0%)
Urinary hesitation	3(0.1%)	1(0.0%)
Bladder irritation	3(0.1%)	0
Renal mass	2(0.1%)	7(0.2%)
Perinephritis	2(0.1%)	4(0.1%)
Renal disorder	2(0.1%)	4(0.1%)
Urethral stenosis	2(0.1%)	4(0.1%)
Renal atrophy	2(0.1%)	3(0.1%)
Bladder hypertrophy	2(0.1%)	2(0.1%)
Bladder outlet obstruction	2(0.1%)	2(0.1%)
Pyelocaliectasis	2(0.1%)	2(0.1%)
Microalbuminuria	2(0.1%)	1(0.0%)
Nephroangiosclerosis	2(0.1%)	1(0.0%)
Ureteric obstruction	2(0.1%)	1(0.0%)
Bladder disorder	2(0.1%)	0
Chromaturia	2(0.1%)	0
Micturition disorder	2(0.1%)	0
Urate nephropathy	2(0.1%)	0
Renal injury	1(0.0%)	3(0.1%)
Renal pain	1(0.0%)	3(0.1%)
Renal aneurysm	1(0.0%)	2(0.1%)
Bladder diverticulum	1(0.0%)	1(0.0%)
Hypertensive nephropathy	1(0.0%)	1(0.0%)
Nephrosclerosis	1(0.0%)	1(0.0%)
Renal hypertension	1(0.0%)	1(0.0%)
Renal hypertrophy	1(0.0%)	1(0.0%)
Tubulointerstitial nephritis	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Bladder cyst	1(0.0%)	0
Bladder obstruction	1(0.0%)	0
Bladder pain	1(0.0%)	0
Bladder perforation	1(0.0%)	0
Bladder spasm	1(0.0%)	0
Cystitis haemorrhagic	1(0.0%)	0
Cystitis noninfective	1(0.0%)	0
Focal segmental glomerulosclerosis	1(0.0%)	0
Hydrocalyx	1(0.0%)	0
Hypotonic urinary bladder	1(0.0%)	0
Prerenal failure	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Renal vessel disorder	1(0.0%)	0
Strangury	1(0.0%)	0
Urethral pain	1(0.0%)	0
Incontinence	0	3(0.1%)
Intercapillary glomerulosclerosis	0	3(0.1%)
Renal artery arteriosclerosis	0	3(0.1%)
Glomerulonephritis chronic	0	2(0.1%)
Nephrocalcinosis	0	2(0.1%)
Renal haemorrhage	0	2(0.1%)
Sterile pyuria	0	2(0.1%)
Ureteric stenosis	0	2(0.1%)
Urine abnormality	0	2(0.1%)
Urine odour abnormal	0	2(0.1%)
Anuria	0	1(0.0%)
Bladder mass	0	1(0.0%)
Bladder neck obstruction	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Glycosuria	0	1(0.0%)
Kidney fibrosis	0	1(0.0%)
Nephroptosis	0	1(0.0%)
Pelvi-ureteric obstruction	0	1(0.0%)
Perinephric collection	0	1(0.0%)
Renal haematoma	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Ureteric dilatation	0	1(0.0%)
Urinary tract inflammation	0	1(0.0%)
Vesical fistula	0	1(0.0%)
General Disorders And Administration Site Conditions	739(18.6%)	906(22.8%)
Oedema peripheral	263(6.6%)	400(10.1%)
Chest pain	111(2.8%)	128(3.2%)
Fatigue	102(2.6%)	92(2.3%)
Pyrexia	60(1.5%)	54(1.4%)
Asthenia	56(1.4%)	83(2.1%)
Oedema	55(1.4%)	69(1.7%)
Peripheral swelling	49(1.2%)	60(1.5%)
Chest discomfort	26(0.7%)	26(0.7%)
Influenza like illness	18(0.5%)	24(0.6%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pain	18(0.5%)	19(0.5%)
Malaise	18(0.5%)	15(0.4%)
Inflammation	15(0.4%)	18(0.5%)
Gait disturbance	8(0.2%)	16(0.4%)
Chills	7(0.2%)	6(0.2%)
Face oedema	7(0.2%)	6(0.2%)
Non-cardiac chest pain	6(0.2%)	10(0.3%)
Generalised oedema	6(0.2%)	8(0.2%)
General physical health deterioration	5(0.1%)	7(0.2%)
Feeling cold	5(0.1%)	6(0.2%)
Illness	5(0.1%)	2(0.1%)
Impaired healing	5(0.1%)	2(0.1%)
Unevaluable event	5(0.1%)	0
Death	4(0.1%)	8(0.2%)
Feeling abnormal	4(0.1%)	4(0.1%)
Drug intolerance	4(0.1%)	3(0.1%)
Mass	4(0.1%)	3(0.1%)
Nodule	3(0.1%)	3(0.1%)
Discomfort	3(0.1%)	2(0.1%)
Swelling face	3(0.1%)	1(0.0%)
Cyst	2(0.1%)	6(0.2%)
Polyp	2(0.1%)	6(0.2%)
Localised oedema	2(0.1%)	3(0.1%)
Oedema due to renal disease	2(0.1%)	3(0.1%)
Gravitational oedema	2(0.1%)	1(0.0%)
Hernia	2(0.1%)	0
Medical device site reaction	2(0.1%)	0
Stent-graft endoleak	2(0.1%)	0
Feeling hot	1(0.0%)	2(0.1%)
Vascular stent stenosis	1(0.0%)	2(0.1%)
Xerosis	1(0.0%)	2(0.1%)
Adverse drug reaction	1(0.0%)	1(0.0%)
Calcinosis	1(0.0%)	1(0.0%)
Early satiety	1(0.0%)	1(0.0%)
Hernia pain	1(0.0%)	1(0.0%)
Hunger	1(0.0%)	1(0.0%)
Hypothermia	1(0.0%)	1(0.0%)
Injection site pain	1(0.0%)	1(0.0%)
Injection site pruritus	1(0.0%)	1(0.0%)
Multiple organ dysfunction syndrome	1(0.0%)	1(0.0%)
Swelling	1(0.0%)	1(0.0%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Adverse event	1(0.0%)	0
Application site reaction	1(0.0%)	0
Catheter site inflammation	1(0.0%)	0
Chronic fatigue syndrome	1(0.0%)	0
Complication associated with device	1(0.0%)	0
Crepitations	1(0.0%)	0
Cyst rupture	1(0.0%)	0
Exercise tolerance decreased	1(0.0%)	0
Granuloma	1(0.0%)	0
Implant site erosion	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Injection site erosion	1(0.0%)	0
Injection site extravasation	1(0.0%)	0
Injection site nodule	1(0.0%)	0
Medical device site pain	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Precancerous condition	1(0.0%)	0
Pseudopolyp	1(0.0%)	0
Sensation of foreign body	1(0.0%)	0
Thirst	1(0.0%)	0
Facial pain	0	2(0.1%)
Medical device site ulcer	0	2(0.1%)
Suprapubic pain	0	2(0.1%)
Vessel puncture site bruise	0	2(0.1%)
Adhesion	0	1(0.0%)
Axillary pain	0	1(0.0%)
Catheter site discharge	0	1(0.0%)
Device intolerance	0	1(0.0%)
Drug ineffective	0	1(0.0%)
Facial discomfort	0	1(0.0%)
Hyperpyrexia	0	1(0.0%)
Hyperthermia	0	1(0.0%)
Induration	0	1(0.0%)
Injection site atrophy	0	1(0.0%)
Injection site erythema	0	1(0.0%)
Injection site swelling	0	1(0.0%)
Medical device site nerve damage	0	1(0.0%)
Medical device site pruritus	0	1(0.0%)
Non-pitting oedema	0	1(0.0%)
Performance status decreased	0	1(0.0%)
Puncture site pain	0	1(0.0%)
Sense of oppression	0	1(0.0%)
Soft tissue inflammation	0	1(0.0%)
Temperature intolerance	0	1(0.0%)
Vascular stent thrombosis	0	1(0.0%)
Vessel puncture site haematoma	0	1(0.0%)
Vessel puncture site haemorrhage	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	718(18.1%)	740(18.7%)
Cough	179(4.5%)	187(4.7%)
Dyspnoea	152(3.8%)	143(3.6%)
Chronic obstructive pulmonary disease	67(1.7%)	57(1.4%)
Dyspnoea exertional	37(0.9%)	43(1.1%)
Sleep apnoea syndrome	35(0.9%)	49(1.2%)
Oropharyngeal pain	35(0.9%)	24(0.6%)
Epistaxis	33(0.8%)	28(0.7%)
Pleural effusion	31(0.8%)	19(0.5%)
Rhinitis allergic	28(0.7%)	21(0.5%)
Pulmonary mass	25(0.6%)	16(0.4%)
Asthma	19(0.5%)	29(0.7%)
Bronchitis chronic	18(0.5%)	17(0.4%)
Productive cough	17(0.4%)	21(0.5%)
Respiratory failure	17(0.4%)	16(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Rhinorrhoea	17(0.4%)	16(0.4%)
Respiratory disorder	16(0.4%)	11(0.3%)
Interstitial lung disease	13(0.3%)	8(0.2%)
Acute respiratory failure	12(0.3%)	20(0.5%)
Pulmonary hypertension	11(0.3%)	14(0.4%)
Upper respiratory tract inflammation	10(0.3%)	12(0.3%)
Catarrh	10(0.3%)	6(0.2%)
Pulmonary embolism	9(0.2%)	9(0.2%)
Emphysema	8(0.2%)	7(0.2%)
Nasal congestion	8(0.2%)	7(0.2%)
Pulmonary fibrosis	6(0.2%)	5(0.1%)
Hiccups	6(0.2%)	2(0.1%)
Atelectasis	5(0.1%)	8(0.2%)
Sinus congestion	5(0.1%)	5(0.1%)
Hypoxia	5(0.1%)	3(0.1%)
Pulmonary congestion	4(0.1%)	10(0.3%)
Bronchospasm	4(0.1%)	8(0.2%)
Dysphonia	4(0.1%)	8(0.2%)
Pneumonia aspiration	4(0.1%)	6(0.2%)
Acute pulmonary oedema	4(0.1%)	5(0.1%)
Bronchiectasis	4(0.1%)	3(0.1%)
Obstructive airways disorder	4(0.1%)	2(0.1%)
Rales	3(0.1%)	6(0.2%)
Pleurisy	3(0.1%)	3(0.1%)
Pneumothorax	3(0.1%)	3(0.1%)
Respiratory tract congestion	3(0.1%)	3(0.1%)
Laryngeal oedema	3(0.1%)	1(0.0%)
Lung opacity	3(0.1%)	1(0.0%)
Nasal septum deviation	3(0.1%)	1(0.0%)
Sneezing	3(0.1%)	0
Pulmonary oedema	2(0.1%)	17(0.4%)
Pneumonitis	2(0.1%)	5(0.1%)
Upper-airway cough syndrome	2(0.1%)	4(0.1%)
Wheezing	2(0.1%)	4(0.1%)
Restrictive pulmonary disease	2(0.1%)	3(0.1%)
Dyspnoea paroxysmal nocturnal	2(0.1%)	2(0.1%)
Chronic respiratory failure	2(0.1%)	1(0.0%)
Lower respiratory tract inflammation	2(0.1%)	1(0.0%)
Vasomotor rhinitis	2(0.1%)	1(0.0%)
Asthmatic crisis	2(0.1%)	0
Laryngeal mass	2(0.1%)	0
Nasal crusting	2(0.1%)	0
Nasal disorder	2(0.1%)	0
Oropharyngeal discomfort	2(0.1%)	0
Nasal obstruction	1(0.0%)	6(0.2%)
Haemoptysis	1(0.0%)	4(0.1%)
Bronchial hyperreactivity	1(0.0%)	3(0.1%)
Orthopnoea	1(0.0%)	3(0.1%)
Pulmonary arterial hypertension	1(0.0%)	3(0.1%)
Throat irritation	1(0.0%)	3(0.1%)
Nasal turbinate hypertrophy	1(0.0%)	2(0.1%)
Vocal cord polyp	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Dry throat	1(0.0%)	1(0.0%)
Hydrothorax	1(0.0%)	1(0.0%)
Lung disorder	1(0.0%)	1(0.0%)
Paranasal sinus hypersecretion	1(0.0%)	1(0.0%)
Pharyngeal inflammation	1(0.0%)	1(0.0%)
Tonsillar hypertrophy	1(0.0%)	1(0.0%)
Allergic bronchitis	1(0.0%)	0
Alveolar lung disease	1(0.0%)	0
Bronchial disorder	1(0.0%)	0
Combined pulmonary fibrosis and emphysema	1(0.0%)	0
Dyspnoea at rest	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Hyperventilation	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Lung consolidation	1(0.0%)	0
Nasal mucosal disorder	1(0.0%)	0
Nasal pruritus	1(0.0%)	0
Oropharyngeal dysplasia	1(0.0%)	0
Paranasal cyst	1(0.0%)	0
Pharyngeal disorder	1(0.0%)	0
Pharyngeal erythema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pharyngeal paraesthesia	1(0.0%)	0
Pleural fibrosis	1(0.0%)	0
Pleuritic pain	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Reversible airways obstruction	1(0.0%)	0
Sinus disorder	1(0.0%)	0
Sputum discoloured	1(0.0%)	0
Tonsillar inflammation	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Aspiration	0	3(0.1%)
Idiopathic pulmonary fibrosis	0	3(0.1%)
Cough variant asthma	0	2(0.1%)
Haemothorax	0	2(0.1%)
Hypercapnia	0	2(0.1%)
Lung cyst	0	2(0.1%)
Paranasal sinus discomfort	0	2(0.1%)
Pulmonary granuloma	0	2(0.1%)
Respiration abnormal	0	2(0.1%)
Respiratory acidosis	0	2(0.1%)
Respiratory distress	0	2(0.1%)
Upper respiratory tract congestion	0	2(0.1%)
Allergic cough	0	1(0.0%)
Allergic sinusitis	0	1(0.0%)
Atopic cough	0	1(0.0%)
Bronchopneumopathy	0	1(0.0%)
Choking	0	1(0.0%)
Epiglottic oedema	0	1(0.0%)
Hepatic hydrothorax	0	1(0.0%)
Hypersensitivity pneumonitis	0	1(0.0%)
Hypopnoea	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Laryngeal disorder	0	1(0.0%)
Laryngeal inflammation	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Laryngospasm	0	1(0.0%)
Lung perforation	0	1(0.0%)
Nasal dryness	0	1(0.0%)
Nasal polyps	0	1(0.0%)
Nasal varices	0	1(0.0%)
Paranasal sinus inflammation	0	1(0.0%)
Pharyngeal stenosis	0	1(0.0%)
Pickwickian syndrome	0	1(0.0%)
Pleural thickening	0	1(0.0%)
Pulmonary calcification	0	1(0.0%)
Pulmonary haematoma	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)
Respiratory tract inflammation	0	1(0.0%)
Rhinitis perennial	0	1(0.0%)
Rhonchi	0	1(0.0%)
Sinus polyp	0	1(0.0%)
Small airways disease	0	1(0.0%)
Snoring	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Throat tightness	0	1(0.0%)
Vocal cord disorder	0	1(0.0%)
Vocal cord leukoplakia	0	1(0.0%)
Injury, Poisoning And Procedural Complications	683(17.2%)	701(17.7%)
Limb injury	111(2.8%)	75(1.9%)
Fall	91(2.3%)	94(2.4%)
Contusion	89(2.2%)	88(2.2%)
Ligament sprain	40(1.0%)	42(1.1%)
Skin abrasion	33(0.8%)	32(0.8%)
Skin laceration	25(0.6%)	24(0.6%)
Rib fracture	24(0.6%)	29(0.7%)
Thermal burn	24(0.6%)	17(0.4%)
Joint injury	24(0.6%)	13(0.3%)
Foot fracture	22(0.6%)	20(0.5%)
Post-traumatic pain	18(0.5%)	7(0.2%)
Head injury	17(0.4%)	24(0.6%)
Radius fracture	17(0.4%)	16(0.4%)
Procedural pain	15(0.4%)	12(0.3%)
Accident	15(0.4%)	10(0.3%)
Ankle fracture	14(0.4%)	18(0.5%)
Muscle strain	11(0.3%)	12(0.3%)
Femur fracture	10(0.3%)	15(0.4%)
Hand fracture	10(0.3%)	10(0.3%)
Road traffic accident	10(0.3%)	7(0.2%)
Femoral neck fracture	10(0.3%)	3(0.1%)
Humerus fracture	9(0.2%)	22(0.6%)
Upper limb fracture	9(0.2%)	10(0.3%)
Spinal compression fracture	9(0.2%)	8(0.2%)
Hip fracture	9(0.2%)	7(0.2%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Bone contusion	9(0.2%)	5(0.1%)
Joint dislocation	8(0.2%)	11(0.3%)
Tooth fracture	8(0.2%)	9(0.2%)
Wound	8(0.2%)	9(0.2%)
Wrist fracture	8(0.2%)	6(0.2%)
Muscle rupture	8(0.2%)	5(0.1%)
Scratch	8(0.2%)	5(0.1%)
Tibia fracture	8(0.2%)	4(0.1%)
Subdural haematoma	7(0.2%)	10(0.3%)
Skin wound	7(0.2%)	8(0.2%)
Soft tissue injury	7(0.2%)	8(0.2%)
Subcutaneous haematoma	7(0.2%)	7(0.2%)
Patella fracture	7(0.2%)	5(0.1%)
Chest injury	6(0.2%)	6(0.2%)
Fibula fracture	6(0.2%)	3(0.1%)
Clavicle fracture	6(0.2%)	0
Concussion	5(0.1%)	6(0.2%)
Arthropod sting	5(0.1%)	4(0.1%)
Ulna fracture	5(0.1%)	4(0.1%)
Arthropod bite	4(0.1%)	6(0.2%)
Accidental overdose	4(0.1%)	5(0.1%)
Tendon rupture	4(0.1%)	5(0.1%)
Eye injury	4(0.1%)	3(0.1%)
Craniocerebral injury	4(0.1%)	2(0.1%)
Heat illness	4(0.1%)	1(0.0%)
Lower limb fracture	4(0.1%)	1(0.0%)
Meniscus injury	3(0.1%)	15(0.4%)
Facial bones fracture	3(0.1%)	8(0.2%)
Overdose	3(0.1%)	8(0.2%)
Epicondylitis	3(0.1%)	7(0.2%)
Animal bite	3(0.1%)	5(0.1%)
Back injury	3(0.1%)	4(0.1%)
Incisional hernia	3(0.1%)	4(0.1%)
Traumatic haematoma	3(0.1%)	4(0.1%)
Muscle injury	3(0.1%)	3(0.1%)
Toxicity to various agents	3(0.1%)	3(0.1%)
Ligament rupture	3(0.1%)	2(0.1%)
Subdural haemorrhage	3(0.1%)	2(0.1%)
Anaemia postoperative	3(0.1%)	1(0.0%)
Cervical vertebral fracture	3(0.1%)	1(0.0%)
Chillblains	3(0.1%)	1(0.0%)
Scar	3(0.1%)	1(0.0%)
Tendon injury	3(0.1%)	1(0.0%)
Inflammation of wound	3(0.1%)	0
Scapula fracture	3(0.1%)	0
Injury	2(0.1%)	10(0.3%)
Lumbar vertebral fracture	2(0.1%)	5(0.1%)
Traumatic fracture	2(0.1%)	5(0.1%)
Incision site pain	2(0.1%)	4(0.1%)
Post procedural haemorrhage	2(0.1%)	4(0.1%)
Corneal abrasion	2(0.1%)	3(0.1%)
Fractured coccyx	2(0.1%)	3(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Heat stroke	2(0.1%)	3(0.1%)
Procedural haemorrhage	2(0.1%)	3(0.1%)
Face injury	2(0.1%)	2(0.1%)
Post procedural complication	2(0.1%)	2(0.1%)
Spinal column injury	2(0.1%)	2(0.1%)
Wound complication	2(0.1%)	2(0.1%)
Post procedural haematoma	2(0.1%)	1(0.0%)
Foreign body	2(0.1%)	0
Foreign body in ear	2(0.1%)	0
Hyphaema	2(0.1%)	0
Postoperative wound complication	2(0.1%)	0
Skeletal injury	2(0.1%)	0
Wound secretion	2(0.1%)	0
Skin injury	1(0.0%)	6(0.2%)
Burns second degree	1(0.0%)	5(0.1%)
Spinal fracture	1(0.0%)	5(0.1%)
Arteriovenous fistula site complication	1(0.0%)	3(0.1%)
Lip injury	1(0.0%)	2(0.1%)
Pelvic fracture	1(0.0%)	2(0.1%)
Post procedural inflammation	1(0.0%)	2(0.1%)
Spinal cord injury cervical	1(0.0%)	2(0.1%)
Acetabulum fracture	1(0.0%)	1(0.0%)
Brain contusion	1(0.0%)	1(0.0%)
Cataract operation complication	1(0.0%)	1(0.0%)
Dental restoration failure	1(0.0%)	1(0.0%)
Dislocation of vertebra	1(0.0%)	1(0.0%)
Ear injury	1(0.0%)	1(0.0%)
Exposure to communicable disease	1(0.0%)	1(0.0%)
Foreign body in throat	1(0.0%)	1(0.0%)
Incision site haematoma	1(0.0%)	1(0.0%)
Injury corneal	1(0.0%)	1(0.0%)
Multiple fractures	1(0.0%)	1(0.0%)
Nail injury	1(0.0%)	1(0.0%)
Post procedural hypothyroidism	1(0.0%)	1(0.0%)
Post-traumatic neck syndrome	1(0.0%)	1(0.0%)
Skull fracture	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Thoracic vertebral fracture	1(0.0%)	1(0.0%)
Urinary retention postoperative	1(0.0%)	1(0.0%)
Wound dehiscence	1(0.0%)	1(0.0%)
Wound haemorrhage	1(0.0%)	1(0.0%)
Abdominal wound dehiscence	1(0.0%)	0
Asbestosis	1(0.0%)	0
Avulsion fracture	1(0.0%)	0
Barotitis media	1(0.0%)	0
Barotrauma	1(0.0%)	0
Bladder injury	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Closed globe injury	1(0.0%)	0
Colon injury	1(0.0%)	0
Ear canal injury	1(0.0%)	0
Extradural haematoma	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Foreign body aspiration	1(0.0%)	0
Foreign body in eye	1(0.0%)	0
Foreign body in gastrointestinal tract	1(0.0%)	0
Gun shot wound	1(0.0%)	0
Incision site complication	1(0.0%)	0
Incision site inflammation	1(0.0%)	0
Injury of conjunctiva	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Ligament injury	1(0.0%)	0
Mallet finger	1(0.0%)	0
Mouth injury	1(0.0%)	0
Muscle contusion	1(0.0%)	0
Musculoskeletal injury	1(0.0%)	0
Nail avulsion	1(0.0%)	0
Nerve root injury lumbar	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Periorbital haematoma	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Peripheral nerve injury	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Post procedural haematuria	1(0.0%)	0
Postoperative delirium	1(0.0%)	0
Radial head dislocation	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Radiation proctopathy	1(0.0%)	0
Radiation skin injury	1(0.0%)	0
Scrotal injury	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Snake bite	1(0.0%)	0
Splenic injury	1(0.0%)	0
Splenic rupture	1(0.0%)	0
Superficial injury of eye	1(0.0%)	0
Synovial rupture	1(0.0%)	0
Testicular injury	1(0.0%)	0
Tongue injury	1(0.0%)	0
Tooth injury	1(0.0%)	0
Traumatic arthritis	1(0.0%)	0
Urostomy complication	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Vascular access steal syndrome	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Seroma	0	5(0.1%)
Nasal injury	0	4(0.1%)
Vascular pseudoaneurysm	0	3(0.1%)
Alcohol poisoning	0	2(0.1%)
Animal scratch	0	2(0.1%)
Fractured sacrum	0	2(0.1%)
Traumatic ulcer	0	2(0.1%)
Abdominal injury	0	1(0.0%)
Bite	0	1(0.0%)
Brachial plexus injury	0	1(0.0%)
Burns third degree	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Cardiac procedure complication	0	1(0.0%)
Cartilage injury	0	1(0.0%)
Cold burn	0	1(0.0%)
Compression fracture	0	1(0.0%)
Eschar	0	1(0.0%)
Exposure to SARS-CoV-2	0	1(0.0%)
Eye contusion	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Fracture	0	1(0.0%)
Gastroenteritis radiation	0	1(0.0%)
Iliotibial band syndrome	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Incorrect dose administered	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Limb fracture	0	1(0.0%)
Multiple injuries	0	1(0.0%)
Open globe injury	0	1(0.0%)
Pelvic bone injury	0	1(0.0%)
Pelvic organ injury	0	1(0.0%)
Penis injury	0	1(0.0%)
Periprosthetic fracture	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural hypoparathyroidism	0	1(0.0%)
Post procedural oedema	0	1(0.0%)
Procedural complication	0	1(0.0%)
Procedural intestinal perforation	0	1(0.0%)
Procedural nausea	0	1(0.0%)
Procedural vomiting	0	1(0.0%)
Reactive gastropathy	0	1(0.0%)
Reproductive tract procedural complication	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Stab wound	0	1(0.0%)
Stomal hernia	0	1(0.0%)
Stress fracture	0	1(0.0%)
Tooth dislocation	0	1(0.0%)
Tracheal deviation	0	1(0.0%)
Transfusion reaction	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
VIIIth nerve injury	0	1(0.0%)
Vascular anastomosis aneurysm	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	666(16.8%)	649(16.4%)
Pruritus	147(3.7%)	102(2.6%)
Skin ulcer	91(2.3%)	90(2.3%)
Eczema	68(1.7%)	58(1.5%)
Rash	52(1.3%)	50(1.3%)
Diabetic foot	41(1.0%)	43(1.1%)
Dry skin	35(0.9%)	30(0.8%)
Dermatitis	31(0.8%)	28(0.7%)
Urticaria	25(0.6%)	18(0.5%)
Skin lesion	19(0.5%)	26(0.7%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hyperkeratosis	18(0.5%)	19(0.5%)
Actinic keratosis	17(0.4%)	19(0.5%)
Dermatitis allergic	14(0.4%)	13(0.3%)
Erythema	13(0.3%)	23(0.6%)
Dermal cyst	12(0.3%)	13(0.3%)
Decubitus ulcer	12(0.3%)	12(0.3%)
Dermatitis contact	12(0.3%)	12(0.3%)
Eczema asteatotic	12(0.3%)	9(0.2%)
Psoriasis	11(0.3%)	9(0.2%)
Alopecia	11(0.3%)	6(0.2%)
Stasis dermatitis	11(0.3%)	4(0.1%)
Ingrowing nail	10(0.3%)	9(0.2%)
Skin disorder	10(0.3%)	0
Blister	8(0.2%)	21(0.5%)
Hyperhidrosis	8(0.2%)	7(0.2%)
Acne	7(0.2%)	7(0.2%)
Dermatitis atopic	7(0.2%)	6(0.2%)
Skin exfoliation	7(0.2%)	2(0.1%)
Angioedema	6(0.2%)	6(0.2%)
Palmoplantar keratoderma	6(0.2%)	3(0.1%)
Hand dermatitis	6(0.2%)	2(0.1%)
Xeroderma	6(0.2%)	2(0.1%)
Drug eruption	5(0.1%)	9(0.2%)
Skin fissures	5(0.1%)	3(0.1%)
Seborrhoeic dermatitis	4(0.1%)	9(0.2%)
Rosacea	4(0.1%)	6(0.2%)
Neurodermatitis	4(0.1%)	3(0.1%)
Pemphigoid	3(0.1%)	6(0.2%)
Rash papular	3(0.1%)	4(0.1%)
Rash pruritic	3(0.1%)	4(0.1%)
Rash macular	3(0.1%)	3(0.1%)
Diabetic ulcer	3(0.1%)	2(0.1%)
Eczema nummular	3(0.1%)	2(0.1%)
Petechiae	3(0.1%)	2(0.1%)
Night sweats	3(0.1%)	1(0.0%)
Onychoclasis	3(0.1%)	1(0.0%)
Rash maculo-papular	3(0.1%)	1(0.0%)
Erythema nodosum	3(0.1%)	0
Skin necrosis	3(0.1%)	0
Ecchymosis	2(0.1%)	7(0.2%)
Intertrigo	2(0.1%)	5(0.1%)
Dermatitis bullous	2(0.1%)	4(0.1%)
Skin hyperpigmentation	2(0.1%)	4(0.1%)
Hidradenitis	2(0.1%)	2(0.1%)
Skin discolouration	2(0.1%)	2(0.1%)
Skin mass	2(0.1%)	2(0.1%)
Pruritus allergic	2(0.1%)	1(0.0%)
Androgenetic alopecia	2(0.1%)	0
Blood blister	2(0.1%)	0
Nail disorder	2(0.1%)	0
Nail dystrophy	2(0.1%)	0
Papule	2(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Skin hypertrophy	2(0.1%)	0
Vitiligo	2(0.1%)	0
Prurigo	1(0.0%)	5(0.1%)
Pigmentation disorder	1(0.0%)	3(0.1%)
Asteatosis	1(0.0%)	2(0.1%)
Dermatosis	1(0.0%)	2(0.1%)
Dyshidrotic eczema	1(0.0%)	2(0.1%)
Lipodystrophy acquired	1(0.0%)	2(0.1%)
Rash erythematous	1(0.0%)	2(0.1%)
Skin haemorrhage	1(0.0%)	2(0.1%)
Haemorrhage subcutaneous	1(0.0%)	1(0.0%)
Lichen planopilaris	1(0.0%)	1(0.0%)
Neuropathic ulcer	1(0.0%)	1(0.0%)
Onycholysis	1(0.0%)	1(0.0%)
Pain of skin	1(0.0%)	1(0.0%)
Reactive perforating collagenosis	1(0.0%)	1(0.0%)
Skin dystrophy	1(0.0%)	1(0.0%)
Toxic skin eruption	1(0.0%)	1(0.0%)
Acanthosis nigricans	1(0.0%)	0
Alopecia scarring	1(0.0%)	0
Angiodermatitis	1(0.0%)	0
Chronic pigmented purpura	1(0.0%)	0
Chronic spontaneous urticaria	1(0.0%)	0
Dandruff	1(0.0%)	0
Dermatitis exfoliative	1(0.0%)	0
Dermatitis herpetiformis	1(0.0%)	0
Diffuse alopecia	1(0.0%)	0
Erythematotelangiectatic rosacea	1(0.0%)	0
Granuloma annulare	1(0.0%)	0
Itching scar	1(0.0%)	0
Lichen planus	1(0.0%)	0
Lichen sclerosus	1(0.0%)	0
Lichenoid keratosis	1(0.0%)	0
Macule	1(0.0%)	0
Myxoid cyst	1(0.0%)	0
Nail bed inflammation	1(0.0%)	0
Necrobiosis lipoidica diabeticorum	1(0.0%)	0
Onychomadesis	1(0.0%)	0
Pemphigus	1(0.0%)	0
Photosensitivity reaction	1(0.0%)	0
Post inflammatory pigmentation change	1(0.0%)	0
Scab	1(0.0%)	0
Skin discomfort	1(0.0%)	0
Skin fibrosis	1(0.0%)	0
Skin reaction	1(0.0%)	0
Solar lentigo	1(0.0%)	0
Skin irritation	0	5(0.1%)
Lipohypertrophy	0	3(0.1%)
Diabetic dermopathy	0	2(0.1%)
Erythema multiforme	0	2(0.1%)
Ischaemic skin ulcer	0	2(0.1%)
Purpura	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Skin oedema	0	2(0.1%)
Angiokeratoma	0	1(0.0%)
Blister rupture	0	1(0.0%)
Circumoral oedema	0	1(0.0%)
Cutaneous amyloidosis	0	1(0.0%)
Dermatomyositis	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Fracture blisters	0	1(0.0%)
Granuloma skin	0	1(0.0%)
Hangnail	0	1(0.0%)
Hypertrophic scar	0	1(0.0%)
Hypotrichosis	0	1(0.0%)
Ingrown hair	0	1(0.0%)
Lentigo	0	1(0.0%)
Leukoderma	0	1(0.0%)
Leukoplakia	0	1(0.0%)
Miliaria	0	1(0.0%)
Palmoplantar pustulosis	0	1(0.0%)
Parapsoriasis	0	1(0.0%)
Penile ulceration	0	1(0.0%)
Pustular psoriasis	0	1(0.0%)
Skin erosion	0	1(0.0%)
Skin weeping	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Trichorrhexis	0	1(0.0%)
Cardiac Disorders	504(12.7%)	585(14.8%)
Cardiac failure	49(1.2%)	86(2.2%)
Angina pectoris	49(1.2%)	52(1.3%)
Bradycardia	38(1.0%)	36(0.9%)
Coronary artery disease	36(0.9%)	43(1.1%)
Ventricular extrasystoles	30(0.8%)	32(0.8%)
Myocardial ischaemia	28(0.7%)	37(0.9%)
Atrial fibrillation	28(0.7%)	33(0.8%)
Mitral valve incompetence	27(0.7%)	28(0.7%)
Sinus bradycardia	25(0.6%)	19(0.5%)
Atrioventricular block first degree	23(0.6%)	20(0.5%)
Cardiac failure congestive	22(0.6%)	33(0.8%)
Palpitations	22(0.6%)	33(0.8%)
Cardiac failure chronic	19(0.5%)	39(1.0%)
Bundle branch block right	19(0.5%)	14(0.4%)
Bundle branch block left	18(0.5%)	15(0.4%)
Supraventricular extrasystoles	18(0.5%)	14(0.4%)
Tricuspid valve incompetence	15(0.4%)	16(0.4%)
Tachycardia	14(0.4%)	15(0.4%)
Arteriosclerosis coronary artery	14(0.4%)	11(0.3%)
Angina unstable	12(0.3%)	16(0.4%)
Atrioventricular block second degree	12(0.3%)	15(0.4%)
Hypertensive heart disease	12(0.3%)	3(0.1%)
Left ventricular hypertrophy	11(0.3%)	19(0.5%)
Coronary artery stenosis	10(0.3%)	12(0.3%)
Diastolic dysfunction	10(0.3%)	12(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Aortic valve stenosis	10(0.3%)	10(0.3%)
Left ventricular dysfunction	9(0.2%)	6(0.2%)
Atrial flutter	8(0.2%)	5(0.1%)
Aortic valve incompetence	7(0.2%)	16(0.4%)
Arrhythmia	7(0.2%)	8(0.2%)
Sinus tachycardia	7(0.2%)	8(0.2%)
Congestive cardiomyopathy	6(0.2%)	2(0.1%)
Cardiomegaly	5(0.1%)	9(0.2%)
Pericardial effusion	5(0.1%)	9(0.2%)
Sinus node dysfunction	5(0.1%)	6(0.2%)
Ventricular hypokinesia	5(0.1%)	3(0.1%)
Myocardial infarction	5(0.1%)	2(0.1%)
Cardiac failure acute	4(0.1%)	4(0.1%)
Left ventricular failure	4(0.1%)	3(0.1%)
Ischaemic cardiomyopathy	3(0.1%)	7(0.2%)
Supraventricular tachycardia	3(0.1%)	7(0.2%)
Atrioventricular block	3(0.1%)	4(0.1%)
Ventricular tachycardia	3(0.1%)	4(0.1%)
Acute left ventricular failure	3(0.1%)	2(0.1%)
Aortic valve sclerosis	3(0.1%)	2(0.1%)
Myocardial fibrosis	3(0.1%)	2(0.1%)
Pericarditis	3(0.1%)	2(0.1%)
Arrhythmia supraventricular	3(0.1%)	1(0.0%)
Degenerative aortic valve disease	3(0.1%)	1(0.0%)
Extrasystoles	2(0.1%)	7(0.2%)
Left atrial enlargement	2(0.1%)	5(0.1%)
Left atrial dilatation	2(0.1%)	4(0.1%)
Cardiac valve disease	2(0.1%)	3(0.1%)
Mitral valve stenosis	2(0.1%)	3(0.1%)
Sinus arrhythmia	2(0.1%)	2(0.1%)
Aortic valve calcification	2(0.1%)	1(0.0%)
Cardio-respiratory arrest	2(0.1%)	1(0.0%)
Chronic left ventricular failure	2(0.1%)	1(0.0%)
Degenerative mitral valve disease	2(0.1%)	1(0.0%)
Mitral valve calcification	2(0.1%)	1(0.0%)
Mitral valve sclerosis	2(0.1%)	1(0.0%)
Atrial tachycardia	2(0.1%)	0
Cardiac discomfort	2(0.1%)	0
Acute coronary syndrome	1(0.0%)	5(0.1%)
Cardiac arrest	1(0.0%)	4(0.1%)
Aortic valve disease mixed	1(0.0%)	3(0.1%)
Atrioventricular block complete	1(0.0%)	3(0.1%)
Cardiomyopathy	1(0.0%)	3(0.1%)
Atrial thrombosis	1(0.0%)	2(0.1%)
Cardiac asthma	1(0.0%)	2(0.1%)
Left ventricular dilatation	1(0.0%)	2(0.1%)
Metabolic cardiomyopathy	1(0.0%)	2(0.1%)
Mitral valve disease	1(0.0%)	2(0.1%)
Systolic dysfunction	1(0.0%)	2(0.1%)
Wandering pacemaker	1(0.0%)	2(0.1%)
Aortic valve disease	1(0.0%)	1(0.0%)
Bifascicular block	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Cardiac aneurysm	1(0.0%)	1(0.0%)
Cardiac hypertrophy	1(0.0%)	1(0.0%)
Tachyarrhythmia	1(0.0%)	1(0.0%)
Atrial enlargement	1(0.0%)	0
Bundle branch block bilateral	1(0.0%)	0
Cardiac septal hypertrophy	1(0.0%)	0
Cor pulmonale	1(0.0%)	0
Coronary ostial stenosis	1(0.0%)	0
Intracardiac mass	1(0.0%)	0
Myocarditis	1(0.0%)	0
Pericarditis adhesive	1(0.0%)	0
Pulseless electrical activity	1(0.0%)	0
Rhythm idioventricular	1(0.0%)	0
Right atrial dilatation	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Tachycardia paroxysmal	1(0.0%)	0
Ventricular hypertrophy	1(0.0%)	0
Ventricular tachyarrhythmia	1(0.0%)	0
Wellens' syndrome	1(0.0%)	0
Cardiac dysfunction	0	2(0.1%)
Cardiovascular disorder	0	2(0.1%)
Coronary artery occlusion	0	2(0.1%)
Hypertensive cardiomyopathy	0	2(0.1%)
Pulmonary valve incompetence	0	2(0.1%)
Acute myocardial infarction	0	1(0.0%)
Atrial conduction time prolongation	0	1(0.0%)
Bundle branch block	0	1(0.0%)
Cardiac amyloidosis	0	1(0.0%)
Cardiac disorder	0	1(0.0%)
Cardiac tamponade	0	1(0.0%)
Cardiac valve sclerosis	0	1(0.0%)
Cardiac valve thickening	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiomyopathy acute	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Cardiovascular insufficiency	0	1(0.0%)
Conduction disorder	0	1(0.0%)
Coronary artery insufficiency	0	1(0.0%)
Coronary artery perforation	0	1(0.0%)
Diabetic cardiomyopathy	0	1(0.0%)
Left atrial hypertrophy	0	1(0.0%)
Mitral valve prolapse	0	1(0.0%)
Paroxysmal arrhythmia	0	1(0.0%)
Pericardial disease	0	1(0.0%)
Right ventricular dilatation	0	1(0.0%)
Right ventricular failure	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Ventricular arrhythmia	0	1(0.0%)
Ventricular remodelling	0	1(0.0%)
Eye Disorders	492(12.4%)	525(13.2%)
Cataract	176(4.4%)	189(4.8%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Diabetic retinopathy	71(1.8%)	87(2.2%)
Vitreous haemorrhage	35(0.9%)	38(1.0%)
Glaucoma	30(0.8%)	33(0.8%)
Dry eye	28(0.7%)	28(0.7%)
Visual impairment	24(0.6%)	19(0.5%)
Macular oedema	17(0.4%)	17(0.4%)
Vision blurred	15(0.4%)	18(0.5%)
Blepharitis	11(0.3%)	9(0.2%)
Conjunctival haemorrhage	11(0.3%)	9(0.2%)
Conjunctivitis allergic	11(0.3%)	9(0.2%)
Diabetic retinal oedema	11(0.3%)	9(0.2%)
Retinal haemorrhage	8(0.2%)	17(0.4%)
Eye haemorrhage	8(0.2%)	3(0.1%)
Retinopathy	7(0.2%)	6(0.2%)
Ocular hypertension	7(0.2%)	4(0.1%)
Macular degeneration	6(0.2%)	9(0.2%)
Macular fibrosis	6(0.2%)	7(0.2%)
Retinopathy hypertensive	6(0.2%)	6(0.2%)
Diplopia	6(0.2%)	3(0.1%)
Asthenopia	6(0.2%)	0
Eye pruritus	5(0.1%)	5(0.1%)
Keratitis	5(0.1%)	4(0.1%)
Posterior capsule opacification	5(0.1%)	4(0.1%)
Vitreous opacities	5(0.1%)	4(0.1%)
Maculopathy	5(0.1%)	3(0.1%)
Retinal vein occlusion	5(0.1%)	3(0.1%)
Open angle glaucoma	5(0.1%)	2(0.1%)
Age-related macular degeneration	5(0.1%)	0
Eyelid ptosis	4(0.1%)	3(0.1%)
Chalazion	4(0.1%)	2(0.1%)
Eye inflammation	4(0.1%)	2(0.1%)
Periorbital oedema	4(0.1%)	2(0.1%)
Astigmatism	4(0.1%)	1(0.0%)
Meibomian gland dysfunction	4(0.1%)	1(0.0%)
Retinal detachment	3(0.1%)	10(0.3%)
Eye pain	3(0.1%)	7(0.2%)
Presbyopia	3(0.1%)	5(0.1%)
Refraction disorder	3(0.1%)	2(0.1%)
Vitreous detachment	3(0.1%)	2(0.1%)
Cataract nuclear	3(0.1%)	1(0.0%)
Ocular hyperaemia	3(0.1%)	1(0.0%)
Retinal vascular disorder	3(0.1%)	1(0.0%)
Strabismus	3(0.1%)	1(0.0%)
Visual acuity reduced	3(0.1%)	1(0.0%)
Vitreous floaters	2(0.1%)	6(0.2%)
Blindness unilateral	2(0.1%)	5(0.1%)
Pterygium	2(0.1%)	4(0.1%)
Tractional retinal detachment	2(0.1%)	4(0.1%)
Ocular discomfort	2(0.1%)	3(0.1%)
Eye irritation	2(0.1%)	2(0.1%)
Iritis	2(0.1%)	2(0.1%)
Lacrimation increased	2(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Periorbital swelling	2(0.1%)	2(0.1%)
Retinopathy proliferative	2(0.1%)	2(0.1%)
Cataract subcapsular	2(0.1%)	1(0.0%)
Dry age-related macular degeneration	2(0.1%)	1(0.0%)
Non-proliferative retinopathy	2(0.1%)	1(0.0%)
Conjunctival deposit	2(0.1%)	0
Conjunctival oedema	2(0.1%)	0
Polypoidal choroidal vasculopathy	2(0.1%)	0
Eyelid oedema	1(0.0%)	5(0.1%)
Macular hole	1(0.0%)	4(0.1%)
Cystoid macular oedema	1(0.0%)	3(0.1%)
Dacryostenosis acquired	1(0.0%)	3(0.1%)
Arteriosclerotic retinopathy	1(0.0%)	2(0.1%)
Corneal erosion	1(0.0%)	2(0.1%)
Ectropion	1(0.0%)	2(0.1%)
Photophobia	1(0.0%)	2(0.1%)
Retinal artery occlusion	1(0.0%)	2(0.1%)
Retinal oedema	1(0.0%)	2(0.1%)
Ulcerative keratitis	1(0.0%)	2(0.1%)
Vitreous degeneration	1(0.0%)	2(0.1%)
Xerophthalmia	1(0.0%)	2(0.1%)
Corneal disorder	1(0.0%)	1(0.0%)
Dermatochalasis	1(0.0%)	1(0.0%)
Entropion	1(0.0%)	1(0.0%)
Eyelid cyst	1(0.0%)	1(0.0%)
Hypermetropia	1(0.0%)	1(0.0%)
Keratopathy	1(0.0%)	1(0.0%)
Lens dislocation	1(0.0%)	1(0.0%)
Optic disc haemorrhage	1(0.0%)	1(0.0%)
Retinal aneurysm	1(0.0%)	1(0.0%)
Retinal degeneration	1(0.0%)	1(0.0%)
Retinal neovascularisation	1(0.0%)	1(0.0%)
Rhegmatogenous retinal detachment	1(0.0%)	1(0.0%)
Scleral haemorrhage	1(0.0%)	1(0.0%)
Uveitis	1(0.0%)	1(0.0%)
Vitreoretinal traction syndrome	1(0.0%)	1(0.0%)
Atrophy of globe	1(0.0%)	0
Chorioretinopathy	1(0.0%)	0
Conjunctival disorder	1(0.0%)	0
Corneal epithelium defect	1(0.0%)	0
Corneal leukoma	1(0.0%)	0
Diabetic glaucoma	1(0.0%)	0
Erythema of eyelid	1(0.0%)	0
Eye disorder	1(0.0%)	0
Eye haematoma	1(0.0%)	0
Eyelid skin dryness	1(0.0%)	0
Foreign body sensation in eyes	1(0.0%)	0
Lacrimation decreased	1(0.0%)	0
Myopia	1(0.0%)	0
Normal tension glaucoma	1(0.0%)	0
Optic nerve cupping	1(0.0%)	0
Punctate keratitis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Retinal deposits	1(0.0%)	0
Retinal disorder	1(0.0%)	0
Retinal exudates	1(0.0%)	0
Scleritis	1(0.0%)	0
Staphyloma	1(0.0%)	0
Sudden visual loss	1(0.0%)	0
Swelling of eyelid	1(0.0%)	0
Trichiasis	1(0.0%)	0
Vernal keratoconjunctivitis	1(0.0%)	0
Eye discharge	0	5(0.1%)
Amaurosis fugax	0	3(0.1%)
Blindness	0	3(0.1%)
Iridocyclitis	0	3(0.1%)
Meibomianitis	0	3(0.1%)
Retinal tear	0	3(0.1%)
Angle closure glaucoma	0	2(0.1%)
Optic atrophy	0	2(0.1%)
Photopsia	0	2(0.1%)
Abnormal sensation in eye	0	1(0.0%)
Amblyopia	0	1(0.0%)
Aphakia	0	1(0.0%)
Blepharitis allergic	0	1(0.0%)
Borderline glaucoma	0	1(0.0%)
Cataract diabetic	0	1(0.0%)
Chorioretinal atrophy	0	1(0.0%)
Conjunctival hyperaemia	0	1(0.0%)
Corneal oedema	0	1(0.0%)
Endocrine ophthalmopathy	0	1(0.0%)
Extraocular muscle paresis	0	1(0.0%)
Eye allergy	0	1(0.0%)
Eye oedema	0	1(0.0%)
Eyelid retraction	0	1(0.0%)
Glaucomatous optic disc atrophy	0	1(0.0%)
Iris disorder	0	1(0.0%)
Keratoconus	0	1(0.0%)
Lens disorder	0	1(0.0%)
Lenticular opacities	0	1(0.0%)
Macular rupture	0	1(0.0%)
Metamorphopsia	0	1(0.0%)
Optic disc disorder	0	1(0.0%)
Optic ischaemic neuropathy	0	1(0.0%)
Orbital oedema	0	1(0.0%)
Papilloedema	0	1(0.0%)
Retinal artery embolism	0	1(0.0%)
Retinal vascular occlusion	0	1(0.0%)
Visual acuity reduced transiently	0	1(0.0%)
Blood And Lymphatic System Disorders	444(11.2%)	434(10.9%)
Anaemia	290(7.3%)	278(7.0%)
Iron deficiency anaemia	41(1.0%)	49(1.2%)
Nephrogenic anaemia	38(1.0%)	29(0.7%)
Thrombocytopenia	22(0.6%)	23(0.6%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Lymphadenopathy	12(0.3%)	9(0.2%)
Normocytic anaemia	10(0.3%)	5(0.1%)
Blood loss anaemia	8(0.2%)	3(0.1%)
Thrombocytosis	7(0.2%)	7(0.2%)
Microcytic anaemia	7(0.2%)	6(0.2%)
Leukocytosis	6(0.2%)	11(0.3%)
Splenomegaly	5(0.1%)	6(0.2%)
Hypochromic anaemia	4(0.1%)	8(0.2%)
Abdominal lymphadenopathy	4(0.1%)	0
Polycythaemia	3(0.1%)	6(0.2%)
Lymphadenitis	3(0.1%)	2(0.1%)
Lymphadenopathy mediastinal	3(0.1%)	2(0.1%)
Anaemia of chronic disease	3(0.1%)	1(0.0%)
Macrocytosis	3(0.1%)	1(0.0%)
Pancytopenia	2(0.1%)	6(0.2%)
Eosinophilia	2(0.1%)	3(0.1%)
Anaemia macrocytic	2(0.1%)	1(0.0%)
Spontaneous haematoma	2(0.1%)	0
Normochromic normocytic anaemia	1(0.0%)	5(0.1%)
Anaemia folate deficiency	1(0.0%)	1(0.0%)
Coagulopathy	1(0.0%)	1(0.0%)
Hypocoagulable state	1(0.0%)	1(0.0%)
Normochromic anaemia	1(0.0%)	1(0.0%)
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Immune thrombocytopenia	1(0.0%)	0
Lymph node pain	1(0.0%)	0
Lymphocytic infiltration	1(0.0%)	0
Lymphopenia	1(0.0%)	0
Neutrophilia	1(0.0%)	0
Retroperitoneal lymphadenopathy	1(0.0%)	0
Splenic granuloma	1(0.0%)	0
Acquired haemophilia	0	1(0.0%)
Anaemia megaloblastic	0	1(0.0%)
Anaemia of malignant disease	0	1(0.0%)
B-lymphocyte abnormalities	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Bone marrow oedema	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)
Haemoconcentration	0	1(0.0%)
Haemoglobinaemia	0	1(0.0%)
Hyperglobulinaemia	0	1(0.0%)
Hyperviscosity syndrome	0	1(0.0%)
Increased tendency to bruise	0	1(0.0%)
Neutropenia	0	1(0.0%)
Spleen disorder	0	1(0.0%)
Splenic embolism	0	1(0.0%)
Spontaneous haemorrhage	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	327(8.2%)	324(8.2%)
Basal cell carcinoma	34(0.9%)	33(0.8%)
Prostate cancer	24(0.6%)	25(0.6%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Colon adenoma	16(0.4%)	15(0.4%)
Lung neoplasm malignant	15(0.4%)	10(0.3%)
Skin papilloma	13(0.3%)	10(0.3%)
Squamous cell carcinoma of skin	12(0.3%)	9(0.2%)
Bladder cancer	10(0.3%)	10(0.3%)
Colon cancer	10(0.3%)	8(0.2%)
Breast cancer	8(0.2%)	6(0.2%)
Haemangioma of liver	8(0.2%)	5(0.1%)
Lipoma	7(0.2%)	12(0.3%)
Seborrhoeic keratosis	7(0.2%)	3(0.1%)
Adenoma benign	6(0.2%)	4(0.1%)
Bladder neoplasm	6(0.2%)	4(0.1%)
Renal neoplasm	5(0.1%)	6(0.2%)
Uterine leiomyoma	5(0.1%)	6(0.2%)
Pancreatic carcinoma	5(0.1%)	3(0.1%)
Renal cell carcinoma	5(0.1%)	1(0.0%)
Malignant melanoma	4(0.1%)	8(0.2%)
Squamous cell carcinoma	4(0.1%)	3(0.1%)
Metastases to lung	4(0.1%)	2(0.1%)
Bladder cancer recurrent	4(0.1%)	1(0.0%)
Clear cell renal cell carcinoma	4(0.1%)	1(0.0%)
Oesophageal adenocarcinoma	4(0.1%)	0
Pancreatic neoplasm	4(0.1%)	0
Adrenal adenoma	3(0.1%)	7(0.2%)
Metastases to liver	3(0.1%)	6(0.2%)
Hepatocellular carcinoma	3(0.1%)	4(0.1%)
Plasma cell myeloma	3(0.1%)	4(0.1%)
Prostatic adenoma	3(0.1%)	4(0.1%)
Adenocarcinoma of colon	3(0.1%)	3(0.1%)
Bladder transitional cell carcinoma	3(0.1%)	3(0.1%)
Melanocytic naevus	3(0.1%)	3(0.1%)
Metastases to lymph nodes	3(0.1%)	3(0.1%)
Meningioma	3(0.1%)	2(0.1%)
Skin cancer	3(0.1%)	2(0.1%)
Metastases to bone	3(0.1%)	1(0.0%)
Metastases to central nervous system	3(0.1%)	1(0.0%)
Metastases to spine	3(0.1%)	1(0.0%)
Lung neoplasm	2(0.1%)	5(0.1%)
Lung adenocarcinoma	2(0.1%)	4(0.1%)
Anogenital warts	2(0.1%)	3(0.1%)
Renal hamartoma	2(0.1%)	3(0.1%)
Adenocarcinoma	2(0.1%)	2(0.1%)
Hepatic cancer	2(0.1%)	2(0.1%)
Neoplasm	2(0.1%)	2(0.1%)
Transitional cell carcinoma	2(0.1%)	2(0.1%)
Cholangiocarcinoma	2(0.1%)	1(0.0%)
Chronic lymphocytic leukaemia	2(0.1%)	1(0.0%)
Keratoacanthoma	2(0.1%)	1(0.0%)
Myelodysplastic syndrome	2(0.1%)	1(0.0%)
Prostate cancer recurrent	2(0.1%)	1(0.0%)
Rectal adenocarcinoma	2(0.1%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Benign lung neoplasm	2(0.1%)	0
Benign renal neoplasm	2(0.1%)	0
Brain neoplasm malignant	2(0.1%)	0
Breast cancer metastatic	2(0.1%)	0
Cancer pain	2(0.1%)	0
Endometrial adenocarcinoma	2(0.1%)	0
Haemangioma	2(0.1%)	0
Hypergammaglobulinaemia benign monoclonal	2(0.1%)	0
Intraductal papillary mucinous neoplasm	2(0.1%)	0
Oral papilloma	2(0.1%)	0
Prostate cancer metastatic	2(0.1%)	0
Small cell lung cancer	1(0.0%)	4(0.1%)
Adenocarcinoma gastric	1(0.0%)	3(0.1%)
Blepharal papilloma	1(0.0%)	3(0.1%)
Breast neoplasm	1(0.0%)	3(0.1%)
Colorectal cancer	1(0.0%)	3(0.1%)
Large intestine benign neoplasm	1(0.0%)	3(0.1%)
Neoplasm skin	1(0.0%)	3(0.1%)
Oesophageal carcinoma	1(0.0%)	3(0.1%)
Renal cancer	1(0.0%)	3(0.1%)
Salivary gland neoplasm	1(0.0%)	3(0.1%)
Acute myeloid leukaemia	1(0.0%)	2(0.1%)
Pancreatic carcinoma metastatic	1(0.0%)	2(0.1%)
Benign neoplasm of thyroid gland	1(0.0%)	1(0.0%)
Bladder transitional cell carcinoma recurrent	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Gastrointestinal tract adenoma	1(0.0%)	1(0.0%)
Haemangioma of bone	1(0.0%)	1(0.0%)
Hepatic neoplasm	1(0.0%)	1(0.0%)
Infected neoplasm	1(0.0%)	1(0.0%)
Lip squamous cell carcinoma	1(0.0%)	1(0.0%)
Lipofibroma	1(0.0%)	1(0.0%)
Lung cancer metastatic	1(0.0%)	1(0.0%)
Lymphoma	1(0.0%)	1(0.0%)
Malignant pleural effusion	1(0.0%)	1(0.0%)
Monoclonal gammopathy	1(0.0%)	1(0.0%)
Oesophageal neoplasm	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Papilloma	1(0.0%)	1(0.0%)
Pituitary tumour	1(0.0%)	1(0.0%)
Soft tissue neoplasm	1(0.0%)	1(0.0%)
Thyroid cancer	1(0.0%)	1(0.0%)
Angiomyofibroblastoma	1(0.0%)	0
Angiomyolipoma	1(0.0%)	0
Atypical fibroxanthoma	1(0.0%)	0
Benign bone neoplasm	1(0.0%)	0
Benign gastric neoplasm	1(0.0%)	0
Benign neoplasm of conjunctiva	1(0.0%)	0
Benign neoplasm of skin	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Cerebral haemangioma	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Dermatofibrosarcoma protuberans	1(0.0%)	0
Enchondromatosis	1(0.0%)	0
Epithelioid mesothelioma	1(0.0%)	0
Eye naevus	1(0.0%)	0
Fallopian tube leiomyoma	1(0.0%)	0
Fibroma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Gastrointestinal stromal tumour	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Inflammatory carcinoma of the breast	1(0.0%)	0
Intraocular melanoma	1(0.0%)	0
Invasive ductal breast carcinoma	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Laryngeal squamous cell carcinoma	1(0.0%)	0
Light chain disease	1(0.0%)	0
Lip and/or oral cavity cancer stage 0	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0
Muscle neoplasm	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Neuroendocrine tumour	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Oral fibroma	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Osteochondroma	1(0.0%)	0
Paraneoplastic syndrome	1(0.0%)	0
Polycythaemia vera	1(0.0%)	0
Pyogenic granuloma	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm benign	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Uterine cancer	1(0.0%)	0
Acrochordon	0	3(0.1%)
Brain neoplasm	0	3(0.1%)
Gastric cancer	0	3(0.1%)
Malignant melanoma in situ	0	3(0.1%)
Benign neoplasm of bladder	0	2(0.1%)
Benign pancreatic neoplasm	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Bowen's disease	0	2(0.1%)
Colon neoplasm	0	2(0.1%)
Endometrial cancer	0	2(0.1%)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Pituitary tumour benign	0	2(0.1%)
Acoustic neuroma	0	1(0.0%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Adrenal neoplasm	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign anorectal neoplasm	0	1(0.0%)
Benign gastrointestinal neoplasm	0	1(0.0%)
Benign hepatic neoplasm	0	1(0.0%)
Benign neoplasm of prostate	0	1(0.0%)
Bladder papilloma	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Carcinoma in situ of skin	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Dysplastic naevus	0	1(0.0%)
Eyelid tumour	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Ganglioneuroma	0	1(0.0%)
Gastric adenoma	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Haemangioblastoma	0	1(0.0%)
Hepatic cancer metastatic	0	1(0.0%)
Intraductal papillary-mucinous carcinoma of pancreas	0	1(0.0%)
Intraductal papilloma of breast	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Kaposi's sarcoma	0	1(0.0%)
Lentigo maligna	0	1(0.0%)
Lymphocytic leukaemia	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Metastasis	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neoplasm malignant	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Ovarian neoplasm	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pleomorphic adenoma	0	1(0.0%)
Prostate cancer stage IV	0	1(0.0%)
Rectal adenoma	0	1(0.0%)
Renal adenoma	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Retroperitoneal neoplasm	0	1(0.0%)
Sarcoma	0	1(0.0%)
Sarcomatoid carcinoma of the lung	0	1(0.0%)
Schwannoma	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Sweat gland tumour	0	1(0.0%)
Thymoma	0	1(0.0%)
Thyroid neoplasm	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Vulvovaginal warts	0	1(0.0%)
Waldenstrom's macroglobulinaemia	0	1(0.0%)
Surgical And Medical Procedures	281(7.1%)	282(7.1%)
Cataract operation	64(1.6%)	75(1.9%)
Tooth extraction	27(0.7%)	26(0.7%)
Toe amputation	13(0.3%)	7(0.2%)
Large intestinal polypectomy	11(0.3%)	6(0.2%)
Skin neoplasm excision	11(0.3%)	5(0.1%)
Knee arthroplasty	9(0.2%)	13(0.3%)
Intraocular lens implant	8(0.2%)	8(0.2%)
Arteriovenous fistula operation	7(0.2%)	3(0.1%)
Vitrectomy	6(0.2%)	10(0.3%)
Polypectomy	6(0.2%)	4(0.1%)
Hip arthroplasty	5(0.1%)	7(0.2%)
Carpal tunnel decompression	5(0.1%)	4(0.1%)
Cardiac pacemaker insertion	4(0.1%)	1(0.0%)
Diabetes mellitus management	4(0.1%)	1(0.0%)
Cholecystectomy	3(0.1%)	7(0.2%)
Tendon sheath incision	3(0.1%)	5(0.1%)
Skin lesion removal	3(0.1%)	2(0.1%)
Colectomy	3(0.1%)	1(0.0%)
Endodontic procedure	3(0.1%)	1(0.0%)
Peripheral artery angioplasty	3(0.1%)	1(0.0%)
Eye operation	3(0.1%)	0
Foot operation	3(0.1%)	0
Parathyroidectomy	3(0.1%)	0
Skin graft	3(0.1%)	0
Dental implantation	2(0.1%)	5(0.1%)
Transurethral prostatectomy	2(0.1%)	4(0.1%)
Coronary angioplasty	2(0.1%)	2(0.1%)
Debridement	2(0.1%)	2(0.1%)
Gastrectomy	2(0.1%)	2(0.1%)
Haemodialysis	2(0.1%)	2(0.1%)
Inguinal hernia repair	2(0.1%)	2(0.1%)
Prostatectomy	2(0.1%)	2(0.1%)
Coronary artery bypass	2(0.1%)	1(0.0%)
Eye laser surgery	2(0.1%)	1(0.0%)
Gastric bypass	2(0.1%)	1(0.0%)
Leg amputation	2(0.1%)	1(0.0%)
Metabolic surgery	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Spinal laminectomy	2(0.1%)	1(0.0%)
Aortic valve replacement	2(0.1%)	0
Dental operation	2(0.1%)	0
Dialysis	2(0.1%)	0
Hysterectomy	2(0.1%)	0
Lens capsulotomy	2(0.1%)	0
Parotidectomy	2(0.1%)	0
Rehabilitation therapy	2(0.1%)	0
Shoulder arthroplasty	2(0.1%)	0
Umbilical hernia repair	1(0.0%)	5(0.1%)
Intervertebral disc operation	1(0.0%)	4(0.1%)
Lens extraction	1(0.0%)	4(0.1%)
Dialysis device insertion	1(0.0%)	2(0.1%)
Foot amputation	1(0.0%)	2(0.1%)
Spinal operation	1(0.0%)	2(0.1%)
Transurethral bladder resection	1(0.0%)	2(0.1%)
Aortic aneurysm repair	1(0.0%)	1(0.0%)
Blepharoplasty	1(0.0%)	1(0.0%)
Circumcision	1(0.0%)	1(0.0%)
Coronary revascularisation	1(0.0%)	1(0.0%)
Glaucoma drainage device placement	1(0.0%)	1(0.0%)
Intestinal polypectomy	1(0.0%)	1(0.0%)
Knee operation	1(0.0%)	1(0.0%)
Papilloma excision	1(0.0%)	1(0.0%)
Peripheral artery bypass	1(0.0%)	1(0.0%)
Peripheral artery stent insertion	1(0.0%)	1(0.0%)
Preoperative care	1(0.0%)	1(0.0%)
Pterygium operation	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Retinal operation	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Tenotomy	1(0.0%)	1(0.0%)
Aneurysm repair	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Biliary catheter removal	1(0.0%)	0
Bladder calculus removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Brachytherapy	1(0.0%)	0
Breast prosthesis removal	1(0.0%)	0
Cancer surgery	1(0.0%)	0
Canthoplasty	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Cerumen removal	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Dental care	1(0.0%)	0
Epidural injection	1(0.0%)	0
Femoral hernia repair	1(0.0%)	0
Finger amputation	1(0.0%)	0
Finger repair operation	1(0.0%)	0
Fistula repair	1(0.0%)	0
Gingival operation	1(0.0%)	0
Hernia repair	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Implantable defibrillator insertion	1(0.0%)	0
Infiltration anaesthesia	1(0.0%)	0
Internal fixation of fracture	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Intra-ocular injection	1(0.0%)	0
Lithotripsy	1(0.0%)	0
Mass excision	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Medical device removal	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Micrographic skin surgery	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nail operation	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Nerve block	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Oophorectomy bilateral	1(0.0%)	0
Oral surgery	1(0.0%)	0
Orthopaedic procedure	1(0.0%)	0
Ostectomy	1(0.0%)	0
Pancreatic stent placement	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Radical hysterectomy	1(0.0%)	0
Radical mastectomy	1(0.0%)	0
Removal of foreign body from eye	1(0.0%)	0
Removal of internal fixation	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Suture insertion	1(0.0%)	0
Synovectomy	1(0.0%)	0
Tenolysis	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Thyroidectomy	1(0.0%)	0
Tooth repair	1(0.0%)	0
Ureteric calculus removal	1(0.0%)	0
Urethral bulking agent injection	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Vasectomy	1(0.0%)	0
Wound treatment	1(0.0%)	0
Insertion of ambulatory peritoneal catheter	0	3(0.1%)
Sebaceous cyst excision	0	3(0.1%)
Angioplasty	0	2(0.1%)
Hydrocele operation	0	2(0.1%)
Percutaneous coronary intervention	0	2(0.1%)
Retinopexy	0	2(0.1%)
Stent placement	0	2(0.1%)
Amputation	0	1(0.0%)
Antitussive therapy	0	1(0.0%)
Appendicectomy	0	1(0.0%)
Arthrodesis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Artificial crown procedure	0	1(0.0%)
Astringent therapy	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder neck resection	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Caecum operation	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cardioversion	0	1(0.0%)
Central venous catheter removal	0	1(0.0%)
Central venous catheterisation	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Colon operation	0	1(0.0%)
Colostomy	0	1(0.0%)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Cystostomy	0	1(0.0%)
Dermal filler injection	0	1(0.0%)
Ear tube insertion	0	1(0.0%)
Eye excision	0	1(0.0%)
Eyelid operation	0	1(0.0%)
Facial lesion excision	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Gastric electrical stimulation	0	1(0.0%)
Glaucoma surgery	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Intraocular lens repositioning	0	1(0.0%)
Intravitreal implant	0	1(0.0%)
Joint injection	0	1(0.0%)
Laser therapy	0	1(0.0%)
Limb operation	0	1(0.0%)
Lipoma excision	0	1(0.0%)
Matrixectomy	0	1(0.0%)
Meniscus operation	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Neurosurgery	0	1(0.0%)
Pharyngeal polypectomy	0	1(0.0%)
Phlebotomy	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Posterior lens capsulotomy	0	1(0.0%)
Radioactive iodine therapy	0	1(0.0%)
Rectocele repair	0	1(0.0%)
Removal of foreign body from larynx	0	1(0.0%)
Renal cyst excision	0	1(0.0%)
Renal disorder prophylaxis	0	1(0.0%)
Sclerotherapy	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Urinary cystectomy	0	1(0.0%)
Varicose vein operation	0	1(0.0%)
Vascular catheterisation	0	1(0.0%)

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Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Vascular graft	0	1(0.0%)
Wisdom teeth removal	0	1(0.0%)
Zonulolysis	0	1(0.0%)
Psychiatric Disorders	235(5.9%)	309(7.8%)
Insomnia	92(2.3%)	100(2.5%)
Depression	52(1.3%)	74(1.9%)
Anxiety	32(0.8%)	48(1.2%)
Sleep disorder	13(0.3%)	16(0.4%)
Confusional state	10(0.3%)	12(0.3%)
Delirium	5(0.1%)	10(0.3%)
Hallucination	5(0.1%)	5(0.1%)
Stress	4(0.1%)	5(0.1%)
Major depression	4(0.1%)	4(0.1%)
Mental status changes	3(0.1%)	7(0.2%)
Mixed anxiety and depressive disorder	3(0.1%)	3(0.1%)
Disorientation	3(0.1%)	1(0.0%)
Bipolar disorder	3(0.1%)	0
Depressed mood	2(0.1%)	10(0.3%)
Anxiety disorder	2(0.1%)	3(0.1%)
Aggression	2(0.1%)	2(0.1%)
Apathy	2(0.1%)	2(0.1%)
Restlessness	2(0.1%)	1(0.0%)
Completed suicide	2(0.1%)	0
Nightmare	2(0.1%)	0
Personality change due to a general medical condition	2(0.1%)	0
Tic	2(0.1%)	0
Adjustment disorder with depressed mood	1(0.0%)	3(0.1%)
Suicidal ideation	1(0.0%)	3(0.1%)
Alcohol abuse	1(0.0%)	1(0.0%)
Enuresis	1(0.0%)	1(0.0%)
Initial insomnia	1(0.0%)	1(0.0%)
Middle insomnia	1(0.0%)	1(0.0%)
Neurosis	1(0.0%)	1(0.0%)
Tension	1(0.0%)	1(0.0%)
Abnormal behaviour	1(0.0%)	0
Affective disorder	1(0.0%)	0
Agitation	1(0.0%)	0
Alcohol withdrawal syndrome	1(0.0%)	0
Drug dependence	1(0.0%)	0
Generalised anxiety disorder	1(0.0%)	0
Grief reaction	1(0.0%)	0
Mania	1(0.0%)	0
Mental disorder	1(0.0%)	0
Mental disorder due to a general medical condition	1(0.0%)	0
Nervousness	1(0.0%)	0
Persistent depressive disorder	1(0.0%)	0
Phonophobia	1(0.0%)	0
Psychotic disorder	1(0.0%)	0
Schizophrenia	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Post-traumatic stress disorder	0	5(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Adjustment disorder	0	2(0.1%)
Mood altered	0	2(0.1%)
Panic disorder	0	2(0.1%)
Abulia	0	1(0.0%)
Acute stress disorder	0	1(0.0%)
Affect lability	0	1(0.0%)
Alcoholism	0	1(0.0%)
Anorgasmia	0	1(0.0%)
Claustrophobia	0	1(0.0%)
Daydreaming	0	1(0.0%)
Delusional disorder, unspecified type	0	1(0.0%)
Drug abuse	0	1(0.0%)
Dysphemia	0	1(0.0%)
Dyssomnia	0	1(0.0%)
Executive dysfunction	0	1(0.0%)
Irritability	0	1(0.0%)
Parasomnia	0	1(0.0%)
Personality change	0	1(0.0%)
Social avoidant behaviour	0	1(0.0%)
Tobacco abuse	0	1(0.0%)
Reproductive System And Breast Disorders	199(5.0%)	203(5.1%)
Benign prostatic hyperplasia	85(2.1%)	79(2.0%)
Erectile dysfunction	17(0.4%)	23(0.6%)
Prostatomegaly	17(0.4%)	17(0.4%)
Prostatitis	10(0.3%)	11(0.3%)
Gynaecomastia	8(0.2%)	7(0.2%)
Pelvic pain	7(0.2%)	4(0.1%)
Breast pain	7(0.2%)	3(0.1%)
Prostatism	5(0.1%)	4(0.1%)
Uterine haemorrhage	4(0.1%)	2(0.1%)
Vaginal haemorrhage	4(0.1%)	2(0.1%)
Postmenopausal haemorrhage	4(0.1%)	1(0.0%)
Balanoposthitis	3(0.1%)	3(0.1%)
Atrophic vulvovaginitis	3(0.1%)	2(0.1%)
Vulvovaginal pruritus	3(0.1%)	1(0.0%)
Breast mass	2(0.1%)	4(0.1%)
Prostatic calcification	2(0.1%)	4(0.1%)
Endometrial hyperplasia	2(0.1%)	3(0.1%)
Uterine polyp	2(0.1%)	3(0.1%)
Cervical dysplasia	2(0.1%)	2(0.1%)
Nipple pain	2(0.1%)	1(0.0%)
Testicular pain	2(0.1%)	1(0.0%)
Prostatic mass	2(0.1%)	0
Prostatic disorder	1(0.0%)	5(0.1%)
Fibrocystic breast disease	1(0.0%)	2(0.1%)
Metrorrhagia	1(0.0%)	2(0.1%)
Breast cyst	1(0.0%)	1(0.0%)
Cystocele	1(0.0%)	1(0.0%)
Pelvic fluid collection	1(0.0%)	1(0.0%)
Scrotal dermatitis	1(0.0%)	1(0.0%)
Uterine prolapse	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Amenorrhoea	1(0.0%)	0
Breast discharge	1(0.0%)	0
Breast disorder	1(0.0%)	0
Breast necrosis	1(0.0%)	0
Cervical polyp	1(0.0%)	0
Ectropion of cervix	1(0.0%)	0
Menstruation irregular	1(0.0%)	0
Pelvic haematoma	1(0.0%)	0
Penile pain	1(0.0%)	0
Prostatic dysplasia	1(0.0%)	0
Prostatovesiculitis	1(0.0%)	0
Sexual dysfunction	1(0.0%)	0
Testicular perforation	1(0.0%)	0
Uterine disorder	1(0.0%)	0
Vaginal disorder	1(0.0%)	0
Vulvovaginal dryness	1(0.0%)	0
Ovarian cyst	0	6(0.2%)
Breast hyperplasia	0	3(0.1%)
Pruritus genital	0	2(0.1%)
Vulvovaginal pain	0	2(0.1%)
Adnexa uteri cyst	0	1(0.0%)
Adnexa uteri mass	0	1(0.0%)
Breast calcifications	0	1(0.0%)
Breast dysplasia	0	1(0.0%)
Breast inflammation	0	1(0.0%)
Cervical cyst	0	1(0.0%)
Dysfunctional uterine bleeding	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Epididymal enlargement	0	1(0.0%)
Genital hypoaesthesia	0	1(0.0%)
Genital lesion	0	1(0.0%)
Genital tract inflammation	0	1(0.0%)
Hydrometra	0	1(0.0%)
Menorrhagia	0	1(0.0%)
Nipple exudate bloody	0	1(0.0%)
Nipple inflammation	0	1(0.0%)
Ovarian enlargement	0	1(0.0%)
Pelvic discomfort	0	1(0.0%)
Penile erythema	0	1(0.0%)
Penile vascular disorder	0	1(0.0%)
Prostatic cyst	0	1(0.0%)
Rectocele	0	1(0.0%)
Scrotal oedema	0	1(0.0%)
Scrotal pain	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine mass	0	1(0.0%)
Vaginal oedema	0	1(0.0%)
Hepatobiliary Disorders	188(4.7%)	194(4.9%)
Cholelithiasis	54(1.4%)	51(1.3%)
Hepatic steatosis	44(1.1%)	64(1.6%)
Hepatic function abnormal	15(0.4%)	14(0.4%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Cholecystitis	13(0.3%)	13(0.3%)
Cholecystitis acute	11(0.3%)	13(0.3%)
Hepatic cirrhosis	11(0.3%)	12(0.3%)
Hepatic cyst	8(0.2%)	5(0.1%)
Gallbladder polyp	8(0.2%)	4(0.1%)
Cholecystitis chronic	6(0.2%)	5(0.1%)
Biliary colic	6(0.2%)	3(0.1%)
Hepatomegaly	6(0.2%)	2(0.1%)
Bile duct stone	5(0.1%)	4(0.1%)
Cholestasis	5(0.1%)	4(0.1%)
Non-alcoholic steatohepatitis	3(0.1%)	4(0.1%)
Hepatic lesion	3(0.1%)	2(0.1%)
Liver disorder	3(0.1%)	2(0.1%)
Hepatitis	3(0.1%)	1(0.0%)
Cholangitis	2(0.1%)	6(0.2%)
Drug-induced liver injury	2(0.1%)	2(0.1%)
Portal hypertension	2(0.1%)	2(0.1%)
Gallbladder disorder	2(0.1%)	1(0.0%)
Nonalcoholic fatty liver disease	2(0.1%)	1(0.0%)
Biliary obstruction	2(0.1%)	0
Chronic hepatitis	2(0.1%)	0
Hepatic fibrosis	2(0.1%)	0
Hepatocellular injury	2(0.1%)	0
Cholangitis acute	1(0.0%)	3(0.1%)
Biliary dilatation	1(0.0%)	2(0.1%)
Hyperplastic cholecystopathy	1(0.0%)	2(0.1%)
Alcoholic liver disease	1(0.0%)	1(0.0%)
Gallbladder cholesterolosis	1(0.0%)	1(0.0%)
Gallbladder enlargement	1(0.0%)	1(0.0%)
Hepatic pain	1(0.0%)	1(0.0%)
Hepatitis acute	1(0.0%)	1(0.0%)
Hyperbilirubinaemia	1(0.0%)	1(0.0%)
Hypertransaminasaemia	1(0.0%)	1(0.0%)
Jaundice cholestatic	1(0.0%)	1(0.0%)
Bile duct stenosis	1(0.0%)	0
Biliary dyskinesia	1(0.0%)	0
Gallbladder fistula	1(0.0%)	0
Hepatic calcification	1(0.0%)	0
Hepatic failure	1(0.0%)	0
Jaundice	1(0.0%)	0
Ocular icterus	1(0.0%)	0
Porcelain gallbladder	1(0.0%)	0
Congestive hepatopathy	0	2(0.1%)
Hepatic mass	0	2(0.1%)
Hepatitis alcoholic	0	2(0.1%)
Cardiac cirrhosis	0	1(0.0%)
Cholecystocholangitis	0	1(0.0%)
Granulomatous liver disease	0	1(0.0%)
Hepatic vascular thrombosis	0	1(0.0%)
Hepatosplenomegaly	0	1(0.0%)
Hydrocholecystis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Ear And Labyrinth Disorders	175(4.4%)	166(4.2%)
Vertigo	82(2.1%)	71(1.8%)
Tinnitus	22(0.6%)	28(0.7%)
Ear pain	10(0.3%)	10(0.3%)
Cerumen impaction	9(0.2%)	7(0.2%)
Hypoacusis	9(0.2%)	4(0.1%)
Deafness neurosensory	8(0.2%)	4(0.1%)
Vertigo positional	7(0.2%)	7(0.2%)
Vestibular disorder	7(0.2%)	5(0.1%)
Presbyacusis	6(0.2%)	1(0.0%)
Deafness	5(0.1%)	5(0.1%)
Excessive cerumen production	4(0.1%)	8(0.2%)
Sudden hearing loss	4(0.1%)	5(0.1%)
Deafness unilateral	3(0.1%)	3(0.1%)
Ear pruritus	3(0.1%)	0
Tympanic membrane perforation	2(0.1%)	4(0.1%)
Meniere's disease	2(0.1%)	1(0.0%)
Inner ear disorder	2(0.1%)	0
Motion sickness	1(0.0%)	2(0.1%)
Acute vestibular syndrome	1(0.0%)	0
Aural polyp	1(0.0%)	0
Auricular pseudocyst	1(0.0%)	0
Conductive deafness	1(0.0%)	0
Mixed deafness	1(0.0%)	0
Deafness bilateral	0	5(0.1%)
Ear congestion	0	1(0.0%)
Eustachian tube dysfunction	0	1(0.0%)
Eustachian tube patulous	0	1(0.0%)
Middle ear inflammation	0	1(0.0%)
Neurosensory hypoacusis	0	1(0.0%)
Tympanic membrane hyperaemia	0	1(0.0%)
Vestibular ataxia	0	1(0.0%)
Endocrine Disorders	122(3.1%)	129(3.3%)
Hypothyroidism	40(1.0%)	41(1.0%)
Hyperparathyroidism secondary	23(0.6%)	17(0.4%)
Thyroid mass	15(0.4%)	14(0.4%)
Hyperparathyroidism	9(0.2%)	16(0.4%)
Hyperthyroidism	8(0.2%)	12(0.3%)
Goitre	5(0.1%)	11(0.3%)
Adrenal mass	3(0.1%)	4(0.1%)
Adrenomegaly	3(0.1%)	0
Thyroid disorder	3(0.1%)	0
Euthyroid sick syndrome	2(0.1%)	2(0.1%)
Hypogonadism	2(0.1%)	2(0.1%)
Androgen deficiency	2(0.1%)	0
Thyroid cyst	1(0.0%)	4(0.1%)
Autoimmune thyroiditis	1(0.0%)	1(0.0%)
Basedow's disease	1(0.0%)	1(0.0%)
Hypoparathyroidism	1(0.0%)	1(0.0%)
Primary hyperaldosteronism	1(0.0%)	1(0.0%)
Primary hypothyroidism	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Cushing's syndrome	1(0.0%)	0
Empty sella syndrome	1(0.0%)	0
Hyperandrogenism	1(0.0%)	0
Hyperparathyroidism primary	1(0.0%)	0
Hyperpituitarism	1(0.0%)	0
Hypopituitarism	1(0.0%)	0
Thyroiditis subacute	1(0.0%)	0
Toxic nodular goitre	1(0.0%)	0
Hyperplasia adrenal	0	2(0.1%)
Pituitary-dependent Cushing's syndrome	0	2(0.1%)
Adrenal disorder	0	1(0.0%)
Hyperprolactinaemia	0	1(0.0%)
Secondary hyperthyroidism	0	1(0.0%)
Thyroiditis	0	1(0.0%)
Immune System Disorders	46(1.2%)	38(1.0%)
Seasonal allergy	21(0.5%)	18(0.5%)
Drug hypersensitivity	10(0.3%)	4(0.1%)
Hypersensitivity	8(0.2%)	10(0.3%)
Allergy to arthropod sting	2(0.1%)	1(0.0%)
Food allergy	1(0.0%)	1(0.0%)
Allergy to animal	1(0.0%)	0
Amyloidosis	1(0.0%)	0
Dust allergy	1(0.0%)	0
Multiple allergies	1(0.0%)	0
Selective IgM immunodeficiency	1(0.0%)	0
Allergy to vaccine	0	1(0.0%)
Anaphylactic reaction	0	1(0.0%)
Contrast media allergy	0	1(0.0%)
Mite allergy	0	1(0.0%)
Congenital, Familial And Genetic Disorders	20(0.5%)	24(0.6%)
Congenital cystic kidney disease	3(0.1%)	0
Hydrocele	2(0.1%)	5(0.1%)
Phimosis	2(0.1%)	5(0.1%)
Type V hyperlipidaemia	2(0.1%)	2(0.1%)
Congenital renal cyst	2(0.1%)	0
Hypertrophic cardiomyopathy	1(0.0%)	1(0.0%)
Arteriovenous malformation	1(0.0%)	0
Bicuspid aortic valve	1(0.0%)	0
Factor VIII deficiency	1(0.0%)	0
Factor XII deficiency	1(0.0%)	0
Keratosis follicular	1(0.0%)	0
Limb malformation	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Ventricular septal defect	1(0.0%)	0
Adenomatous polyposis coli	0	1(0.0%)
Atrial septal defect	0	1(0.0%)
Birth mark	0	1(0.0%)
Congenital aortic anomaly	0	1(0.0%)
Congenital poikiloderma	0	1(0.0%)
Dermoid cyst	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.1: Frequency Summary of Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Distichiasis	0	1(0.0%)
Epidermolysis bullosa	0	1(0.0%)
Hereditary palmoplantar keratoderma	0	1(0.0%)
Hypospadias	0	1(0.0%)
Left-to-right cardiac shunt	0	1(0.0%)
Product Issues	6(0.2%)	6(0.2%)
Lead dislodgement	2(0.1%)	0
Device malfunction	1(0.0%)	2(0.1%)
Device leakage	1(0.0%)	1(0.0%)
Device capturing issue	1(0.0%)	0
Device lead damage	1(0.0%)	0
Device loosening	1(0.0%)	0
Device dislocation	0	2(0.1%)
Patient-device incompatibility	0	1(0.0%)
Social Circumstances	2(0.1%)	3(0.1%)
Social stay hospitalisation	1(0.0%)	0
Substance use	1(0.0%)	0
Walking disability	0	2(0.1%)
Pregnancy of partner	0	1(0.0%)
Pregnancy, Puerperium And Perinatal Conditions	0	1(0.0%)
Umbilical granuloma	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Any TEAE	1329(33.4%)	1415(35.7%)
Infections And Infestations	405(10.2%)	429(10.8%)
Pneumonia	98(2.5%)	146(3.7%)
Cellulitis	44(1.1%)	32(0.8%)
Urinary tract infection	27(0.7%)	48(1.2%)
Sepsis	23(0.6%)	27(0.7%)
Osteomyelitis	17(0.4%)	12(0.3%)
Erysipelas	16(0.4%)	17(0.4%)
Gastroenteritis	14(0.4%)	21(0.5%)
Pyelonephritis	12(0.3%)	7(0.2%)
Influenza	11(0.3%)	7(0.2%)
COVID-19	11(0.3%)	6(0.2%)
Bronchitis	10(0.3%)	15(0.4%)
Urosepsis	10(0.3%)	10(0.3%)
Gangrene	8(0.2%)	6(0.2%)
Localised infection	8(0.2%)	5(0.1%)
Respiratory tract infection	7(0.2%)	7(0.2%)
Pyelonephritis acute	6(0.2%)	0
Diabetic foot infection	5(0.1%)	6(0.2%)
Abscess limb	5(0.1%)	2(0.1%)
Pulmonary sepsis	5(0.1%)	2(0.1%)
Gastroenteritis viral	5(0.1%)	0
Septic shock	4(0.1%)	9(0.2%)
Lower respiratory tract infection	4(0.1%)	8(0.2%)
Wound infection	4(0.1%)	4(0.1%)
COVID-19 pneumonia	4(0.1%)	2(0.1%)
Bacteraemia	4(0.1%)	1(0.0%)
Postoperative wound infection	4(0.1%)	1(0.0%)
Arthritis bacterial	4(0.1%)	0
Diverticulitis	3(0.1%)	5(0.1%)
Pulmonary tuberculosis	3(0.1%)	3(0.1%)
Herpes zoster	3(0.1%)	1(0.0%)
Infection	3(0.1%)	1(0.0%)
Appendicitis	2(0.1%)	6(0.2%)
Upper respiratory tract infection	2(0.1%)	6(0.2%)
Liver abscess	2(0.1%)	5(0.1%)
Infected skin ulcer	2(0.1%)	3(0.1%)
Anal abscess	2(0.1%)	2(0.1%)
Orchitis	2(0.1%)	2(0.1%)
Staphylococcal sepsis	2(0.1%)	2(0.1%)
Viral infection	2(0.1%)	2(0.1%)
Abdominal abscess	2(0.1%)	1(0.0%)
Clostridium difficile infection	2(0.1%)	1(0.0%)
Otitis media	2(0.1%)	1(0.0%)
Soft tissue infection	2(0.1%)	1(0.0%)
Tracheobronchitis	2(0.1%)	1(0.0%)
Appendicitis perforated	2(0.1%)	0
Aspergilloma	2(0.1%)	0
Emphysematous pyelonephritis	2(0.1%)	0
Groin abscess	2(0.1%)	0
Osteomyelitis chronic	2(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pneumonia streptococcal	2(0.1%)	0
Prostatic abscess	2(0.1%)	0
Pyelocystitis	2(0.1%)	0
Subcutaneous abscess	2(0.1%)	0
Pneumonia bacterial	1(0.0%)	6(0.2%)
Cystitis	1(0.0%)	3(0.1%)
Epididymitis	1(0.0%)	3(0.1%)
Escherichia urinary tract infection	1(0.0%)	2(0.1%)
Pyelonephritis chronic	1(0.0%)	2(0.1%)
Abdominal wall abscess	1(0.0%)	1(0.0%)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Gastroenteritis norovirus	1(0.0%)	1(0.0%)
Gastroenteritis salmonella	1(0.0%)	1(0.0%)
Labyrinthitis	1(0.0%)	1(0.0%)
Large intestine infection	1(0.0%)	1(0.0%)
Otitis externa	1(0.0%)	1(0.0%)
Peritonsillitis	1(0.0%)	1(0.0%)
Pneumonia viral	1(0.0%)	1(0.0%)
Tuberculosis	1(0.0%)	1(0.0%)
Abscess neck	1(0.0%)	0
Acute sinusitis	1(0.0%)	0
Bacterial sepsis	1(0.0%)	0
Borrelia infection	1(0.0%)	0
Chronic sinusitis	1(0.0%)	0
Dengue fever	1(0.0%)	0
Device related sepsis	1(0.0%)	0
Enteritis infectious	1(0.0%)	0
Enterococcal sepsis	1(0.0%)	0
Genitourinary tract infection	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infected bite	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Infectious pleural effusion	1(0.0%)	0
Infective myositis	1(0.0%)	0
Infective spondylitis	1(0.0%)	0
Infective tenosynovitis	1(0.0%)	0
Kidney infection	1(0.0%)	0
Leptospirosis	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Oral infection	1(0.0%)	0
Paronychia	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pharyngitis streptococcal	1(0.0%)	0
Pilonidal cyst	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Pyonephrosis	1(0.0%)	0
Rectal abscess	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Sialoadenitis	1(0.0%)	0
Sinusitis	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Stoma site infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Urinary tract infection fungal	1(0.0%)	0
Urinary tract infection staphylococcal	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Wound infection bacterial	1(0.0%)	0
Intervertebral discitis	0	4(0.1%)
Acute hepatitis B	0	3(0.1%)
Atypical pneumonia	0	3(0.1%)
Infective exacerbation of bronchiectasis	0	3(0.1%)
Periodontitis	0	2(0.1%)
Skin infection	0	2(0.1%)
Arteriosclerotic gangrene	0	1(0.0%)
Bullous erysipelas	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Cystitis bacterial	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Ear infection	0	1(0.0%)
Endocarditis	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Epiglottitis	0	1(0.0%)
Escherichia sepsis	0	1(0.0%)
Eye infection	0	1(0.0%)
Febrile infection	0	1(0.0%)
Gastritis viral	0	1(0.0%)
Gastrointestinal viral infection	0	1(0.0%)
H1N1 influenza	0	1(0.0%)
Hepatitis B	0	1(0.0%)
Infected seroma	0	1(0.0%)
Infective exacerbation of chronic obstructive airways disease	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Mastoiditis	0	1(0.0%)
Medical device site joint infection	0	1(0.0%)
Necrotising fasciitis	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Oesophageal candidiasis	0	1(0.0%)
Periorbital cellulitis	0	1(0.0%)
Peritonitis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Renal abscess	0	1(0.0%)
Respiratory syncytial virus infection	0	1(0.0%)
Staphylococcal infection	0	1(0.0%)
Subacute endocarditis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Tooth abscess	0	1(0.0%)
Tooth infection	0	1(0.0%)
Urethritis	0	1(0.0%)
Urinary tract infection bacterial	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	224(5.6%)	223(5.6%)
Hyperkalaemia	54(1.4%)	14(0.4%)
Hyperglycaemia	31(0.8%)	28(0.7%)
Hypoglycaemia	30(0.8%)	47(1.2%)
Diabetes mellitus inadequate control	18(0.5%)	23(0.6%)
Type 2 diabetes mellitus	17(0.4%)	24(0.6%)
Diabetes mellitus	15(0.4%)	20(0.5%)
Diabetic metabolic decompensation	14(0.4%)	16(0.4%)
Dehydration	11(0.3%)	11(0.3%)
Hyponatraemia	10(0.3%)	6(0.2%)
Diabetic ketoacidosis	8(0.2%)	13(0.3%)
Fluid overload	6(0.2%)	9(0.2%)
Hypovolaemia	5(0.1%)	2(0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	4(0.1%)	7(0.2%)
Hypercalcaemia	4(0.1%)	0
Hypokalaemia	3(0.1%)	9(0.2%)
Metabolic acidosis	3(0.1%)	3(0.1%)
Gout	2(0.1%)	8(0.2%)
Fluid retention	2(0.1%)	2(0.1%)
Diabetic complication	2(0.1%)	0
Hypervolaemia	2(0.1%)	0
Hypocalcaemia	1(0.0%)	2(0.1%)
Hypomagnesaemia	1(0.0%)	1(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Obesity	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Hypoglycaemia unawareness	1(0.0%)	0
Malnutrition	1(0.0%)	0
Decreased appetite	0	2(0.1%)
Hypoproteinaemia	0	2(0.1%)
Hyperosmolar state	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Periarthritis calcarea	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)
Renal And Urinary Disorders	177(4.5%)	204(5.1%)
Acute kidney injury	77(1.9%)	83(2.1%)
Diabetic nephropathy	21(0.5%)	19(0.5%)
Chronic kidney disease	14(0.4%)	26(0.7%)
Renal failure	10(0.3%)	7(0.2%)
Nephrolithiasis	9(0.2%)	4(0.1%)
Renal impairment	8(0.2%)	11(0.3%)
Urinary retention	8(0.2%)	5(0.1%)
Haematuria	5(0.1%)	6(0.2%)
Ureterolithiasis	4(0.1%)	6(0.2%)
End stage renal disease	4(0.1%)	5(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Urinary tract obstruction	4(0.1%)	2(0.1%)
Nephrotic syndrome	3(0.1%)	9(0.2%)
Renal colic	3(0.1%)	2(0.1%)
Hydronephrosis	2(0.1%)	4(0.1%)
Calculus bladder	2(0.1%)	2(0.1%)
Calculus urinary	2(0.1%)	2(0.1%)
Bladder outlet obstruction	2(0.1%)	1(0.0%)
Urinary incontinence	2(0.1%)	0
Nephropathy	1(0.0%)	2(0.1%)
Urethral stenosis	1(0.0%)	2(0.1%)
Dysuria	1(0.0%)	1(0.0%)
Renal artery stenosis	1(0.0%)	1(0.0%)
Renal cyst	1(0.0%)	1(0.0%)
Tubulointerstitial nephritis	1(0.0%)	1(0.0%)
Urinary bladder polyp	1(0.0%)	1(0.0%)
Bladder cyst	1(0.0%)	0
Chromaturia	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0
Nocturia	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Ureteric obstruction	1(0.0%)	0
Intercapillary glomerulosclerosis	0	2(0.1%)
Proteinuria	0	2(0.1%)
Renal haemorrhage	0	2(0.1%)
Azotaemia	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Glomerular vascular disorder	0	1(0.0%)
Hypertensive nephropathy	0	1(0.0%)
Lower urinary tract symptoms	0	1(0.0%)
Nephrosclerosis	0	1(0.0%)
Perinephritis	0	1(0.0%)
Renal mass	0	1(0.0%)
Subcapsular renal haematoma	0	1(0.0%)
Urinary tract disorder	0	1(0.0%)
Gastrointestinal Disorders	172(4.3%)	145(3.7%)
Gastrointestinal haemorrhage	15(0.4%)	12(0.3%)
Large intestine polyp	12(0.3%)	13(0.3%)
Diarrhoea	12(0.3%)	8(0.2%)
Pancreatitis acute	9(0.2%)	10(0.3%)
Rectal haemorrhage	9(0.2%)	3(0.1%)
Lower gastrointestinal haemorrhage	8(0.2%)	1(0.0%)
Abdominal pain	7(0.2%)	8(0.2%)
Upper gastrointestinal haemorrhage	5(0.1%)	8(0.2%)
Constipation	5(0.1%)	4(0.1%)
Vomiting	5(0.1%)	4(0.1%)
Abdominal pain upper	4(0.1%)	6(0.2%)
Intestinal obstruction	4(0.1%)	5(0.1%)
Gastritis	4(0.1%)	4(0.1%)
Duodenal ulcer	4(0.1%)	3(0.1%)
Nausea	4(0.1%)	1(0.0%)
Colitis	4(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pancreatitis	3(0.1%)	4(0.1%)
Gastrooesophageal reflux disease	3(0.1%)	2(0.1%)
Haemorrhoids	3(0.1%)	1(0.0%)
Dyspepsia	3(0.1%)	0
Gastroduodenal ulcer	3(0.1%)	0
Inguinal hernia	2(0.1%)	6(0.2%)
Umbilical hernia	2(0.1%)	3(0.1%)
Haematemesis	2(0.1%)	2(0.1%)
Small intestinal obstruction	2(0.1%)	2(0.1%)
Gastric ulcer	2(0.1%)	1(0.0%)
Haematochezia	2(0.1%)	1(0.0%)
Incarcerated umbilical hernia	2(0.1%)	1(0.0%)
Diverticulum intestinal haemorrhagic	2(0.1%)	0
Gastric haemorrhage	2(0.1%)	0
Gastric ulcer haemorrhage	2(0.1%)	0
Gastritis erosive	2(0.1%)	0
Haemorrhoidal haemorrhage	2(0.1%)	0
Ileus	2(0.1%)	0
Peptic ulcer	2(0.1%)	0
Small intestinal haemorrhage	2(0.1%)	0
Colitis ischaemic	1(0.0%)	3(0.1%)
Duodenal ulcer haemorrhage	1(0.0%)	3(0.1%)
Ascites	1(0.0%)	2(0.1%)
Pancreatitis chronic	1(0.0%)	2(0.1%)
Abdominal hernia	1(0.0%)	1(0.0%)
Anal fistula	1(0.0%)	1(0.0%)
Dental caries	1(0.0%)	1(0.0%)
Diverticulum intestinal	1(0.0%)	1(0.0%)
Gastric ulcer perforation	1(0.0%)	1(0.0%)
Intestinal ischaemia	1(0.0%)	1(0.0%)
Melaena	1(0.0%)	1(0.0%)
Pancreatic cyst	1(0.0%)	1(0.0%)
Pancreatic duct stenosis	1(0.0%)	1(0.0%)
Varices oesophageal	1(0.0%)	1(0.0%)
Abdominal symptom	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Chilaiditi's syndrome	1(0.0%)	0
Dental cyst	1(0.0%)	0
Diarrhoea haemorrhagic	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Enteritis	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastritis haemorrhagic	1(0.0%)	0
Gastrointestinal disorder	1(0.0%)	0
Gastrointestinal necrosis	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Intestinal angina	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Intra-abdominal fluid collection	1(0.0%)	0
Mechanical ileus	1(0.0%)	0
Obstructive pancreatitis	1(0.0%)	0
Oedematous pancreatitis	1(0.0%)	0
Oesophageal obstruction	1(0.0%)	0
Oesophageal ulcer haemorrhage	1(0.0%)	0
Oesophagitis	1(0.0%)	0
Parotid gland enlargement	1(0.0%)	0
Proctitis	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Abdominal wall haematoma	0	2(0.1%)
Diverticulum	0	2(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Gastric polyps	0	2(0.1%)
Impaired gastric emptying	0	2(0.1%)
Rectal polyp	0	2(0.1%)
Abdominal mass	0	1(0.0%)
Abdominal pain lower	0	1(0.0%)
Abdominal strangulated hernia	0	1(0.0%)
Anal haemorrhage	0	1(0.0%)
Change of bowel habit	0	1(0.0%)
Chronic gastritis	0	1(0.0%)
Colitis ulcerative	0	1(0.0%)
Faecaloma	0	1(0.0%)
Food poisoning	0	1(0.0%)
Gastric dysplasia	0	1(0.0%)
Gastric mucosal lesion	0	1(0.0%)
Gastrointestinal motility disorder	0	1(0.0%)
Gastrointestinal pain	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Oesophageal achalasia	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Oesophageal polyp	0	1(0.0%)
Pancreatic mass	0	1(0.0%)
Peptic ulcer haemorrhage	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Salivary gland calculus	0	1(0.0%)
Small intestinal perforation	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Subileus	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	157(4.0%)	159(4.0%)
Prostate cancer	14(0.4%)	14(0.4%)
Lung neoplasm malignant	13(0.3%)	7(0.2%)
Colon cancer	9(0.2%)	8(0.2%)
Bladder cancer	7(0.2%)	9(0.2%)
Breast cancer	5(0.1%)	6(0.2%)
Pancreatic carcinoma	5(0.1%)	3(0.1%)
Renal cell carcinoma	4(0.1%)	1(0.0%)
Colon adenoma	4(0.1%)	0
Oesophageal adenocarcinoma	4(0.1%)	0
Hepatocellular carcinoma	3(0.1%)	4(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Bladder neoplasm	3(0.1%)	3(0.1%)
Bladder transitional cell carcinoma	3(0.1%)	3(0.1%)
Basal cell carcinoma	3(0.1%)	1(0.0%)
Clear cell renal cell carcinoma	3(0.1%)	1(0.0%)
Metastases to central nervous system	3(0.1%)	1(0.0%)
Plasma cell myeloma	3(0.1%)	1(0.0%)
Bladder cancer recurrent	3(0.1%)	0
Metastases to liver	2(0.1%)	5(0.1%)
Lung adenocarcinoma	2(0.1%)	4(0.1%)
Renal neoplasm	2(0.1%)	4(0.1%)
Adenocarcinoma of colon	2(0.1%)	3(0.1%)
Malignant melanoma	2(0.1%)	3(0.1%)
Metastases to lymph nodes	2(0.1%)	3(0.1%)
Hepatic cancer	2(0.1%)	2(0.1%)
Adenocarcinoma	2(0.1%)	1(0.0%)
Cholangiocarcinoma	2(0.1%)	1(0.0%)
Metastases to bone	2(0.1%)	1(0.0%)
Metastases to lung	2(0.1%)	1(0.0%)
Prostate cancer recurrent	2(0.1%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.1%)	1(0.0%)
Breast cancer metastatic	2(0.1%)	0
Endometrial adenocarcinoma	2(0.1%)	0
Metastases to spine	2(0.1%)	0
Pancreatic neoplasm	2(0.1%)	0
Prostate cancer metastatic	2(0.1%)	0
Squamous cell carcinoma of skin	2(0.1%)	0
Lung neoplasm	1(0.0%)	4(0.1%)
Small cell lung cancer	1(0.0%)	4(0.1%)
Adenocarcinoma gastric	1(0.0%)	3(0.1%)
Oesophageal carcinoma	1(0.0%)	3(0.1%)
Renal cancer	1(0.0%)	3(0.1%)
Acute myeloid leukaemia	1(0.0%)	2(0.1%)
Colorectal cancer	1(0.0%)	2(0.1%)
Pancreatic carcinoma metastatic	1(0.0%)	2(0.1%)
Bladder transitional cell carcinoma recurrent	1(0.0%)	1(0.0%)
Breast neoplasm	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Lipoma	1(0.0%)	1(0.0%)
Lung cancer metastatic	1(0.0%)	1(0.0%)
Lymphoma	1(0.0%)	1(0.0%)
Myelodysplastic syndrome	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Rectal adenocarcinoma	1(0.0%)	1(0.0%)
Squamous cell carcinoma	1(0.0%)	1(0.0%)
Transitional cell carcinoma	1(0.0%)	1(0.0%)
Adenoma benign	1(0.0%)	0
Angiomyofibroblastoma	1(0.0%)	0
Benign salivary gland neoplasm	1(0.0%)	0
Cancer pain	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Enchondromatosis	1(0.0%)	0
Epithelioid mesothelioma	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Haemangioma	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Hypergammaglobulinaemia benign monoclonal	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Laryngeal squamous cell carcinoma	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Lung squamous cell carcinoma stage IV	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Malignant urinary tract neoplasm	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Metastatic renal cell carcinoma	1(0.0%)	0
Neoplasm	1(0.0%)	0
Neuroendocrine carcinoma of the skin	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Skin cancer	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Squamous cell carcinoma of the tongue	1(0.0%)	0
Tongue neoplasm	1(0.0%)	0
Tongue neoplasm malignant stage unspecified	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Uterine cancer	1(0.0%)	0
Brain neoplasm	0	3(0.1%)
Adrenal adenoma	0	2(0.1%)
Benign pancreatic neoplasm	0	2(0.1%)
Endometrial cancer	0	2(0.1%)
Gastric cancer	0	2(0.1%)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Benign anorectal neoplasm	0	1(0.0%)
Benign gastrointestinal neoplasm	0	1(0.0%)
Benign neoplasm of bladder	0	1(0.0%)
Benign neoplasm of prostate	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Chronic lymphocytic leukaemia	0	1(0.0%)
Colon neoplasm	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Haemangioblastoma	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hepatic cancer metastatic	0	1(0.0%)
Intraductal proliferative breast lesion	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Metastasis	0	1(0.0%)
Monoclonal gammopathy	0	1(0.0%)
Nasal cavity cancer	0	1(0.0%)
Neoplasm malignant	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Neoplasm skin	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oesophageal neoplasm	0	1(0.0%)
Ovarian neoplasm	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Retroperitoneal neoplasm	0	1(0.0%)
Salivary gland neoplasm	0	1(0.0%)
Sarcoma	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Thymoma	0	1(0.0%)
Thyroid cancer	0	1(0.0%)
Urethral neoplasm	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Injury, Poisoning And Procedural Complications	137(3.4%)	127(3.2%)
Femur fracture	10(0.3%)	13(0.3%)
Femoral neck fracture	9(0.2%)	3(0.1%)
Ankle fracture	8(0.2%)	7(0.2%)
Hip fracture	8(0.2%)	5(0.1%)
Fall	6(0.2%)	9(0.2%)
Subdural haematoma	5(0.1%)	7(0.2%)
Tibia fracture	5(0.1%)	2(0.1%)
Contusion	5(0.1%)	1(0.0%)
Humerus fracture	4(0.1%)	9(0.2%)
Rib fracture	4(0.1%)	6(0.2%)
Radius fracture	4(0.1%)	3(0.1%)
Limb injury	4(0.1%)	2(0.1%)
Clavicle fracture	4(0.1%)	0
Road traffic accident	3(0.1%)	3(0.1%)
Accidental overdose	3(0.1%)	2(0.1%)
Foot fracture	3(0.1%)	1(0.0%)
Craniocerebral injury	3(0.1%)	0
Joint injury	3(0.1%)	0
Lower limb fracture	3(0.1%)	0
Post procedural haemorrhage	2(0.1%)	3(0.1%)
Incisional hernia	2(0.1%)	2(0.1%)
Subdural haemorrhage	2(0.1%)	2(0.1%)
Toxicity to various agents	2(0.1%)	2(0.1%)
Traumatic fracture	2(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Accident	2(0.1%)	1(0.0%)
Fibula fracture	2(0.1%)	1(0.0%)
Spinal compression fracture	2(0.1%)	1(0.0%)
Cervical vertebral fracture	2(0.1%)	0
Patella fracture	2(0.1%)	0
Skin laceration	2(0.1%)	0
Meniscus injury	1(0.0%)	4(0.1%)
Head injury	1(0.0%)	3(0.1%)
Pelvic fracture	1(0.0%)	2(0.1%)
Spinal fracture	1(0.0%)	2(0.1%)
Thermal burn	1(0.0%)	2(0.1%)
Ulna fracture	1(0.0%)	2(0.1%)
Acetabulum fracture	1(0.0%)	1(0.0%)
Brain contusion	1(0.0%)	1(0.0%)
Concussion	1(0.0%)	1(0.0%)
Facial bones fracture	1(0.0%)	1(0.0%)
Spinal cord injury cervical	1(0.0%)	1(0.0%)
Sternal fracture	1(0.0%)	1(0.0%)
Tendon injury	1(0.0%)	1(0.0%)
Upper limb fracture	1(0.0%)	1(0.0%)
Abdominal wound dehiscence	1(0.0%)	0
Back injury	1(0.0%)	0
Bone contusion	1(0.0%)	0
Cardiac contusion	1(0.0%)	0
Chest injury	1(0.0%)	0
Foreign body aspiration	1(0.0%)	0
Gun shot wound	1(0.0%)	0
Incision site haematoma	1(0.0%)	0
Inflammation of wound	1(0.0%)	0
Intentional overdose	1(0.0%)	0
Ligament injury	1(0.0%)	0
Ligament rupture	1(0.0%)	0
Muscle strain	1(0.0%)	0
Ocular procedural complication	1(0.0%)	0
Post concussion syndrome	1(0.0%)	0
Postoperative wound complication	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Scapula fracture	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Soft tissue injury	1(0.0%)	0
Splenic injury	1(0.0%)	0
Thoracic vertebral fracture	1(0.0%)	0
Vascular access malfunction	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Wrist fracture	1(0.0%)	0
Joint dislocation	0	2(0.1%)
Overdose	0	2(0.1%)
Alcohol poisoning	0	1(0.0%)
Arteriovenous fistula site complication	0	1(0.0%)
Burns second degree	0	1(0.0%)
Dislocation of vertebra	0	1(0.0%)
Forearm fracture	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hand fracture	0	1(0.0%)
Heat stroke	0	1(0.0%)
Incarcerated incisional hernia	0	1(0.0%)
Injury	0	1(0.0%)
Lumbar vertebral fracture	0	1(0.0%)
Multiple injuries	0	1(0.0%)
Muscle rupture	0	1(0.0%)
Periprosthetic fracture	0	1(0.0%)
Poisoning deliberate	0	1(0.0%)
Post procedural haematoma	0	1(0.0%)
Post procedural inflammation	0	1(0.0%)
Procedural complication	0	1(0.0%)
Procedural haemorrhage	0	1(0.0%)
Procedural intestinal perforation	0	1(0.0%)
Reproductive tract procedural complication	0	1(0.0%)
Shunt malfunction	0	1(0.0%)
Skin injury	0	1(0.0%)
Skull fracture	0	1(0.0%)
Tendon rupture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Vascular anastomosis aneurysm	0	1(0.0%)
Vascular pseudoaneurysm	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	108(2.7%)	119(3.0%)
Chronic obstructive pulmonary disease	23(0.6%)	15(0.4%)
Dyspnoea	16(0.4%)	10(0.3%)
Acute respiratory failure	10(0.3%)	19(0.5%)
Respiratory failure	9(0.2%)	9(0.2%)
Pleural effusion	9(0.2%)	3(0.1%)
Pulmonary embolism	8(0.2%)	9(0.2%)
Sleep apnoea syndrome	5(0.1%)	4(0.1%)
Pulmonary mass	4(0.1%)	0
Acute pulmonary oedema	3(0.1%)	3(0.1%)
Interstitial lung disease	3(0.1%)	3(0.1%)
Pneumothorax	3(0.1%)	3(0.1%)
Asthma	2(0.1%)	9(0.2%)
Pulmonary oedema	2(0.1%)	6(0.2%)
Pneumonia aspiration	2(0.1%)	4(0.1%)
Cough	2(0.1%)	2(0.1%)
Chronic respiratory failure	2(0.1%)	1(0.0%)
Hypoxia	2(0.1%)	1(0.0%)
Epistaxis	2(0.1%)	0
Laryngeal oedema	2(0.1%)	0
Pulmonary congestion	1(0.0%)	3(0.1%)
Obstructive airways disorder	1(0.0%)	1(0.0%)
Alveolar lung disease	1(0.0%)	0
Asthmatic crisis	1(0.0%)	0
Dyspnoea at rest	1(0.0%)	0
Epiglottic cyst	1(0.0%)	0
Laryngeal dysplasia	1(0.0%)	0
Laryngeal mass	1(0.0%)	0
Nasal septum deviation	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Restrictive pulmonary disease	1(0.0%)	0
Vocal cord cyst	1(0.0%)	0
Aspiration	0	2(0.1%)
Bronchitis chronic	0	2(0.1%)
Dyspnoea exertional	0	2(0.1%)
Idiopathic pulmonary fibrosis	0	2(0.1%)
Pneumonitis	0	2(0.1%)
Pulmonary hypertension	0	2(0.1%)
Bronchial hyperreactivity	0	1(0.0%)
Bronchiectasis	0	1(0.0%)
Bronchopneumopathy	0	1(0.0%)
Dysphonia	0	1(0.0%)
Emphysema	0	1(0.0%)
Haemoptysis	0	1(0.0%)
Hepatic hydrothorax	0	1(0.0%)
Hypercapnia	0	1(0.0%)
Laryngeal disorder	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Lung perforation	0	1(0.0%)
Pulmonary hilum mass	0	1(0.0%)
Respiratory distress	0	1(0.0%)
Small airways disease	0	1(0.0%)
Vocal cord polyp	0	1(0.0%)
Wheezing	0	1(0.0%)
Nervous System Disorders	104(2.6%)	135(3.4%)
Syncope	21(0.5%)	33(0.8%)
Diabetic neuropathy	9(0.2%)	6(0.2%)
Dizziness	8(0.2%)	13(0.3%)
Presyncope	5(0.1%)	4(0.1%)
Seizure	5(0.1%)	4(0.1%)
Loss of consciousness	5(0.1%)	2(0.1%)
Subarachnoid haemorrhage	4(0.1%)	4(0.1%)
Headache	4(0.1%)	3(0.1%)
Cerebrovascular disorder	4(0.1%)	1(0.0%)
Facial paralysis	3(0.1%)	2(0.1%)
Cerebral haemorrhage	3(0.1%)	0
Sciatica	2(0.1%)	2(0.1%)
Transient ischaemic attack	2(0.1%)	2(0.1%)
Polyneuropathy	2(0.1%)	1(0.0%)
Dysarthria	2(0.1%)	0
Hepatic encephalopathy	2(0.1%)	0
Normal pressure hydrocephalus	2(0.1%)	0
Vascular headache	2(0.1%)	0
Carotid artery stenosis	1(0.0%)	3(0.1%)
Aphasia	1(0.0%)	2(0.1%)
Cerebral infarction	1(0.0%)	2(0.1%)
Hemiparesis	1(0.0%)	2(0.1%)
Lacunar infarction	1(0.0%)	2(0.1%)
Neuralgia	1(0.0%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Radiculopathy	1(0.0%)	2(0.1%)
Balance disorder	1(0.0%)	1(0.0%)
Cognitive disorder	1(0.0%)	1(0.0%)
IIIrd nerve paralysis	1(0.0%)	1(0.0%)
Ischaemic stroke	1(0.0%)	1(0.0%)
Lethargy	1(0.0%)	1(0.0%)
Lumbar radiculopathy	1(0.0%)	1(0.0%)
Myelopathy	1(0.0%)	1(0.0%)
Vascular encephalopathy	1(0.0%)	1(0.0%)
Amnesia	1(0.0%)	0
Angiopathic neuropathy	1(0.0%)	0
Cerebral vasoconstriction	1(0.0%)	0
Cerebrospinal fluid leakage	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Drop attacks	1(0.0%)	0
Generalised tonic-clonic seizure	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
Metabolic encephalopathy	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Partial seizures	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Thrombotic cerebral infarction	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Vertebrobasilar insufficiency	1(0.0%)	0
Cervicobrachial syndrome	0	3(0.1%)
Epilepsy	0	3(0.1%)
Facial paresis	0	3(0.1%)
Carpal tunnel syndrome	0	2(0.1%)
Neuropathy peripheral	0	2(0.1%)
Alcohol induced persisting dementia	0	1(0.0%)
Altered state of consciousness	0	1(0.0%)
Arachnoid cyst	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid arteriosclerosis	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cerebral ischaemia	0	1(0.0%)
Cerebral microangiopathy	0	1(0.0%)
Cerebrovascular accident	0	1(0.0%)
Cerebrovascular insufficiency	0	1(0.0%)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Dementia Alzheimer's type	0	1(0.0%)
Dizziness postural	0	1(0.0%)
Facial nerve disorder	0	1(0.0%)
Hyperglycaemic unconsciousness	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypoglycaemic unconsciousness	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Intracranial aneurysm	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Lumbosacral radiculopathy	0	1(0.0%)
Migraine	0	1(0.0%)
Mononeuropathy	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Paraesthesia	0	1(0.0%)
Peripheral nerve paresis	0	1(0.0%)
Post herpetic neuralgia	0	1(0.0%)
Posthaemorrhagic hydrocephalus	0	1(0.0%)
Secondary cerebellar degeneration	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Surgical And Medical Procedures	101(2.5%)	109(2.7%)
Knee arthroplasty	8(0.2%)	11(0.3%)
Cataract operation	7(0.2%)	13(0.3%)
Toe amputation	5(0.1%)	5(0.1%)
Arteriovenous fistula operation	5(0.1%)	3(0.1%)
Hip arthroplasty	4(0.1%)	6(0.2%)
Colectomy	3(0.1%)	1(0.0%)
Diabetes mellitus management	3(0.1%)	0
Transurethral prostatectomy	2(0.1%)	4(0.1%)
Gastrectomy	2(0.1%)	2(0.1%)
Prostatectomy	2(0.1%)	2(0.1%)
Skin neoplasm excision	2(0.1%)	2(0.1%)
Coronary artery bypass	2(0.1%)	1(0.0%)
Metabolic surgery	2(0.1%)	1(0.0%)
Peripheral artery angioplasty	2(0.1%)	1(0.0%)
Spinal laminectomy	2(0.1%)	1(0.0%)
Aortic valve replacement	2(0.1%)	0
Cardiac pacemaker insertion	2(0.1%)	0
Hysterectomy	2(0.1%)	0
Parathyroidectomy	2(0.1%)	0
Skin graft	2(0.1%)	0
Cholecystectomy	1(0.0%)	5(0.1%)
Vitrectomy	1(0.0%)	4(0.1%)
Foot amputation	1(0.0%)	2(0.1%)
Aortic aneurysm repair	1(0.0%)	1(0.0%)
Dialysis device insertion	1(0.0%)	1(0.0%)
Gastric bypass	1(0.0%)	1(0.0%)
Haemodialysis	1(0.0%)	1(0.0%)
Leg amputation	1(0.0%)	1(0.0%)
Peripheral artery bypass	1(0.0%)	1(0.0%)
Polypectomy	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Rhinoplasty	1(0.0%)	1(0.0%)
Aneurysm repair	1(0.0%)	0
Bile duct stent removal	1(0.0%)	0
Biliary catheter removal	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Bladder calculus removal	1(0.0%)	0
Bowel preparation	1(0.0%)	0
Brachytherapy	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Chemotherapy	1(0.0%)	0
Circumcision	1(0.0%)	0
Coronary angioplasty	1(0.0%)	0
Eye operation	1(0.0%)	0
Foot operation	1(0.0%)	0
Implantable defibrillator insertion	1(0.0%)	0
Internal fixation of spine	1(0.0%)	0
Intestinal operation	1(0.0%)	0
Intraocular lens implant	1(0.0%)	0
Lithotripsy	1(0.0%)	0
Maxillofacial operation	1(0.0%)	0
Metatarsal excision	1(0.0%)	0
Myomectomy	1(0.0%)	0
Nail operation	1(0.0%)	0
Nephrectomy	1(0.0%)	0
Oophorectomy	1(0.0%)	0
Pancreatic stent placement	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Parotidectomy	1(0.0%)	0
Radical hysterectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0
Renal stone removal	1(0.0%)	0
Retinal operation	1(0.0%)	0
Shoulder arthroplasty	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Tenotomy	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Thyroidectomy	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Wound treatment	1(0.0%)	0
Intervertebral disc operation	0	4(0.1%)
Insertion of ambulatory peritoneal catheter	0	3(0.1%)
Hydrocele operation	0	2(0.1%)
Inguinal hernia repair	0	2(0.1%)
Spinal operation	0	2(0.1%)
Transurethral bladder resection	0	2(0.1%)
Umbilical hernia repair	0	2(0.1%)
Amputation	0	1(0.0%)
Appendicectomy	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Bladder neck operation	0	1(0.0%)
Bladder neck resection	0	1(0.0%)
Bladder polypectomy	0	1(0.0%)
Caecum operation	0	1(0.0%)
Cardiac pacemaker replacement	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Colon operation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Continuous positive airway pressure	0	1(0.0%)
Corneal transplant	0	1(0.0%)
Coronary revascularisation	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Knee operation	0	1(0.0%)
Large intestinal polypectomy	0	1(0.0%)
Meniscus operation	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Nephroureterectomy	0	1(0.0%)
Neurosurgery	0	1(0.0%)
Physiotherapy	0	1(0.0%)
Preoperative care	0	1(0.0%)
Pterygium operation	0	1(0.0%)
Radioactive iodine therapy	0	1(0.0%)
Rectocele repair	0	1(0.0%)
Removal of foreign body from larynx	0	1(0.0%)
Renal cyst excision	0	1(0.0%)
Renal disorder prophylaxis	0	1(0.0%)
Retinopexy	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Tooth extraction	0	1(0.0%)
Urethral dilation procedure	0	1(0.0%)
Varicose vein operation	0	1(0.0%)
Vascular graft	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	82(2.1%)	93(2.3%)
Osteoarthritis	20(0.5%)	13(0.3%)
Intervertebral disc protrusion	8(0.2%)	14(0.4%)
Back pain	7(0.2%)	5(0.1%)
Arthralgia	5(0.1%)	12(0.3%)
Gouty arthritis	5(0.1%)	4(0.1%)
Lumbar spinal stenosis	4(0.1%)	7(0.2%)
Arthritis	3(0.1%)	3(0.1%)
Pain in extremity	3(0.1%)	1(0.0%)
Spondylolisthesis	3(0.1%)	1(0.0%)
Rhabdomyolysis	2(0.1%)	2(0.1%)
Intervertebral disc disorder	2(0.1%)	1(0.0%)
Muscular weakness	2(0.1%)	1(0.0%)
Spinal stenosis	2(0.1%)	1(0.0%)
Myalgia	2(0.1%)	0
Rotator cuff syndrome	2(0.1%)	0
Spinal osteoarthritis	1(0.0%)	4(0.1%)
Bursitis	1(0.0%)	3(0.1%)
Foot deformity	1(0.0%)	3(0.1%)
Intervertebral disc degeneration	1(0.0%)	2(0.1%)
Neuropathic arthropathy	1(0.0%)	1(0.0%)
Polymyalgia rheumatica	1(0.0%)	1(0.0%)
Cervical spinal stenosis	1(0.0%)	0
Connective tissue inflammation	1(0.0%)	0
Facet joint syndrome	1(0.0%)	0
Flank pain	1(0.0%)	0
Haematoma muscle	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Immobilisation syndrome	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Osteitis	1(0.0%)	0
Spondylitis	1(0.0%)	0
Synovial cyst	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Vertebral lateral recess stenosis	1(0.0%)	0
Neck pain	0	6(0.2%)
Spinal pain	0	3(0.1%)
Musculoskeletal chest pain	0	2(0.1%)
Back disorder	0	1(0.0%)
Costochondritis	0	1(0.0%)
Exostosis	0	1(0.0%)
Limb mass	0	1(0.0%)
Muscle haemorrhage	0	1(0.0%)
Musculoskeletal disorder	0	1(0.0%)
Osteoarthropathy	0	1(0.0%)
Osteolysis	0	1(0.0%)
Osteonecrosis	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Rheumatoid arthritis	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Spinal ligament ossification	0	1(0.0%)
Vertebral foraminal stenosis	0	1(0.0%)
Vascular Disorders	79(2.0%)	100(2.5%)
Hypertension	18(0.5%)	34(0.9%)
Hypotension	7(0.2%)	5(0.1%)
Hypertensive crisis	6(0.2%)	9(0.2%)
Hypertensive urgency	5(0.1%)	3(0.1%)
Aortic stenosis	5(0.1%)	1(0.0%)
Deep vein thrombosis	4(0.1%)	3(0.1%)
Orthostatic hypotension	4(0.1%)	3(0.1%)
Extremity necrosis	4(0.1%)	2(0.1%)
Aortic aneurysm	3(0.1%)	3(0.1%)
Hypertensive emergency	2(0.1%)	5(0.1%)
Peripheral ischaemia	2(0.1%)	5(0.1%)
Circulatory collapse	2(0.1%)	2(0.1%)
Thrombophlebitis	2(0.1%)	2(0.1%)
Diabetic vascular disorder	2(0.1%)	1(0.0%)
Peripheral arterial occlusive disease	1(0.0%)	6(0.2%)
Peripheral artery stenosis	1(0.0%)	2(0.1%)
Thrombosis	1(0.0%)	2(0.1%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Peripheral artery occlusion	1(0.0%)	1(0.0%)
Peripheral vascular disorder	1(0.0%)	1(0.0%)
Aortic dissection	1(0.0%)	0
Arteriovenous fistula	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Peripheral artery aneurysm	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Peripheral embolism	1(0.0%)	0
Post thrombotic syndrome	1(0.0%)	0
Thrombophlebitis superficial	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Varicose vein	1(0.0%)	0
Vasculitis	1(0.0%)	0
Venous occlusion	1(0.0%)	0
Haematoma	0	2(0.1%)
Malignant hypertension	0	2(0.1%)
Arterial thrombosis	0	1(0.0%)
Blood pressure fluctuation	0	1(0.0%)
Embolism venous	0	1(0.0%)
Labile hypertension	0	1(0.0%)
Lymphoedema	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Peripheral artery thrombosis	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Systolic hypertension	0	1(0.0%)
Thromboangiitis obliterans	0	1(0.0%)
General Disorders And Administration Site Conditions	55(1.4%)	82(2.1%)
Chest pain	21(0.5%)	30(0.8%)
Oedema peripheral	6(0.2%)	8(0.2%)
Pyrexia	6(0.2%)	2(0.1%)
Death	4(0.1%)	8(0.2%)
Oedema	4(0.1%)	2(0.1%)
Asthenia	3(0.1%)	2(0.1%)
General physical health deterioration	2(0.1%)	5(0.1%)
Malaise	2(0.1%)	2(0.1%)
Non-cardiac chest pain	1(0.0%)	3(0.1%)
Fatigue	1(0.0%)	2(0.1%)
Generalised oedema	1(0.0%)	2(0.1%)
Multiple organ dysfunction syndrome	1(0.0%)	1(0.0%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Complication associated with device	1(0.0%)	0
Drug intolerance	1(0.0%)	0
Mass	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Swelling face	1(0.0%)	0
Chest discomfort	0	2(0.1%)
Gait disturbance	0	2(0.1%)
Oedema due to renal disease	0	2(0.1%)
Pain	0	2(0.1%)
Peripheral swelling	0	2(0.1%)
Adhesion	0	1(0.0%)
Device intolerance	0	1(0.0%)
Hernia pain	0	1(0.0%)
Hypothermia	0	1(0.0%)
Inflammation	0	1(0.0%)
Polyp	0	1(0.0%)
Soft tissue inflammation	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Vascular stent stenosis	0	1(0.0%)
Eye Disorders	53(1.3%)	51(1.3%)
Cataract	24(0.6%)	14(0.4%)
Vitreous haemorrhage	8(0.2%)	7(0.2%)
Glaucoma	7(0.2%)	1(0.0%)
Diabetic retinopathy	5(0.1%)	4(0.1%)
Retinal detachment	2(0.1%)	4(0.1%)
Retinal haemorrhage	2(0.1%)	2(0.1%)
Macular fibrosis	2(0.1%)	1(0.0%)
Visual impairment	2(0.1%)	1(0.0%)
Eye haemorrhage	2(0.1%)	0
Lens dislocation	1(0.0%)	1(0.0%)
Retinopathy	1(0.0%)	1(0.0%)
Rhegmatogenous retinal detachment	1(0.0%)	1(0.0%)
Tractional retinal detachment	1(0.0%)	1(0.0%)
Age-related macular degeneration	1(0.0%)	0
Cataract subcapsular	1(0.0%)	0
Diabetic retinal oedema	1(0.0%)	0
Eye disorder	1(0.0%)	0
Retinopathy proliferative	1(0.0%)	0
Macular hole	0	3(0.1%)
Macular oedema	0	2(0.1%)
Pterygium	0	2(0.1%)
Ulcerative keratitis	0	2(0.1%)
Blindness	0	1(0.0%)
Cataract diabetic	0	1(0.0%)
Ectropion	0	1(0.0%)
Open angle glaucoma	0	1(0.0%)
Optic disc haemorrhage	0	1(0.0%)
Optic ischaemic neuropathy	0	1(0.0%)
Papilloedema	0	1(0.0%)
Retinal artery occlusion	0	1(0.0%)
Cardiac Disorders	46(1.2%)	73(1.8%)
Coronary artery disease	9(0.2%)	5(0.1%)
Bradycardia	4(0.1%)	3(0.1%)
Cardiac failure	3(0.1%)	16(0.4%)
Angina pectoris	3(0.1%)	4(0.1%)
Cardiac failure acute	3(0.1%)	1(0.0%)
Angina unstable	2(0.1%)	5(0.1%)
Atrial fibrillation	2(0.1%)	3(0.1%)
Cardiac failure chronic	2(0.1%)	3(0.1%)
Sinus node dysfunction	2(0.1%)	2(0.1%)
Acute left ventricular failure	2(0.1%)	1(0.0%)
Arteriosclerosis coronary artery	2(0.1%)	1(0.0%)
Cardio-respiratory arrest	2(0.1%)	1(0.0%)
Myocardial ischaemia	1(0.0%)	6(0.2%)
Cardiac arrest	1(0.0%)	4(0.1%)
Aortic valve stenosis	1(0.0%)	3(0.1%)
Acute coronary syndrome	1(0.0%)	2(0.1%)
Arrhythmia	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Aortic valve calcification	1(0.0%)	0
Aortic valve disease mixed	1(0.0%)	0
Bifascicular block	1(0.0%)	0
Coronary artery stenosis	1(0.0%)	0
Hypertensive heart disease	1(0.0%)	0
Left ventricular dysfunction	1(0.0%)	0
Left ventricular failure	1(0.0%)	0
Pericarditis	1(0.0%)	0
Pulseless electrical activity	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Ventricular hypokinesia	1(0.0%)	0
Cardiac failure congestive	0	8(0.2%)
Atrial thrombosis	0	2(0.1%)
Aortic valve incompetence	0	1(0.0%)
Atrial flutter	0	1(0.0%)
Atrioventricular block	0	1(0.0%)
Atrioventricular block complete	0	1(0.0%)
Bundle branch block left	0	1(0.0%)
Cardiac asthma	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Coronary artery occlusion	0	1(0.0%)
Left ventricular hypertrophy	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	45(1.1%)	57(1.4%)
Diabetic foot	21(0.5%)	18(0.5%)
Skin ulcer	15(0.4%)	20(0.5%)
Angioedema	3(0.1%)	1(0.0%)
Pemphigoid	2(0.1%)	2(0.1%)
Decubitus ulcer	1(0.0%)	1(0.0%)
Ingrowing nail	1(0.0%)	1(0.0%)
Dermatitis herpetiformis	1(0.0%)	0
Diabetic ulcer	1(0.0%)	0
Drug eruption	1(0.0%)	0
Palmoplantar keratoderma	1(0.0%)	0
Rash	1(0.0%)	0
Skin disorder	1(0.0%)	0
Skin necrosis	1(0.0%)	0
Stasis dermatitis	1(0.0%)	0
Toxic skin eruption	1(0.0%)	0
Blister	0	2(0.1%)
Dermatitis allergic	0	2(0.1%)
Dermal cyst	0	1(0.0%)
Dermatitis	0	1(0.0%)
Dermatitis bullous	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Ecchymosis	0	1(0.0%)
Eczema	0	1(0.0%)
Hyperkeratosis	0	1(0.0%)
Neuropathic ulcer	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Parapsoriasis	0	1(0.0%)
Purpura	0	1(0.0%)
Reactive perforating collagenosis	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Hepatobiliary Disorders	40(1.0%)	46(1.2%)
Cholelithiasis	12(0.3%)	5(0.1%)
Cholecystitis acute	9(0.2%)	12(0.3%)
Cholecystitis	6(0.2%)	7(0.2%)
Bile duct stone	4(0.1%)	2(0.1%)
Cholangitis	2(0.1%)	5(0.1%)
Biliary colic	2(0.1%)	2(0.1%)
Cholecystitis chronic	2(0.1%)	1(0.0%)
Biliary obstruction	2(0.1%)	0
Hepatic function abnormal	2(0.1%)	0
Hepatic cirrhosis	1(0.0%)	6(0.2%)
Cholangitis acute	1(0.0%)	3(0.1%)
Hepatitis acute	1(0.0%)	1(0.0%)
Hepatitis	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0
Biliary dilatation	0	1(0.0%)
Cholecystocholangitis	0	1(0.0%)
Cholestasis	0	1(0.0%)
Drug-induced liver injury	0	1(0.0%)
Hepatitis alcoholic	0	1(0.0%)
Jaundice cholestatic	0	1(0.0%)
Liver disorder	0	1(0.0%)
Portal hypertension	0	1(0.0%)
Investigations	39(1.0%)	52(1.3%)
Glomerular filtration rate decreased	8(0.2%)	4(0.1%)
Blood glucose increased	5(0.1%)	2(0.1%)
Colonoscopy	3(0.1%)	3(0.1%)
Blood creatinine increased	2(0.1%)	5(0.1%)
Weight decreased	2(0.1%)	3(0.1%)
Biopsy kidney	2(0.1%)	2(0.1%)
Blood potassium increased	2(0.1%)	0
Endoscopy	2(0.1%)	0
Angiocardiogram	1(0.0%)	2(0.1%)
Influenza A virus test positive	1(0.0%)	2(0.1%)
C-reactive protein increased	1(0.0%)	1(0.0%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Alanine aminotransferase increased	1(0.0%)	0
Arteriogram	1(0.0%)	0
Aspartate aminotransferase increased	1(0.0%)	0
Biopsy bladder	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood pressure orthostatic decreased	1(0.0%)	0
Cancer staging	1(0.0%)	0
Cardiac function test abnormal	1(0.0%)	0
Cardiac pacemaker evaluation	1(0.0%)	0
Cardiac stress test abnormal	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Colonoscopy normal	1(0.0%)	0
Electrocardiogram abnormal	1(0.0%)	0
Gamma-glutamyltransferase increased	1(0.0%)	0
Haematocrit decreased	1(0.0%)	0
Blood creatine phosphokinase increased	0	4(0.1%)
Hepatic enzyme increased	0	3(0.1%)
Arthroscopy	0	2(0.1%)
Blood pressure increased	0	2(0.1%)
Glycosylated haemoglobin increased	0	2(0.1%)
Liver function test increased	0	2(0.1%)
Anticoagulation drug level above therapeutic	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Blood magnesium decreased	0	1(0.0%)
Blood urine present	0	1(0.0%)
Cardiovascular examination	0	1(0.0%)
Computerised tomogram abdomen	0	1(0.0%)
Endoscopy small intestine	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Inflammatory marker increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Troponin T increased	0	1(0.0%)
Troponin increased	0	1(0.0%)
Blood And Lymphatic System Disorders	37(0.9%)	53(1.3%)
Anaemia	23(0.6%)	31(0.8%)
Iron deficiency anaemia	5(0.1%)	6(0.2%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Microcytic anaemia	2(0.1%)	1(0.0%)
Lymphadenopathy mediastinal	1(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	1(0.0%)
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Hypocoagulable state	1(0.0%)	0
Immune thrombocytopenia	1(0.0%)	0
Lymphadenopathy	1(0.0%)	0
Nephrogenic anaemia	0	5(0.1%)
Thrombocytopenia	0	2(0.1%)
Acquired haemophilia	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)
Leukocytosis	0	1(0.0%)
Neutropenia	0	1(0.0%)
Normochromic normocytic anaemia	0	1(0.0%)
Normocytic anaemia	0	1(0.0%)
Reproductive System And Breast Disorders	19(0.5%)	20(0.5%)
Benign prostatic hyperplasia	9(0.2%)	11(0.3%)
Endometrial hyperplasia	2(0.1%)	0
Prostatomegaly	1(0.0%)	1(0.0%)
Uterine polyp	1(0.0%)	1(0.0%)
Balanoposthitis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Breast necrosis	1(0.0%)	0
Metrorrhagia	1(0.0%)	0
Prostatism	1(0.0%)	0
Scrotal dermatitis	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Ovarian cyst	0	3(0.1%)
Dysfunctional uterine bleeding	0	1(0.0%)
Endometrial thickening	0	1(0.0%)
Prostatitis	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine haemorrhage	0	1(0.0%)
Psychiatric Disorders	17(0.4%)	13(0.3%)
Anxiety	4(0.1%)	0
Confusional state	2(0.1%)	2(0.1%)
Bipolar disorder	2(0.1%)	0
Completed suicide	2(0.1%)	0
Mental status changes	1(0.0%)	5(0.1%)
Depression	1(0.0%)	4(0.1%)
Major depression	1(0.0%)	1(0.0%)
Alcohol abuse	1(0.0%)	0
Insomnia	1(0.0%)	0
Mania	1(0.0%)	0
Mental disorder due to a general medical condition	1(0.0%)	0
Suicide attempt	1(0.0%)	0
Delusional disorder, unspecified type	0	1(0.0%)
Ear And Labyrinth Disorders	14(0.4%)	21(0.5%)
Vertigo	6(0.2%)	9(0.2%)
Sudden hearing loss	2(0.1%)	4(0.1%)
Vestibular disorder	2(0.1%)	2(0.1%)
Tympanic membrane perforation	1(0.0%)	1(0.0%)
Vertigo positional	1(0.0%)	1(0.0%)
Acute vestibular syndrome	1(0.0%)	0
Deafness neurosensory	1(0.0%)	0
Deafness unilateral	0	1(0.0%)
Ear pain	0	1(0.0%)
Tinnitus	0	1(0.0%)
Vestibular ataxia	0	1(0.0%)
Endocrine Disorders	4(0.1%)	7(0.2%)
Hyperparathyroidism	1(0.0%)	0
Hypothyroidism	1(0.0%)	0
Primary hyperaldosteronism	1(0.0%)	0
Toxic nodular goitre	1(0.0%)	0
Goitre	0	2(0.1%)
Thyroid mass	0	2(0.1%)
Hyperthyroidism	0	1(0.0%)
Pituitary-dependent Cushing's syndrome	0	1(0.0%)
Thyroiditis	0	1(0.0%)
Congenital, Familial And Genetic Disorders	3(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.2: Frequency Summary of Treatment-Emergent Serious Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Factor VIII deficiency	1(0.0%)	0
Phimosis	1(0.0%)	0
Truncus arteriosus persistent	1(0.0%)	0
Dermoid cyst	0	1(0.0%)
Hypospadias	0	1(0.0%)
Immune System Disorders	2(0.1%)	0
Drug hypersensitivity	2(0.1%)	0
Product Issues	1(0.0%)	2(0.1%)
Device malfunction	1(0.0%)	0
Device dislocation	0	2(0.1%)
Social Circumstances	1(0.0%)	0
Social stay hospitalisation	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Any TEAE	756(19.0%)	813(20.5%)
Infections And Infestations	202(5.1%)	225(5.7%)
Pneumonia	44(1.1%)	72(1.8%)
Cellulitis	16(0.4%)	21(0.5%)
Sepsis	15(0.4%)	20(0.5%)
COVID-19	12(0.3%)	7(0.2%)
Urinary tract infection	9(0.2%)	18(0.5%)
Urosepsis	7(0.2%)	2(0.1%)
Osteomyelitis	6(0.2%)	11(0.3%)
Gastroenteritis	6(0.2%)	8(0.2%)
Respiratory tract infection	6(0.2%)	3(0.1%)
Erysipelas	6(0.2%)	2(0.1%)
Septic shock	5(0.1%)	7(0.2%)
Pyelonephritis	5(0.1%)	3(0.1%)
Gangrene	4(0.1%)	6(0.2%)
Diabetic foot infection	4(0.1%)	5(0.1%)
Influenza	4(0.1%)	5(0.1%)
Bronchitis	4(0.1%)	4(0.1%)
Localised infection	4(0.1%)	4(0.1%)
COVID-19 pneumonia	4(0.1%)	1(0.0%)
Pulmonary sepsis	4(0.1%)	1(0.0%)
Abscess limb	3(0.1%)	2(0.1%)
Bacteraemia	3(0.1%)	0
Appendicitis	2(0.1%)	3(0.1%)
Herpes zoster	2(0.1%)	2(0.1%)
Nasopharyngitis	2(0.1%)	2(0.1%)
Pulmonary tuberculosis	2(0.1%)	2(0.1%)
Staphylococcal sepsis	2(0.1%)	2(0.1%)
Viral infection	2(0.1%)	1(0.0%)
Appendicitis perforated	2(0.1%)	0
Emphysematous pyelonephritis	2(0.1%)	0
Groin abscess	2(0.1%)	0
Lower respiratory tract infection	1(0.0%)	4(0.1%)
Upper respiratory tract infection	1(0.0%)	4(0.1%)
Anal abscess	1(0.0%)	2(0.1%)
Pneumonia bacterial	1(0.0%)	2(0.1%)
Bacterial sepsis	1(0.0%)	1(0.0%)
Campylobacter gastroenteritis	1(0.0%)	1(0.0%)
Clostridium difficile colitis	1(0.0%)	1(0.0%)
Cystitis	1(0.0%)	1(0.0%)
Epididymitis	1(0.0%)	1(0.0%)
Fournier's gangrene	1(0.0%)	1(0.0%)
Infected skin ulcer	1(0.0%)	1(0.0%)
Otitis media	1(0.0%)	1(0.0%)
Postoperative wound infection	1(0.0%)	1(0.0%)
Skin infection	1(0.0%)	1(0.0%)
Soft tissue infection	1(0.0%)	1(0.0%)
Wound infection	1(0.0%)	1(0.0%)
Abdominal abscess	1(0.0%)	0
Acute sinusitis	1(0.0%)	0
Arthritis bacterial	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Device related sepsis	1(0.0%)	0
Eye infection	1(0.0%)	0
Haematoma infection	1(0.0%)	0
Herpes ophthalmic	1(0.0%)	0
Infected bite	1(0.0%)	0
Infectious mononucleosis	1(0.0%)	0
Kidney infection	1(0.0%)	0
Large intestine infection	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Meningitis	1(0.0%)	0
Nephritis bacterial	1(0.0%)	0
Onychomycosis	1(0.0%)	0
Oral infection	1(0.0%)	0
Orchitis	1(0.0%)	0
Paronychia	1(0.0%)	0
Parotitis	1(0.0%)	0
Periodontitis	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Peritonitis bacterial	1(0.0%)	0
Pneumonia klebsiella	1(0.0%)	0
Pseudomonas infection	1(0.0%)	0
Pyelonephritis acute	1(0.0%)	0
Rectal abscess	1(0.0%)	0
Splenic abscess	1(0.0%)	0
Subcutaneous abscess	1(0.0%)	0
Viraemia	1(0.0%)	0
Viral pericarditis	1(0.0%)	0
Viral upper respiratory tract infection	1(0.0%)	0
Wound infection bacterial	1(0.0%)	0
Atypical pneumonia	0	3(0.1%)
Liver abscess	0	3(0.1%)
Diverticulitis	0	2(0.1%)
Endocarditis	0	2(0.1%)
Intervertebral discitis	0	2(0.1%)
Mastoiditis	0	2(0.1%)
Medical device site joint infection	0	2(0.1%)
Oral candidiasis	0	2(0.1%)
Otitis externa	0	2(0.1%)
Tooth infection	0	2(0.1%)
Acute hepatitis B	0	1(0.0%)
Anorectal infection bacterial	0	1(0.0%)
Arteriosclerotic gangrene	0	1(0.0%)
Bacterial rhinitis	0	1(0.0%)
Bacterial tracheitis	0	1(0.0%)
Burn infection	0	1(0.0%)
Carbuncle	0	1(0.0%)
Coronavirus infection	0	1(0.0%)
Dermo-hypodermitis	0	1(0.0%)
Diabetic gangrene	0	1(0.0%)
Ear infection	0	1(0.0%)
Enterococcal bacteraemia	0	1(0.0%)
Enterococcal infection	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Escherichia sepsis	0	1(0.0%)
Escherichia urinary tract infection	0	1(0.0%)
Gastritis viral	0	1(0.0%)
Gastroenteritis salmonella	0	1(0.0%)
Infected seroma	0	1(0.0%)
Infection	0	1(0.0%)
Infective exacerbation of bronchiectasis	0	1(0.0%)
Klebsiella bacteraemia	0	1(0.0%)
Necrotising fasciitis	0	1(0.0%)
Neutropenic sepsis	0	1(0.0%)
Ophthalmic herpes zoster	0	1(0.0%)
Peritonsillitis	0	1(0.0%)
Pharyngitis	0	1(0.0%)
Pharyngitis bacterial	0	1(0.0%)
Post procedural infection	0	1(0.0%)
Post procedural sepsis	0	1(0.0%)
Psoas abscess	0	1(0.0%)
Salmonella sepsis	0	1(0.0%)
Subacute endocarditis	0	1(0.0%)
Urinary tract infection bacterial	0	1(0.0%)
Viral tracheitis	0	1(0.0%)
Metabolism And Nutrition Disorders	129(3.2%)	118(3.0%)
Hyperkalaemia	44(1.1%)	10(0.3%)
Hypoglycaemia	30(0.8%)	38(1.0%)
Hyperglycaemia	10(0.3%)	11(0.3%)
Dehydration	8(0.2%)	8(0.2%)
Diabetes mellitus inadequate control	6(0.2%)	7(0.2%)
Diabetes mellitus	6(0.2%)	4(0.1%)
Diabetic ketoacidosis	4(0.1%)	5(0.1%)
Gout	4(0.1%)	4(0.1%)
Fluid overload	3(0.1%)	7(0.2%)
Hyponatraemia	3(0.1%)	2(0.1%)
Hypercalcaemia	3(0.1%)	0
Hyperglycaemic hyperosmolar nonketotic syndrome	2(0.1%)	5(0.1%)
Type 2 diabetes mellitus	2(0.1%)	4(0.1%)
Hypokalaemia	2(0.1%)	3(0.1%)
Metabolic acidosis	2(0.1%)	2(0.1%)
Hyperlipidaemia	2(0.1%)	1(0.0%)
Hypovolaemia	2(0.1%)	1(0.0%)
Hypocalcaemia	1(0.0%)	3(0.1%)
Decreased appetite	1(0.0%)	2(0.1%)
Hypertriglyceridaemia	1(0.0%)	2(0.1%)
Fluid retention	1(0.0%)	1(0.0%)
Hypomagnesaemia	1(0.0%)	1(0.0%)
Ketoacidosis	1(0.0%)	1(0.0%)
Calciphylaxis	1(0.0%)	0
Hypercholesterolaemia	1(0.0%)	0
Obesity	1(0.0%)	0
Vitamin D deficiency	0	4(0.1%)
Hypoproteinaemia	0	3(0.1%)
Diabetic metabolic decompensation	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hyperphosphataemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Tumour lysis syndrome	0	1(0.0%)
Renal And Urinary Disorders	91(2.3%)	108(2.7%)
Acute kidney injury	41(1.0%)	57(1.4%)
Renal failure	9(0.2%)	6(0.2%)
Chronic kidney disease	6(0.2%)	13(0.3%)
Renal impairment	5(0.1%)	6(0.2%)
Diabetic nephropathy	3(0.1%)	3(0.1%)
End stage renal disease	3(0.1%)	3(0.1%)
Nephrolithiasis	3(0.1%)	3(0.1%)
Urinary retention	3(0.1%)	2(0.1%)
Nephropathy	2(0.1%)	4(0.1%)
Urinary tract obstruction	2(0.1%)	1(0.0%)
Hydronephrosis	1(0.0%)	3(0.1%)
Nephrotic syndrome	1(0.0%)	3(0.1%)
Ureterolithiasis	1(0.0%)	2(0.1%)
Bladder outlet obstruction	1(0.0%)	1(0.0%)
Pollakiuria	1(0.0%)	1(0.0%)
Bladder perforation	1(0.0%)	0
Dysuria	1(0.0%)	0
Haematuria	1(0.0%)	0
Micturition disorder	1(0.0%)	0
Nephropathy toxic	1(0.0%)	0
Renal artery stenosis	1(0.0%)	0
Renal cyst	1(0.0%)	0
Renal mass	1(0.0%)	0
Renal tubular acidosis	1(0.0%)	0
Ureteric obstruction	1(0.0%)	0
Urethral stenosis	1(0.0%)	0
Azotaemia	0	1(0.0%)
Calculus urinary	0	1(0.0%)
Cystitis ulcerative	0	1(0.0%)
Pelvi-ureteric obstruction	0	1(0.0%)
Polyuria	0	1(0.0%)
Proteinuria	0	1(0.0%)
Renal colic	0	1(0.0%)
Renal haemorrhage	0	1(0.0%)
Urinary bladder polyp	0	1(0.0%)
Urinary incontinence	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	86(2.2%)	104(2.6%)
Lung neoplasm malignant	8(0.2%)	4(0.1%)
Prostate cancer	6(0.2%)	10(0.3%)
Colon cancer	6(0.2%)	6(0.2%)
Bladder cancer	3(0.1%)	5(0.1%)
Hepatocellular carcinoma	3(0.1%)	3(0.1%)
Pancreatic carcinoma	3(0.1%)	3(0.1%)
Renal cell carcinoma	3(0.1%)	1(0.0%)
Metastases to central nervous system	3(0.1%)	0
Oesophageal adenocarcinoma	3(0.1%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pancreatic neoplasm	3(0.1%)	0
Lung adenocarcinoma	2(0.1%)	4(0.1%)
Breast cancer	2(0.1%)	3(0.1%)
Metastases to liver	2(0.1%)	3(0.1%)
Adenocarcinoma of colon	2(0.1%)	2(0.1%)
Bladder transitional cell carcinoma	2(0.1%)	2(0.1%)
Hepatic cancer	2(0.1%)	1(0.0%)
Metastases to bone	2(0.1%)	1(0.0%)
Metastases to spine	2(0.1%)	1(0.0%)
Squamous cell carcinoma of the oral cavity	2(0.1%)	1(0.0%)
Colon adenoma	2(0.1%)	0
Metastases to lung	2(0.1%)	0
Metastases to lymph nodes	2(0.1%)	0
Renal neoplasm	1(0.0%)	4(0.1%)
Oesophageal carcinoma	1(0.0%)	3(0.1%)
Small cell lung cancer	1(0.0%)	3(0.1%)
Lung neoplasm	1(0.0%)	2(0.1%)
Malignant melanoma	1(0.0%)	2(0.1%)
Acute myeloid leukaemia	1(0.0%)	1(0.0%)
Bronchial carcinoma	1(0.0%)	1(0.0%)
Cholangiocarcinoma	1(0.0%)	1(0.0%)
Colorectal cancer	1(0.0%)	1(0.0%)
Lung cancer metastatic	1(0.0%)	1(0.0%)
Pancreatic carcinoma metastatic	1(0.0%)	1(0.0%)
Pancreatic carcinoma stage IV	1(0.0%)	1(0.0%)
Plasma cell myeloma	1(0.0%)	1(0.0%)
Basal cell carcinoma	1(0.0%)	0
Bladder cancer recurrent	1(0.0%)	0
Breast neoplasm	1(0.0%)	0
Colon cancer stage IV	1(0.0%)	0
Endometrial adenocarcinoma	1(0.0%)	0
Epithelioid mesothelioma	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Gastrointestinal carcinoma	1(0.0%)	0
Infected neoplasm	1(0.0%)	0
Invasive lobular breast carcinoma	1(0.0%)	0
Lung carcinoma cell type unspecified stage IV	1(0.0%)	0
Malignant neoplasm progression	1(0.0%)	0
Myelodysplastic syndrome	1(0.0%)	0
Oropharyngeal squamous cell carcinoma	1(0.0%)	0
Prostate cancer metastatic	1(0.0%)	0
Prostate cancer recurrent	1(0.0%)	0
Sarcoma metastatic	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Squamous cell carcinoma of the parotid gland	1(0.0%)	0
Squamous cell carcinoma of the vulva	1(0.0%)	0
Transitional cell carcinoma recurrent	1(0.0%)	0
Tumour rupture	1(0.0%)	0
Undifferentiated sarcoma	1(0.0%)	0
Brain neoplasm	0	3(0.1%)
Adenocarcinoma gastric	0	2(0.1%)
Adrenal adenoma	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Malignant neoplasm of unknown primary site	0	2(0.1%)
Renal cancer	0	2(0.1%)
Transitional cell carcinoma	0	2(0.1%)
Adenocarcinoma metastatic	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
B-cell lymphoma stage IV	0	1(0.0%)
Bladder neoplasm	0	1(0.0%)
Bladder squamous cell carcinoma stage unspecified	0	1(0.0%)
Bone cancer	0	1(0.0%)
Clear cell renal cell carcinoma	0	1(0.0%)
Colon neoplasm	0	1(0.0%)
Colorectal adenocarcinoma	0	1(0.0%)
Diffuse large B-cell lymphoma recurrent	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Endometrial cancer	0	1(0.0%)
Fibroadenoma of breast	0	1(0.0%)
Gallbladder adenocarcinoma	0	1(0.0%)
Gastric cancer	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Gastrointestinal carcinoma in situ	0	1(0.0%)
Hepatic cancer metastatic	0	1(0.0%)
Invasive papillary breast carcinoma	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Metastasis	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Papillary renal cell carcinoma	0	1(0.0%)
Penile cancer	0	1(0.0%)
Pituitary tumour benign	0	1(0.0%)
Prostate cancer stage IV	0	1(0.0%)
Rectal adenocarcinoma	0	1(0.0%)
Retroperitoneal neoplasm	0	1(0.0%)
Sarcoma	0	1(0.0%)
Skin cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Squamous cell carcinoma	0	1(0.0%)
Superficial spreading melanoma stage unspecified	0	1(0.0%)
Thyroid cancer	0	1(0.0%)
Vulval cancer stage 0	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	76(1.9%)	79(2.0%)
Chronic obstructive pulmonary disease	15(0.4%)	10(0.3%)
Respiratory failure	13(0.3%)	8(0.2%)
Acute respiratory failure	10(0.3%)	16(0.4%)
Dyspnoea	8(0.2%)	7(0.2%)
Pulmonary embolism	7(0.2%)	7(0.2%)
Sleep apnoea syndrome	5(0.1%)	6(0.2%)
Pulmonary mass	4(0.1%)	0
Pleural effusion	3(0.1%)	5(0.1%)
Acute pulmonary oedema	3(0.1%)	3(0.1%)
Pulmonary oedema	2(0.1%)	6(0.2%)
Hypoxia	2(0.1%)	1(0.0%)
Pneumothorax	2(0.1%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Chronic respiratory failure	2(0.1%)	0
Pulmonary hypertension	1(0.0%)	3(0.1%)
Cough	1(0.0%)	2(0.1%)
Pneumonia aspiration	1(0.0%)	2(0.1%)
Pneumonitis	1(0.0%)	2(0.1%)
Asthma	1(0.0%)	1(0.0%)
Dyspnoea exertional	1(0.0%)	1(0.0%)
Alveolar lung disease	1(0.0%)	0
Atelectasis	1(0.0%)	0
Bronchitis chronic	1(0.0%)	0
Haemoptysis	1(0.0%)	0
Interstitial lung disease	1(0.0%)	0
Laryngeal oedema	1(0.0%)	0
Pharyngeal oedema	1(0.0%)	0
Pleurisy	1(0.0%)	0
Pulmonary alveolar haemorrhage	1(0.0%)	0
Pulmonary fibrosis	1(0.0%)	0
Haemothorax	0	2(0.1%)
Aspiration	0	1(0.0%)
Emphysema	0	1(0.0%)
Epistaxis	0	1(0.0%)
Idiopathic pulmonary fibrosis	0	1(0.0%)
Laryngeal stenosis	0	1(0.0%)
Obstructive airways disorder	0	1(0.0%)
Productive cough	0	1(0.0%)
Pulmonary congestion	0	1(0.0%)
Rales	0	1(0.0%)
Respiratory acidosis	0	1(0.0%)
Small airways disease	0	1(0.0%)
Thoracic haemorrhage	0	1(0.0%)
Wheezing	0	1(0.0%)
Injury, Poisoning And Procedural Complications	71(1.8%)	67(1.7%)
Femoral neck fracture	8(0.2%)	0
Femur fracture	7(0.2%)	7(0.2%)
Hip fracture	7(0.2%)	4(0.1%)
Fall	5(0.1%)	6(0.2%)
Ankle fracture	3(0.1%)	3(0.1%)
Road traffic accident	3(0.1%)	3(0.1%)
Radius fracture	2(0.1%)	4(0.1%)
Humerus fracture	2(0.1%)	3(0.1%)
Spinal compression fracture	2(0.1%)	3(0.1%)
Skin laceration	2(0.1%)	2(0.1%)
Cervical vertebral fracture	2(0.1%)	0
Craniocerebral injury	2(0.1%)	0
Joint injury	2(0.1%)	0
Patella fracture	2(0.1%)	0
Head injury	1(0.0%)	2(0.1%)
Post procedural haemorrhage	1(0.0%)	2(0.1%)
Procedural pain	1(0.0%)	2(0.1%)
Brain contusion	1(0.0%)	1(0.0%)
Limb injury	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Subdural haemorrhage	1(0.0%)	1(0.0%)
Thoracic vertebral fracture	1(0.0%)	1(0.0%)
Tibia fracture	1(0.0%)	1(0.0%)
Traumatic fracture	1(0.0%)	1(0.0%)
Ulna fracture	1(0.0%)	1(0.0%)
Accidental overdose	1(0.0%)	0
Back injury	1(0.0%)	0
Clavicle fracture	1(0.0%)	0
Fibula fracture	1(0.0%)	0
Foot fracture	1(0.0%)	0
Gun shot wound	1(0.0%)	0
Hand fracture	1(0.0%)	0
Incision site pain	1(0.0%)	0
Ligament rupture	1(0.0%)	0
Lumbar vertebral fracture	1(0.0%)	0
Muscle injury	1(0.0%)	0
Peripheral arterial reocclusion	1(0.0%)	0
Post procedural haematoma	1(0.0%)	0
Radiation proctitis	1(0.0%)	0
Skull fractured base	1(0.0%)	0
Spinal cord injury cervical	1(0.0%)	0
Spinal fracture	1(0.0%)	0
Splenic injury	1(0.0%)	0
Sternal fracture	1(0.0%)	0
Tendon rupture	1(0.0%)	0
Toxicity to various agents	1(0.0%)	0
Wound necrosis	1(0.0%)	0
Rib fracture	0	5(0.1%)
Subdural haematoma	0	4(0.1%)
Contusion	0	2(0.1%)
Acetabulum fracture	0	1(0.0%)
Alcohol poisoning	0	1(0.0%)
Burns third degree	0	1(0.0%)
Cold burn	0	1(0.0%)
Epicondylitis	0	1(0.0%)
Forearm fracture	0	1(0.0%)
Heat stroke	0	1(0.0%)
Injury	0	1(0.0%)
Joint dislocation	0	1(0.0%)
Laryngeal injury	0	1(0.0%)
Ligament sprain	0	1(0.0%)
Multiple injuries	0	1(0.0%)
Nasal injury	0	1(0.0%)
Overdose	0	1(0.0%)
Pelvic fracture	0	1(0.0%)
Post-traumatic pain	0	1(0.0%)
Procedural haemorrhage	0	1(0.0%)
Skull fracture	0	1(0.0%)
Thermal burn	0	1(0.0%)
Tooth fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Gastrointestinal Disorders	70(1.8%)	67(1.7%)
Diarrhoea	9(0.2%)	4(0.1%)
Vomiting	6(0.2%)	1(0.0%)
Gastrointestinal haemorrhage	5(0.1%)	6(0.2%)
Pancreatitis acute	5(0.1%)	5(0.1%)
Abdominal pain	4(0.1%)	7(0.2%)
Rectal haemorrhage	3(0.1%)	1(0.0%)
Upper gastrointestinal haemorrhage	2(0.1%)	7(0.2%)
Intestinal obstruction	2(0.1%)	3(0.1%)
Small intestinal obstruction	2(0.1%)	2(0.1%)
Lower gastrointestinal haemorrhage	2(0.1%)	1(0.0%)
Pancreatitis	2(0.1%)	1(0.0%)
Dyspepsia	2(0.1%)	0
Constipation	1(0.0%)	3(0.1%)
Gastritis	1(0.0%)	2(0.1%)
Haematochezia	1(0.0%)	2(0.1%)
Abdominal discomfort	1(0.0%)	1(0.0%)
Chronic gastritis	1(0.0%)	1(0.0%)
Colitis ischaemic	1(0.0%)	1(0.0%)
Duodenal ulcer	1(0.0%)	1(0.0%)
Nausea	1(0.0%)	1(0.0%)
Abdominal mass	1(0.0%)	0
Alcoholic pancreatitis	1(0.0%)	0
Diarrhoea haemorrhagic	1(0.0%)	0
Diverticulum intestinal haemorrhagic	1(0.0%)	0
Duodenal perforation	1(0.0%)	0
Duodenitis haemorrhagic	1(0.0%)	0
Enterocolitis	1(0.0%)	0
Faecaloma	1(0.0%)	0
Functional gastrointestinal disorder	1(0.0%)	0
Gastric ulcer haemorrhage	1(0.0%)	0
Gastritis haemorrhagic	1(0.0%)	0
Gastrointestinal polyp	1(0.0%)	0
Gastrointestinal ulcer	1(0.0%)	0
Gastrointestinal vascular malformation haemorrhagic	1(0.0%)	0
Glossitis	1(0.0%)	0
Haematemesis	1(0.0%)	0
Haemorrhagic erosive gastritis	1(0.0%)	0
Haemorrhoids	1(0.0%)	0
Ileus	1(0.0%)	0
Incarcerated umbilical hernia	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Mechanical ileus	1(0.0%)	0
Peptic ulcer	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Abdominal wall haematoma	0	2(0.1%)
Ascites	0	2(0.1%)
Duodenal ulcer perforation	0	2(0.1%)
Dysphagia	0	2(0.1%)
Large intestine polyp	0	2(0.1%)
Varices oesophageal	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Abdominal pain lower	0	1(0.0%)
Abdominal pain upper	0	1(0.0%)
Anal fistula	0	1(0.0%)
Colitis	0	1(0.0%)
Colitis ulcerative	0	1(0.0%)
Colon dysplasia	0	1(0.0%)
Dental caries	0	1(0.0%)
Diverticulum	0	1(0.0%)
Duodenal ulcer haemorrhage	0	1(0.0%)
Food poisoning	0	1(0.0%)
Gastric mucosal hypertrophy	0	1(0.0%)
Gastrointestinal inflammation	0	1(0.0%)
Gastrointestinal ulcer haemorrhage	0	1(0.0%)
Inguinal hernia	0	1(0.0%)
Intestinal ischaemia	0	1(0.0%)
Melaena	0	1(0.0%)
Oesophageal dysplasia	0	1(0.0%)
Pancreatitis chronic	0	1(0.0%)
Retroperitoneal haematoma	0	1(0.0%)
Strangulated umbilical hernia	0	1(0.0%)
Subileus	0	1(0.0%)
Nervous System Disorders	63(1.6%)	65(1.6%)
Syncope	9(0.2%)	13(0.3%)
Dizziness	4(0.1%)	4(0.1%)
Seizure	4(0.1%)	4(0.1%)
Loss of consciousness	4(0.1%)	0
Diabetic neuropathy	3(0.1%)	2(0.1%)
Carotid artery stenosis	2(0.1%)	3(0.1%)
Carpal tunnel syndrome	2(0.1%)	3(0.1%)
Sciatica	2(0.1%)	3(0.1%)
Subarachnoid haemorrhage	2(0.1%)	3(0.1%)
Cognitive disorder	2(0.1%)	1(0.0%)
Facial paralysis	2(0.1%)	1(0.0%)
Cerebral haemorrhage	2(0.1%)	0
Headache	2(0.1%)	0
Hepatic encephalopathy	2(0.1%)	0
Partial seizures	2(0.1%)	0
Presyncope	1(0.0%)	2(0.1%)
Encephalopathy	1(0.0%)	1(0.0%)
Metabolic encephalopathy	1(0.0%)	1(0.0%)
Transient ischaemic attack	1(0.0%)	1(0.0%)
Carotid arteriosclerosis	1(0.0%)	0
Cerebrovascular disorder	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Facial paresis	1(0.0%)	0
Generalised tonic-clonic seizure	1(0.0%)	0
Guillain-Barre syndrome	1(0.0%)	0
Hemianaesthesia	1(0.0%)	0
Hypoaesthesia	1(0.0%)	0
IIIrd nerve paralysis	1(0.0%)	0
Ischaemic stroke	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Myelopathy	1(0.0%)	0
Neuroglycopenia	1(0.0%)	0
Normal pressure hydrocephalus	1(0.0%)	0
Parkinson's disease	1(0.0%)	0
Post stroke epilepsy	1(0.0%)	0
Tension headache	1(0.0%)	0
Toxic encephalopathy	1(0.0%)	0
Unresponsive to stimuli	1(0.0%)	0
Vertebral artery occlusion	1(0.0%)	0
Wernicke-Korsakoff syndrome	1(0.0%)	0
Epilepsy	0	3(0.1%)
Migraine	0	2(0.1%)
Altered state of consciousness	0	1(0.0%)
Aphasia	0	1(0.0%)
Brain oedema	0	1(0.0%)
Brain stem infarction	0	1(0.0%)
Brown-Sequard syndrome	0	1(0.0%)
Carotid artery occlusion	0	1(0.0%)
Cerebral arteriosclerosis	0	1(0.0%)
Cerebral disorder	0	1(0.0%)
Cervicobrachial syndrome	0	1(0.0%)
Coma	0	1(0.0%)
Cranial nerve palsies multiple	0	1(0.0%)
Dementia Alzheimer's type	0	1(0.0%)
Hypertensive encephalopathy	0	1(0.0%)
Hypoglycaemic unconsciousness	0	1(0.0%)
Hypoxic-ischaemic encephalopathy	0	1(0.0%)
Intraventricular haemorrhage	0	1(0.0%)
Ischaemic cerebral infarction	0	1(0.0%)
Lacunar infarction	0	1(0.0%)
Myelomalacia	0	1(0.0%)
Neuralgia	0	1(0.0%)
Neurodegenerative disorder	0	1(0.0%)
Paraplegia	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Spinal cord haematoma	0	1(0.0%)
Spondylitic myelopathy	0	1(0.0%)
Thalamic infarction	0	1(0.0%)
Thalamus haemorrhage	0	1(0.0%)
Vascular encephalopathy	0	1(0.0%)
Vascular Disorders	57(1.4%)	61(1.5%)
Hypotension	11(0.3%)	4(0.1%)
Hypertension	7(0.2%)	24(0.6%)
Aortic stenosis	7(0.2%)	1(0.0%)
Orthostatic hypotension	4(0.1%)	0
Peripheral ischaemia	3(0.1%)	5(0.1%)
Hypertensive crisis	3(0.1%)	3(0.1%)
Hypertensive urgency	2(0.1%)	4(0.1%)
Hypertensive emergency	2(0.1%)	3(0.1%)
Peripheral arterial occlusive disease	2(0.1%)	3(0.1%)
Extremity necrosis	2(0.1%)	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Deep vein thrombosis	2(0.1%)	1(0.0%)
Peripheral artery stenosis	1(0.0%)	3(0.1%)
Aortic aneurysm	1(0.0%)	1(0.0%)
Circulatory collapse	1(0.0%)	1(0.0%)
Giant cell arteritis	1(0.0%)	1(0.0%)
Lymphoedema	1(0.0%)	1(0.0%)
Peripheral vascular disorder	1(0.0%)	1(0.0%)
Thrombosis	1(0.0%)	1(0.0%)
Aortic dissection	1(0.0%)	0
Aortic occlusion	1(0.0%)	0
Brachiocephalic arteriosclerosis	1(0.0%)	0
Dry gangrene	1(0.0%)	0
Hypovolaemic shock	1(0.0%)	0
Ischaemic limb pain	1(0.0%)	0
Peripheral artery aneurysm	1(0.0%)	0
Peripheral artery occlusion	1(0.0%)	0
Thrombophlebitis	1(0.0%)	0
Varicose ulceration	1(0.0%)	0
Vasculitis	1(0.0%)	0
Haematoma	0	2(0.1%)
Arterial stenosis	0	1(0.0%)
Arterial thrombosis	0	1(0.0%)
Blood pressure inadequately controlled	0	1(0.0%)
Iliac artery stenosis	0	1(0.0%)
Intermittent claudication	0	1(0.0%)
Microangiopathy	0	1(0.0%)
Peripheral artery aneurysm rupture	0	1(0.0%)
Phlebitis	0	1(0.0%)
Shock haemorrhagic	0	1(0.0%)
Systolic hypertension	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	56(1.4%)	63(1.6%)
Osteoarthritis	11(0.3%)	5(0.1%)
Back pain	6(0.2%)	9(0.2%)
Arthralgia	5(0.1%)	8(0.2%)
Pain in extremity	4(0.1%)	5(0.1%)
Intervertebral disc protrusion	4(0.1%)	3(0.1%)
Gouty arthritis	3(0.1%)	2(0.1%)
Rhabdomyolysis	3(0.1%)	2(0.1%)
Spinal osteoarthritis	2(0.1%)	3(0.1%)
Arthritis	2(0.1%)	1(0.0%)
Rotator cuff syndrome	1(0.0%)	6(0.2%)
Muscle spasms	1(0.0%)	3(0.1%)
Lumbar spinal stenosis	1(0.0%)	2(0.1%)
Myalgia	1(0.0%)	2(0.1%)
Muscular weakness	1(0.0%)	1(0.0%)
Osteitis	1(0.0%)	1(0.0%)
Cervical spinal stenosis	1(0.0%)	0
Facet joint syndrome	1(0.0%)	0
Immobilisation syndrome	1(0.0%)	0
Intervertebral disc compression	1(0.0%)	0
Kyphosis	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Musculoskeletal chest pain	1(0.0%)	0
Musculoskeletal pain	1(0.0%)	0
Polymyalgia rheumatica	1(0.0%)	0
Rheumatoid arthritis	1(0.0%)	0
Spondylitis	1(0.0%)	0
Tendonitis	1(0.0%)	0
Tenosynovitis	1(0.0%)	0
Torticollis	1(0.0%)	0
Trigger finger	1(0.0%)	0
Osteolysis	0	2(0.1%)
Spinal stenosis	0	2(0.1%)
Back disorder	0	1(0.0%)
Bursitis	0	1(0.0%)
Chondrocalcinosis pyrophosphate	0	1(0.0%)
Costochondritis	0	1(0.0%)
Flank pain	0	1(0.0%)
Foot deformity	0	1(0.0%)
Intervertebral disc degeneration	0	1(0.0%)
Intervertebral disc disorder	0	1(0.0%)
Limb discomfort	0	1(0.0%)
Neck pain	0	1(0.0%)
Osteonecrosis of jaw	0	1(0.0%)
Osteopenia	0	1(0.0%)
Psoriatic arthropathy	0	1(0.0%)
Soft tissue necrosis	0	1(0.0%)
Spinal instability	0	1(0.0%)
Spondylolisthesis	0	1(0.0%)
Cardiac Disorders	50(1.3%)	61(1.5%)
Coronary artery disease	11(0.3%)	2(0.1%)
Bradycardia	5(0.1%)	2(0.1%)
Cardiac failure acute	4(0.1%)	0
Cardiac failure	3(0.1%)	17(0.4%)
Cardiac failure congestive	3(0.1%)	6(0.2%)
Angina unstable	2(0.1%)	4(0.1%)
Aortic valve stenosis	2(0.1%)	2(0.1%)
Cardio-respiratory arrest	2(0.1%)	1(0.0%)
Acute left ventricular failure	2(0.1%)	0
Left ventricular dysfunction	2(0.1%)	0
Sinus node dysfunction	2(0.1%)	0
Cardiac failure chronic	1(0.0%)	4(0.1%)
Cardiac arrest	1(0.0%)	3(0.1%)
Angina pectoris	1(0.0%)	2(0.1%)
Atrioventricular block second degree	1(0.0%)	1(0.0%)
Coronary artery stenosis	1(0.0%)	1(0.0%)
Ischaemic cardiomyopathy	1(0.0%)	1(0.0%)
Aortic valve calcification	1(0.0%)	0
Aortic valve disease mixed	1(0.0%)	0
Arrhythmia	1(0.0%)	0
Arrhythmia supraventricular	1(0.0%)	0
Atrial enlargement	1(0.0%)	0
Congestive cardiomyopathy	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Myocarditis	1(0.0%)	0
Pulseless electrical activity	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Ventricular hypokinesia	1(0.0%)	0
Atrial fibrillation	0	4(0.1%)
Acute coronary syndrome	0	2(0.1%)
Left atrial dilatation	0	2(0.1%)
Left ventricular hypertrophy	0	2(0.1%)
Aortic valve incompetence	0	1(0.0%)
Arteriosclerosis coronary artery	0	1(0.0%)
Atrial flutter	0	1(0.0%)
Atrial thrombosis	0	1(0.0%)
Cardiac tamponade	0	1(0.0%)
Cardiogenic shock	0	1(0.0%)
Cardiomyopathy	0	1(0.0%)
Cardiorenal syndrome	0	1(0.0%)
Coronary artery perforation	0	1(0.0%)
Diastolic dysfunction	0	1(0.0%)
Left ventricular failure	0	1(0.0%)
Mitral valve incompetence	0	1(0.0%)
Palpitations	0	1(0.0%)
Sinoatrial block	0	1(0.0%)
Tricuspid valve incompetence	0	1(0.0%)
Wandering pacemaker	0	1(0.0%)
Investigations	36(0.9%)	35(0.9%)
Glomerular filtration rate decreased	15(0.4%)	11(0.3%)
Blood potassium increased	3(0.1%)	1(0.0%)
Blood triglycerides increased	2(0.1%)	0
Gamma-glutamyltransferase increased	2(0.1%)	0
Blood creatinine increased	1(0.0%)	2(0.1%)
Influenza A virus test positive	1(0.0%)	2(0.1%)
Ejection fraction decreased	1(0.0%)	1(0.0%)
Anticoagulation drug level above therapeutic	1(0.0%)	0
Blood alkaline phosphatase increased	1(0.0%)	0
Blood calcium decreased	1(0.0%)	0
Blood pressure increased	1(0.0%)	0
Blood testosterone decreased	1(0.0%)	0
Catheterisation cardiac	1(0.0%)	0
Glycosylated haemoglobin increased	1(0.0%)	0
Haemoglobin decreased	1(0.0%)	0
International normalised ratio increased	1(0.0%)	0
Low density lipoprotein decreased	1(0.0%)	0
Oxygen consumption increased	1(0.0%)	0
Prostatic specific antigen increased	1(0.0%)	0
Liver function test increased	0	2(0.1%)
Angiocardiogram	0	1(0.0%)
Anticoagulation drug level below therapeutic	0	1(0.0%)
Biopsy kidney	0	1(0.0%)
Blood creatine phosphokinase increased	0	1(0.0%)
Blood magnesium decreased	0	1(0.0%)
Blood urine present	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
C-reactive protein increased	0	1(0.0%)
Colonoscopy	0	1(0.0%)
Electrocardiogram T wave inversion	0	1(0.0%)
Haematology test abnormal	0	1(0.0%)
Heart rate increased	0	1(0.0%)
Light chain analysis increased	0	1(0.0%)
N-terminal prohormone brain natriuretic peptide increased	0	1(0.0%)
Peripheral arteriogram	0	1(0.0%)
Troponin increased	0	1(0.0%)
Urine albumin/creatinine ratio increased	0	1(0.0%)
Weight decreased	0	1(0.0%)
General Disorders And Administration Site Conditions	33(0.8%)	49(1.2%)
Chest pain	5(0.1%)	11(0.3%)
Oedema peripheral	5(0.1%)	6(0.2%)
Death	4(0.1%)	8(0.2%)
Fatigue	4(0.1%)	3(0.1%)
Pyrexia	4(0.1%)	0
General physical health deterioration	2(0.1%)	4(0.1%)
Asthenia	1(0.0%)	7(0.2%)
Multiple organ dysfunction syndrome	1(0.0%)	1(0.0%)
Systemic inflammatory response syndrome	1(0.0%)	1(0.0%)
Feeling abnormal	1(0.0%)	0
Malaise	1(0.0%)	0
Oedema	1(0.0%)	0
Oedema due to cardiac disease	1(0.0%)	0
Pain	1(0.0%)	0
Swelling face	1(0.0%)	0
Gait disturbance	0	2(0.1%)
Generalised oedema	0	2(0.1%)
Peripheral swelling	0	2(0.1%)
Adhesion	0	1(0.0%)
Chest discomfort	0	1(0.0%)
Discomfort	0	1(0.0%)
Non-cardiac chest pain	0	1(0.0%)
Polyp	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	28(0.7%)	29(0.7%)
Diabetic foot	11(0.3%)	12(0.3%)
Skin ulcer	5(0.1%)	6(0.2%)
Decubitus ulcer	2(0.1%)	2(0.1%)
Pemphigoid	2(0.1%)	2(0.1%)
Skin lesion	2(0.1%)	1(0.0%)
Angioedema	2(0.1%)	0
Dry skin	2(0.1%)	0
Skin necrosis	2(0.1%)	0
Pruritus	1(0.0%)	1(0.0%)
Drug eruption	1(0.0%)	0
Ingrowing nail	1(0.0%)	0
Palmoplantar keratoderma	1(0.0%)	0
Blister	0	1(0.0%)
Dermatitis	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Dermatitis bullous	0	1(0.0%)
Diabetic cheiroarthropathy	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Surgical And Medical Procedures	28(0.7%)	26(0.7%)
Toe amputation	3(0.1%)	4(0.1%)
Cataract operation	3(0.1%)	1(0.0%)
Hip arthroplasty	3(0.1%)	1(0.0%)
Colectomy	2(0.1%)	0
Leg amputation	2(0.1%)	0
Foot amputation	1(0.0%)	1(0.0%)
Knee arthroplasty	1(0.0%)	1(0.0%)
Prostatectomy	1(0.0%)	1(0.0%)
Radical prostatectomy	1(0.0%)	1(0.0%)
Vitrectomy	1(0.0%)	1(0.0%)
Bladder calculus removal	1(0.0%)	0
Carotid endarterectomy	1(0.0%)	0
Coronary angioplasty	1(0.0%)	0
Coronary artery bypass	1(0.0%)	0
Hysterectomy	1(0.0%)	0
Metabolic surgery	1(0.0%)	0
Parotidectomy	1(0.0%)	0
Rehabilitation therapy	1(0.0%)	0
Spinal fusion surgery	1(0.0%)	0
Spinal laminectomy	1(0.0%)	0
Therapeutic nerve ablation	1(0.0%)	0
Uterine prolapse repair	1(0.0%)	0
Gastrectomy	0	2(0.1%)
Haemodialysis	0	2(0.1%)
Intervertebral disc operation	0	2(0.1%)
Amputation	0	1(0.0%)
Arthrodesis	0	1(0.0%)
Cheilectomy	0	1(0.0%)
Gastric banding	0	1(0.0%)
Gastric banding reversal	0	1(0.0%)
Haemorrhoid operation	0	1(0.0%)
Insertion of ambulatory peritoneal catheter	0	1(0.0%)
Nasal polypectomy	0	1(0.0%)
Radioactive iodine therapy	0	1(0.0%)
Skin ulcer excision	0	1(0.0%)
Spinal operation	0	1(0.0%)
Stent placement	0	1(0.0%)
Umbilical hernia repair	0	1(0.0%)
Blood And Lymphatic System Disorders	27(0.7%)	33(0.8%)
Anaemia	15(0.4%)	21(0.5%)
Iron deficiency anaemia	4(0.1%)	3(0.1%)
Blood loss anaemia	2(0.1%)	1(0.0%)
Lymphadenopathy mediastinal	2(0.1%)	1(0.0%)
Thrombocytopenia	1(0.0%)	2(0.1%)
Normocytic anaemia	1(0.0%)	1(0.0%)
Pancytopenia	1(0.0%)	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Abdominal lymphadenopathy	1(0.0%)	0
Hilar lymphadenopathy	1(0.0%)	0
Hypereosinophilic syndrome	1(0.0%)	0
Immune thrombocytopenia	1(0.0%)	0
Lymphadenopathy	1(0.0%)	0
Splenomegaly	1(0.0%)	0
Acquired haemophilia	0	1(0.0%)
Bicytopenia	0	1(0.0%)
Febrile neutropenia	0	1(0.0%)
Leukocytosis	0	1(0.0%)
Microcytic anaemia	0	1(0.0%)
Nephrogenic anaemia	0	1(0.0%)
Splenic embolism	0	1(0.0%)
Hepatobiliary Disorders	20(0.5%)	21(0.5%)
Cholecystitis	4(0.1%)	3(0.1%)
Cholelithiasis	3(0.1%)	2(0.1%)
Cholangitis	2(0.1%)	4(0.1%)
Cholecystitis acute	2(0.1%)	4(0.1%)
Bile duct stone	2(0.1%)	0
Hepatic cirrhosis	1(0.0%)	3(0.1%)
Cholangitis acute	1(0.0%)	2(0.1%)
Biliary colic	1(0.0%)	0
Cholecystitis chronic	1(0.0%)	0
Gallbladder fistula	1(0.0%)	0
Hepatic steatosis	1(0.0%)	0
Hepatitis	1(0.0%)	0
Hepatomegaly	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0
Jaundice cholestatic	0	1(0.0%)
Liver disorder	0	1(0.0%)
Portal hypertension	0	1(0.0%)
Eye Disorders	17(0.4%)	19(0.5%)
Cataract	6(0.2%)	7(0.2%)
Vitreous haemorrhage	3(0.1%)	3(0.1%)
Diabetic retinopathy	3(0.1%)	1(0.0%)
Glaucoma	2(0.1%)	1(0.0%)
Macular fibrosis	2(0.1%)	1(0.0%)
Retinal vein occlusion	2(0.1%)	1(0.0%)
Retinal detachment	1(0.0%)	2(0.1%)
Retinal haemorrhage	1(0.0%)	1(0.0%)
Tractional retinal detachment	1(0.0%)	1(0.0%)
Eye disorder	1(0.0%)	0
Eye haemorrhage	1(0.0%)	0
Visual impairment	1(0.0%)	0
Blindness	0	2(0.1%)
Blindness unilateral	0	2(0.1%)
Macular oedema	0	1(0.0%)
Retinopathy	0	1(0.0%)
Rhegmatogenous retinal detachment	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.3: Frequency Summary of Severe Treatment-Emergent Adverse Events - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Reproductive System And Breast Disorders	12(0.3%)	6(0.2%)
Benign prostatic hyperplasia	3(0.1%)	3(0.1%)
Prostatomegaly	2(0.1%)	0
Endometrial hyperplasia	1(0.0%)	1(0.0%)
Prostatitis	1(0.0%)	1(0.0%)
Uterine haemorrhage	1(0.0%)	1(0.0%)
Breast necrosis	1(0.0%)	0
Prostatism	1(0.0%)	0
Uterine prolapse	1(0.0%)	0
Vaginal haemorrhage	1(0.0%)	0
Dysfunctional uterine bleeding	0	1(0.0%)
Testicular mass	0	1(0.0%)
Uterine mass	0	1(0.0%)
Psychiatric Disorders	7(0.2%)	13(0.3%)
Anxiety	2(0.1%)	1(0.0%)
Completed suicide	2(0.1%)	0
Depression	1(0.0%)	3(0.1%)
Confusional state	1(0.0%)	1(0.0%)
Aggression	1(0.0%)	0
Alcohol withdrawal syndrome	1(0.0%)	0
Disorientation	1(0.0%)	0
Mental status changes	0	3(0.1%)
Delirium	0	2(0.1%)
Insomnia	0	2(0.1%)
Delusional disorder, unspecified type	0	1(0.0%)
Ear And Labyrinth Disorders	2(0.1%)	6(0.2%)
Vertigo	1(0.0%)	3(0.1%)
Vertigo positional	1(0.0%)	0
Sudden hearing loss	0	2(0.1%)
Deafness	0	1(0.0%)
Endocrine Disorders	2(0.1%)	1(0.0%)
Hypothyroidism	1(0.0%)	0
Primary hyperaldosteronism	1(0.0%)	0
Thyroiditis	0	1(0.0%)
Congenital, Familial And Genetic Disorders	1(0.0%)	1(0.0%)
Truncus arteriosus persistent	1(0.0%)	0
Type V hyperlipidaemia	0	1(0.0%)
Immune System Disorders	1(0.0%)	0
Drug hypersensitivity	1(0.0%)	0
Product Issues	0	2(0.1%)
Device dislocation	0	1(0.0%)
Device leakage	0	1(0.0%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Any TEAE	319(8.0%)	246(6.2%)
Metabolism And Nutrition Disorders	81(2.0%)	34(0.9%)
Hyperkalaemia	76(1.9%)	25(0.6%)
Hyponatraemia	2(0.1%)	1(0.0%)
Decreased appetite	1(0.0%)	1(0.0%)
Diabetes mellitus	1(0.0%)	0
Hypercalcaemia	1(0.0%)	0
Diabetic ketoacidosis	0	1(0.0%)
Fluid overload	0	1(0.0%)
Fluid retention	0	1(0.0%)
Gout	0	1(0.0%)
Hyperglycaemia	0	1(0.0%)
Hypoglycaemia	0	1(0.0%)
Metabolic disorder	0	1(0.0%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	37(0.9%)	42(1.1%)
Lung neoplasm malignant	6(0.2%)	1(0.0%)
Colon cancer	2(0.1%)	2(0.1%)
Oesophageal adenocarcinoma	2(0.1%)	0
Lung adenocarcinoma	1(0.0%)	3(0.1%)
Renal neoplasm	1(0.0%)	3(0.1%)
Small cell lung cancer	1(0.0%)	3(0.1%)
Metastases to lymph nodes	1(0.0%)	2(0.1%)
Pancreatic carcinoma metastatic	1(0.0%)	2(0.1%)
Adenocarcinoma gastric	1(0.0%)	1(0.0%)
Cholangiocarcinoma	1(0.0%)	1(0.0%)
Lung cancer metastatic	1(0.0%)	1(0.0%)
Metastases to liver	1(0.0%)	1(0.0%)
Pancreatic carcinoma	1(0.0%)	1(0.0%)
Transitional cell carcinoma	1(0.0%)	1(0.0%)
Benign salivary gland neoplasm	1(0.0%)	0
Brain neoplasm malignant	1(0.0%)	0
Breast cancer	1(0.0%)	0
Fibrosarcoma	1(0.0%)	0
Hepatobiliary cancer	1(0.0%)	0
Malignant neoplasm of ampulla of Vater	1(0.0%)	0
Metastases to lung	1(0.0%)	0
Metastatic malignant melanoma	1(0.0%)	0
Myelodysplastic syndrome	1(0.0%)	0
Non-Hodgkin's lymphoma stage III	1(0.0%)	0
Pancreatic carcinoma stage IV	1(0.0%)	0
Pancreatic neoplasm	1(0.0%)	0
Prostate cancer	1(0.0%)	0
Prostate cancer metastatic	1(0.0%)	0
Rectal adenocarcinoma	1(0.0%)	0
Renal cell carcinoma	1(0.0%)	0
Squamous cell carcinoma of lung	1(0.0%)	0
Adrenal adenoma	0	2(0.1%)
Bladder cancer	0	2(0.1%)
Brain neoplasm	0	2(0.1%)
Colon neoplasm	0	2(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hepatocellular carcinoma	0	2(0.1%)
Acoustic neuroma	0	1(0.0%)
Acute myeloid leukaemia	0	1(0.0%)
Adenocarcinoma pancreas	0	1(0.0%)
Cervix carcinoma	0	1(0.0%)
Ductal adenocarcinoma of pancreas	0	1(0.0%)
Gastrointestinal cancer metastatic	0	1(0.0%)
Lung neoplasm	0	1(0.0%)
Malignant neoplasm of unknown primary site	0	1(0.0%)
Malignant pleural effusion	0	1(0.0%)
Metastases to spleen	0	1(0.0%)
Neoplasm prostate	0	1(0.0%)
Oesophageal cancer metastatic	0	1(0.0%)
Oesophageal carcinoma	0	1(0.0%)
Renal cancer	0	1(0.0%)
Small cell lung cancer metastatic	0	1(0.0%)
Renal And Urinary Disorders	37(0.9%)	38(1.0%)
Acute kidney injury	11(0.3%)	8(0.2%)
Renal impairment	10(0.3%)	10(0.3%)
Renal failure	5(0.1%)	4(0.1%)
Chronic kidney disease	2(0.1%)	8(0.2%)
Diabetic nephropathy	2(0.1%)	1(0.0%)
Proteinuria	2(0.1%)	1(0.0%)
End stage renal disease	1(0.0%)	1(0.0%)
Nephropathy	1(0.0%)	1(0.0%)
Nephrolithiasis	1(0.0%)	0
Nephrotic syndrome	1(0.0%)	0
Urinary retention	1(0.0%)	0
Renal mass	0	2(0.1%)
Perinephritis	0	1(0.0%)
Pollakiuria	0	1(0.0%)
Renal colic	0	1(0.0%)
Tubulointerstitial nephritis	0	1(0.0%)
Investigations	36(0.9%)	23(0.6%)
Blood potassium increased	18(0.5%)	6(0.2%)
Glomerular filtration rate decreased	9(0.2%)	9(0.2%)
Blood creatinine increased	6(0.2%)	5(0.1%)
Protein urine present	1(0.0%)	1(0.0%)
Blood pressure increased	1(0.0%)	0
Blood urea increased	1(0.0%)	0
Gamma-glutamyltransferase increased	1(0.0%)	0
Weight decreased	1(0.0%)	0
Amylase increased	0	1(0.0%)
Blood glucose increased	0	1(0.0%)
Lipase increased	0	1(0.0%)
Occult blood positive	0	1(0.0%)
Gastrointestinal Disorders	29(0.7%)	28(0.7%)
Diarrhoea	10(0.3%)	9(0.2%)
Nausea	5(0.1%)	12(0.3%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Vomiting	3(0.1%)	4(0.1%)
Constipation	2(0.1%)	3(0.1%)
Abdominal discomfort	1(0.0%)	1(0.0%)
Ascites	1(0.0%)	1(0.0%)
Gastric haemorrhage	1(0.0%)	0
Gastrointestinal haemorrhage	1(0.0%)	0
Intestinal mass	1(0.0%)	0
Intestinal perforation	1(0.0%)	0
Mechanical ileus	1(0.0%)	0
Pancreatic cyst	1(0.0%)	0
Pancreatitis	1(0.0%)	0
Pancreatitis acute	1(0.0%)	0
Retroperitoneal mass	1(0.0%)	0
Abdominal pain upper	0	4(0.1%)
Abdominal pain	0	2(0.1%)
Abdominal distension	0	1(0.0%)
Anal fistula	0	1(0.0%)
Diabetic gastroenteropathy	0	1(0.0%)
Dyspepsia	0	1(0.0%)
Faeces discoloured	0	1(0.0%)
Infections And Infestations	20(0.5%)	15(0.4%)
Sepsis	3(0.1%)	3(0.1%)
Pneumonia	2(0.1%)	5(0.1%)
COVID-19	1(0.0%)	1(0.0%)
COVID-19 pneumonia	1(0.0%)	1(0.0%)
Cellulitis	1(0.0%)	1(0.0%)
Localised infection	1(0.0%)	1(0.0%)
Osteomyelitis	1(0.0%)	1(0.0%)
Acarodermatitis	1(0.0%)	0
Influenza	1(0.0%)	0
Medical device site infection	1(0.0%)	0
Peritoneal tuberculosis	1(0.0%)	0
Pulmonary sepsis	1(0.0%)	0
Pulmonary tuberculosis	1(0.0%)	0
Soft tissue infection	1(0.0%)	0
Streptococcal sepsis	1(0.0%)	0
Tuberculosis	1(0.0%)	0
Urinary tract infection	1(0.0%)	0
Onychomycosis	0	1(0.0%)
Pneumonia respiratory syncytial viral	0	1(0.0%)
Urosepsis	0	1(0.0%)
Nervous System Disorders	18(0.5%)	22(0.6%)
Dizziness	5(0.1%)	5(0.1%)
Cognitive disorder	3(0.1%)	3(0.1%)
Headache	3(0.1%)	1(0.0%)
Dementia	2(0.1%)	4(0.1%)
Memory impairment	1(0.0%)	1(0.0%)
Dementia Alzheimer's type	1(0.0%)	0
Dementia with Lewy bodies	1(0.0%)	0
Seizure	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Tremor	1(0.0%)	0
Somnolence	0	2(0.1%)
Amnestic disorder	0	1(0.0%)
Carotid artery stenosis	0	1(0.0%)
Disturbance in attention	0	1(0.0%)
Epilepsy	0	1(0.0%)
Presyncope	0	1(0.0%)
Spinal cord compression	0	1(0.0%)
Transient ischaemic attack	0	1(0.0%)
Trigeminal neuralgia	0	1(0.0%)
Skin And Subcutaneous Tissue Disorders	18(0.5%)	11(0.3%)
Rash	7(0.2%)	2(0.1%)
Pruritus	5(0.1%)	2(0.1%)
Rash papular	2(0.1%)	0
Eczema	1(0.0%)	3(0.1%)
Dermatitis allergic	1(0.0%)	1(0.0%)
Decubitus ulcer	1(0.0%)	0
Diabetic foot	1(0.0%)	0
Psoriasis	1(0.0%)	0
Blister	0	1(0.0%)
Stevens-Johnson syndrome	0	1(0.0%)
Urticaria	0	1(0.0%)
Musculoskeletal And Connective Tissue Disorders	11(0.3%)	4(0.1%)
Arthralgia	2(0.1%)	0
Musculoskeletal pain	1(0.0%)	1(0.0%)
Myalgia	1(0.0%)	1(0.0%)
Pain in extremity	1(0.0%)	1(0.0%)
Connective tissue inflammation	1(0.0%)	0
Flank pain	1(0.0%)	0
Muscle rigidity	1(0.0%)	0
Muscle spasms	1(0.0%)	0
Polymyalgia rheumatica	1(0.0%)	0
Rhabdomyolysis	1(0.0%)	0
Rotator cuff syndrome	0	1(0.0%)
Respiratory, Thoracic And Mediastinal Disorders	9(0.2%)	7(0.2%)
Respiratory failure	4(0.1%)	0
Dyspnoea	1(0.0%)	3(0.1%)
Interstitial lung disease	1(0.0%)	1(0.0%)
Oropharyngeal pain	1(0.0%)	0
Pleural effusion	1(0.0%)	0
Pulmonary mass	1(0.0%)	0
Acute respiratory failure	0	2(0.1%)
Dyspnoea exertional	0	1(0.0%)
General Disorders And Administration Site Conditions	8(0.2%)	10(0.3%)
Fatigue	4(0.1%)	0
Malaise	2(0.1%)	0
Asthenia	1(0.0%)	1(0.0%)
Oedema	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Pain	1(0.0%)	0
General physical health deterioration	0	2(0.1%)
Oedema peripheral	0	2(0.1%)
Peripheral swelling	0	2(0.1%)
Chest pain	0	1(0.0%)
Chills	0	1(0.0%)
Generalised oedema	0	1(0.0%)
Swelling	0	1(0.0%)
Hepatobiliary Disorders	7(0.2%)	3(0.1%)
Liver disorder	2(0.1%)	2(0.1%)
Hepatic cirrhosis	2(0.1%)	0
Cholecystitis	1(0.0%)	0
Non-alcoholic steatohepatitis	1(0.0%)	0
Nonalcoholic fatty liver disease	1(0.0%)	0
Hepatic pain	0	1(0.0%)
Vascular Disorders	5(0.1%)	7(0.2%)
Hypotension	2(0.1%)	0
Hypertensive crisis	1(0.0%)	1(0.0%)
Hypertensive urgency	1(0.0%)	0
Peripheral ischaemia	1(0.0%)	0
Hypertension	0	2(0.1%)
Arterial thrombosis	0	1(0.0%)
Inferior vena cava syndrome	0	1(0.0%)
Orthostatic hypotension	0	1(0.0%)
Vein disorder	0	1(0.0%)
Surgical And Medical Procedures	4(0.1%)	0
Dialysis	1(0.0%)	0
Leg amputation	1(0.0%)	0
Pancreaticosplenectomy	1(0.0%)	0
Spinal decompression	1(0.0%)	0
Cardiac Disorders	3(0.1%)	7(0.2%)
Cardiac failure	1(0.0%)	3(0.1%)
Ischaemic cardiomyopathy	1(0.0%)	0
Stress cardiomyopathy	1(0.0%)	0
Atrial fibrillation	0	1(0.0%)
Bradycardia	0	1(0.0%)
Palpitations	0	1(0.0%)
Pericardial effusion	0	1(0.0%)
Blood And Lymphatic System Disorders	3(0.1%)	3(0.1%)
Anaemia	2(0.1%)	1(0.0%)
Pancytopenia	1(0.0%)	0
Blood loss anaemia	0	1(0.0%)
Iron deficiency anaemia	0	1(0.0%)
Injury, Poisoning And Procedural Complications	3(0.1%)	3(0.1%)
Road traffic accident	1(0.0%)	1(0.0%)
Femoral neck fracture	1(0.0%)	0

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Table A2.0.4: Frequency Summary of Treatment-Emergent Adverse Events leading to Discontinuation of Study Drug - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

MedDRA SOC and PT	Finerenone (N=3974)	Placebo (N=3966)
Hip fracture	1(0.0%)	0
Concussion	0	1(0.0%)
Fall	0	1(0.0%)
Femur fracture	0	1(0.0%)
Ilium fracture	0	1(0.0%)
Radius fracture	0	1(0.0%)
Rib fracture	0	1(0.0%)
Traumatic haemothorax	0	1(0.0%)
Immune System Disorders	2(0.1%)	1(0.0%)
Hypersensitivity	1(0.0%)	1(0.0%)
Drug hypersensitivity	1(0.0%)	0
Psychiatric Disorders	1(0.0%)	5(0.1%)
Alcohol abuse	1(0.0%)	0
Confusional state	0	2(0.1%)
Anorgasmia	0	1(0.0%)
Depression	0	1(0.0%)
Suicidal ideation	0	1(0.0%)
Eye Disorders	1(0.0%)	0
Scleritis	1(0.0%)	0
Ear And Labyrinth Disorders	0	4(0.1%)
Vertigo	0	4(0.1%)

Abbreviations: eGFR=estimated glomerular filtration rate, MedDRA = Medical Dictionary for Regulatory Activities, N=number of subjects, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

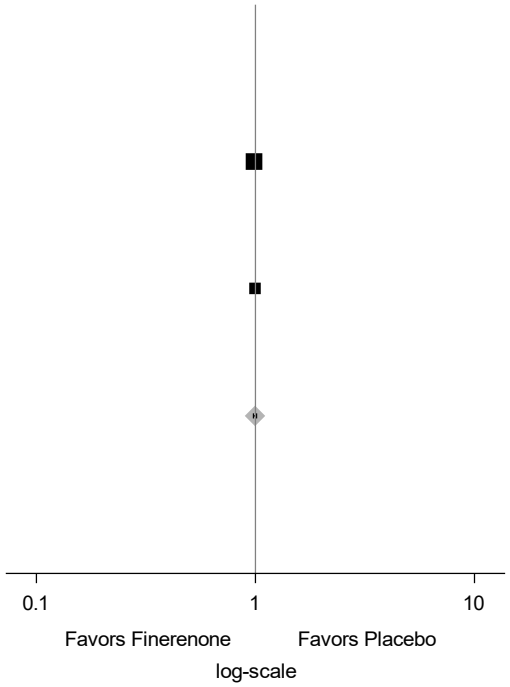
Table A2.0.5: Summary of Treatment Duration - Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

	Finerenone (N=3974)	Placebo (N=3966)	Total (N= 7940
Treatment duration (months)			
n	3974	3966	7940
Mean	29.2	29.8	29.5
SD	13.99	13.72	13.86
Median	29.2	29.6	29.3
Q1-Q3	20.0 - 40.3	20.7 - 40.8	20.3 - 40.6
Range	0.03 - 60.16	0.03 - 60.55	0.03 - 60.55

Abbreviations: eGFR=estimated glomerular filtration rate, N=number of subjects, n=number of subjects with non-missing values in category, Q1=first quartile, Q3=third quartile, SD=standard deviation.
Note: Treatment duration is defined as the time from start of study drug to permanent stop of study drug (in months).

Figure A2.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

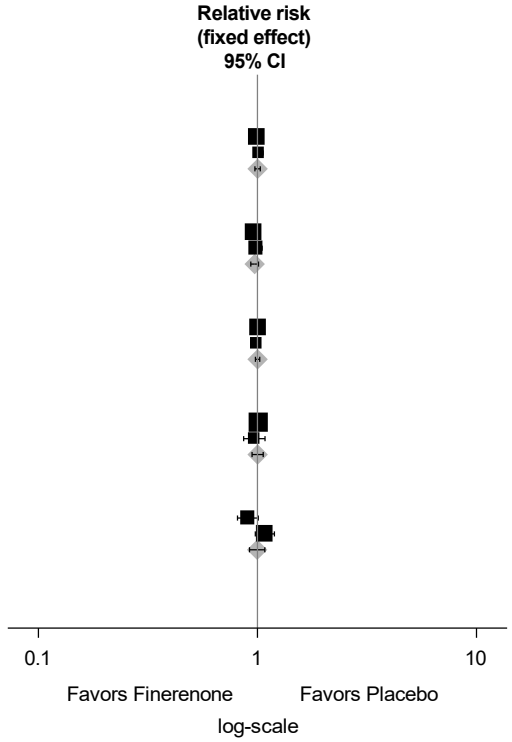
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2287 / 2617	2300 / 2610	65.3	0.99 [0.97,1.01]	
FIGARO-DKD	1195 / 1357	1192 / 1356	34.7	1.00 [0.97,1.03]	
Total	3482 / 3974	3492 / 3966		1.00 [0.98,1.01]	Z=-0.58, p=0.5623
Heterogeneity:	Q=0.33 (df=1)	p=0.5642	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.1.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

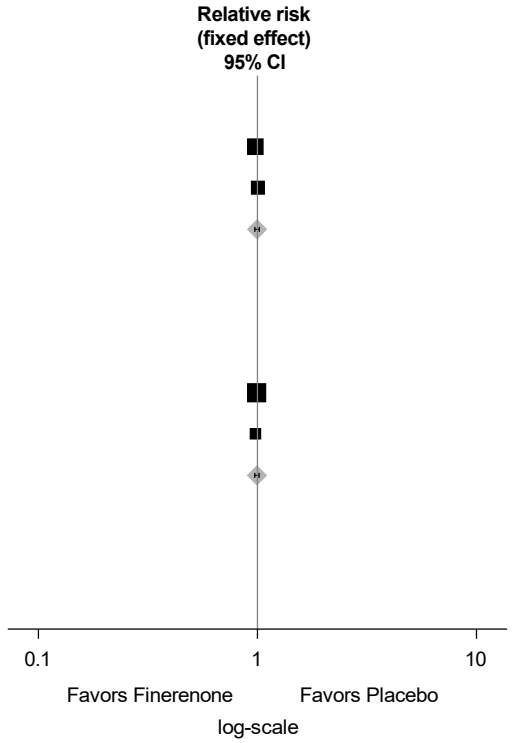
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	912 / 1075	906 / 1062	62.7	0.99 [0.96,1.03]	
FIGARO-DKD	546 / 638	538 / 637	37.3	1.01 [0.97,1.06]	
Total	1458 / 1713	1444 / 1699		1.00 [0.97,1.03]	Z=0.10, p=0.9209
Heterogeneity:	Q=0.40 (df=1)	p=0.5275	I^2=0.0%		
North America					
FIDELIO-DKD	361 / 424	386 / 436	59.9	0.96 [0.91,1.01]	
FIGARO-DKD	232 / 267	239 / 271	40.1	0.99 [0.92,1.05]	
Total	593 / 691	625 / 707		0.97 [0.93,1.01]	Z=-1.43, p=0.1536
Heterogeneity:	Q=0.33 (df=1)	p=0.5650	I^2=0.0%		
Asia					
FIDELIO-DKD	700 / 751	689 / 745	65.5	1.01 [0.98,1.04]	
FIGARO-DKD	272 / 289	276 / 290	34.5	0.99 [0.95,1.03]	
Total	972 / 1040	965 / 1035		1.00 [0.98,1.02]	Z=0.11, p=0.9125
Heterogeneity:	Q=0.60 (df=1)	p=0.4378	I^2=0.0%		
Latin America					
FIDELIO-DKD	236 / 273	230 / 270	73.0	1.01 [0.95,1.09]	
FIGARO-DKD	86 / 102	88 / 101	27.0	0.97 [0.86,1.08]	
Total	322 / 375	318 / 371		1.00 [0.94,1.06]	Z=0.06, p=0.9505
Heterogeneity:	Q=0.50 (df=1)	p=0.4787	I^2=0.0%		
Others					
FIDELIO-DKD	78 / 94	89 / 97	45.7	0.90 [0.81,1.01]	
FIGARO-DKD	59 / 61	51 / 57	54.3	1.08 [0.98,1.20]	
Total	137 / 155	140 / 154		1.00 [0.92,1.08]	Z=-0.07, p=0.9403
Heterogeneity:	Q=5.56 (df=1)	p=0.0184	I^2=82.0%		
Subgroup Heterogeneity:	Q=1.90 (df=4)	p=0.7545	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

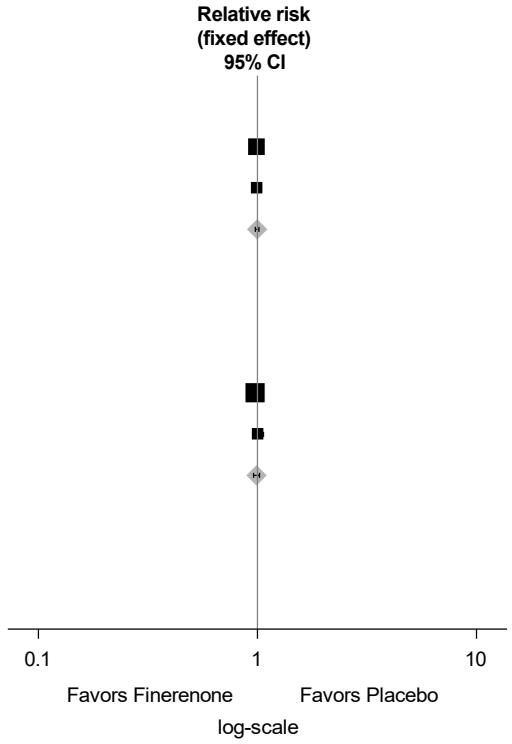
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1046 / 1213	1060 / 1210	57.8	0.98 [0.95,1.02]	
FIGARO-DKD	757 / 862	736 / 848	42.2	1.01 [0.98,1.05]	
Total	1803 / 2075	1796 / 2058		1.00 [0.97,1.02]	Z=-0.35, p=0.7290
Heterogeneity:	Q=1.29 (df=1)	p=0.2566	I^2=22.3%		
Absent					
FIDELIO-DKD	1241 / 1404	1240 / 1400	72.4	1.00 [0.97,1.02]	
FIGARO-DKD	438 / 495	456 / 508	27.6	0.99 [0.94,1.03]	
Total	1679 / 1899	1696 / 1908		0.99 [0.97,1.02]	Z=-0.47, p=0.6385
Heterogeneity:	Q=0.22 (df=1)	p=0.6353	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9382	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.1.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

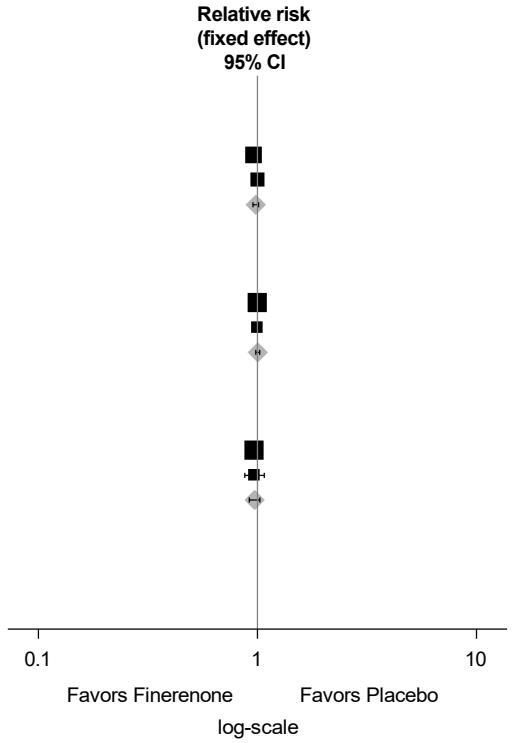
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1539 / 1735	1514 / 1700	64.1	1.00 [0.97,1.02]	
FIGARO-DKD	824 / 924	830 / 929	35.9	1.00 [0.97,1.03]	
Total	2363 / 2659	2344 / 2629		1.00 [0.98,1.02]	Z=-0.33, p=0.7380
Heterogeneity:	Q=0.01 (df=1)	p=0.9152	I^2=0.0%		
> 4.5					
FIDELIO-DKD	748 / 882	786 / 910	68.0	0.98 [0.95,1.02]	
FIGARO-DKD	371 / 433	362 / 426	32.0	1.01 [0.95,1.07]	
Total	1119 / 1315	1148 / 1336		0.99 [0.96,1.02]	Z=-0.61, p=0.5392
Heterogeneity:	Q=0.60 (df=1)	p=0.4389	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7243	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.1.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

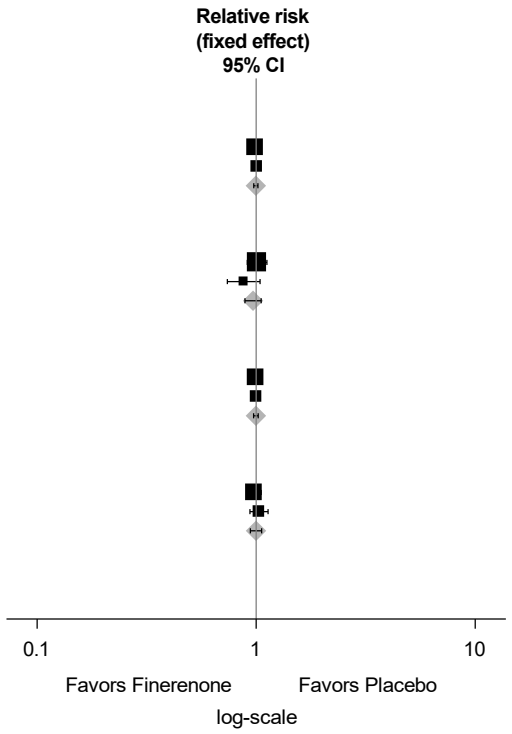
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	624 / 724	645 / 723	58.7	0.97 [0.93,1.00]	
FIGARO-DKD	436 / 494	434 / 495	41.3	1.01 [0.96,1.05]	
Total	1060 / 1218	1079 / 1218		0.98 [0.95,1.01]	Z=-1.16, p=0.2441
Heterogeneity:	Q=1.79 (df=1)	p=0.1805	I^2=44.3%		
130 - < 160					
FIDELIO-DKD	1541 / 1759	1535 / 1760	67.5	1.00 [0.98,1.03]	
FIGARO-DKD	727 / 829	725 / 827	32.5	1.00 [0.96,1.04]	
Total	2268 / 2588	2260 / 2587		1.00 [0.98,1.02]	Z=0.30, p=0.7661
Heterogeneity:	Q=0.03 (df=1)	p=0.8539	I^2=0.0%		
>= 160					
FIDELIO-DKD	122 / 133	120 / 127	70.6	0.97 [0.91,1.04]	
FIGARO-DKD	32 / 34	33 / 34	29.4	0.97 [0.88,1.07]	
Total	154 / 167	153 / 161		0.97 [0.92,1.03]	Z=-1.06, p=0.2899
Heterogeneity:	Q=0.00 (df=1)	p=0.9854	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.06 (df=2)	p=0.3568	I^2=3.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.1.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

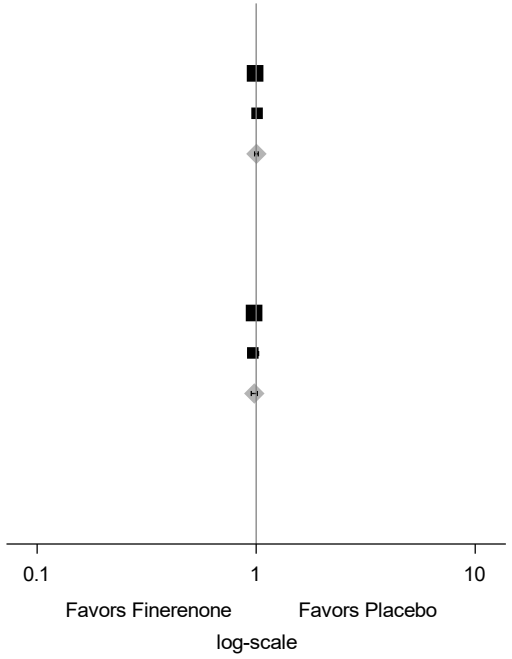
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	1394 / 1634	1428 / 1657	61.6	0.99 [0.96,1.02]	
FIGARO-DKD	872 / 1010	848 / 989	38.4	1.01 [0.97,1.04]	
Total	2266 / 2644	2276 / 2646		1.00 [0.97,1.02]	Z=-0.32, p=0.7475
Heterogeneity:	Q=0.55 (df=1)	p=0.4585	I^2=0.0%		
Black					
FIDELIO-DKD	111 / 129	98 / 115	73.6	1.01 [0.91,1.12]	
FIGARO-DKD	34 / 43	64 / 71	26.4	0.88 [0.74,1.04]	
Total	145 / 172	162 / 186		0.97 [0.89,1.05]	Z=-0.76, p=0.4493
Heterogeneity:	Q=1.91 (df=1)	p=0.1673	I^2=47.6%		
Asian					
FIDELIO-DKD	627 / 678	629 / 677	65.1	1.00 [0.97,1.03]	
FIGARO-DKD	239 / 252	238 / 251	34.9	1.00 [0.96,1.04]	
Total	866 / 930	867 / 928		1.00 [0.97,1.02]	Z=-0.24, p=0.8101
Heterogeneity:	Q=0.04 (df=1)	p=0.8501	I^2=0.0%		
Others					
FIDELIO-DKD	155 / 176	145 / 161	61.8	0.98 [0.91,1.05]	
FIGARO-DKD	50 / 52	42 / 45	38.2	1.03 [0.94,1.13]	
Total	205 / 228	187 / 206		1.00 [0.94,1.06]	Z=-0.06, p=0.9502
Heterogeneity:	Q=0.71 (df=1)	p=0.3981	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.45 (df=3)	p=0.9288	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.1.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

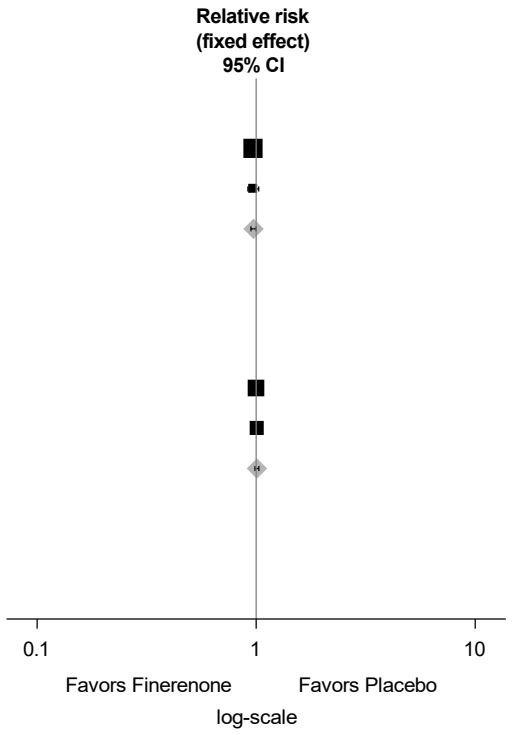
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1582 / 1797	1654 / 1870	64.7	1.00 [0.97,1.02]	
FIGARO-DKD	823 / 917	824 / 933	35.3	1.02 [0.98,1.05]	
Total	2405 / 2714	2478 / 2803		1.00 [0.98,1.02]	Z=0.27, p=0.7850
Heterogeneity:	Q=1.05 (df=1)	p=0.3061	I^2=4.5%		
Female					
FIDELIO-DKD	705 / 820	646 / 740	66.0	0.98 [0.95,1.02]	
FIGARO-DKD	372 / 440	368 / 423	34.0	0.97 [0.92,1.03]	
Total	1077 / 1260	1014 / 1163		0.98 [0.95,1.01]	Z=-1.23, p=0.2206
Heterogeneity:	Q=0.15 (df=1)	p=0.6959	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.42 (df=1)	p=0.2338	I^2=29.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

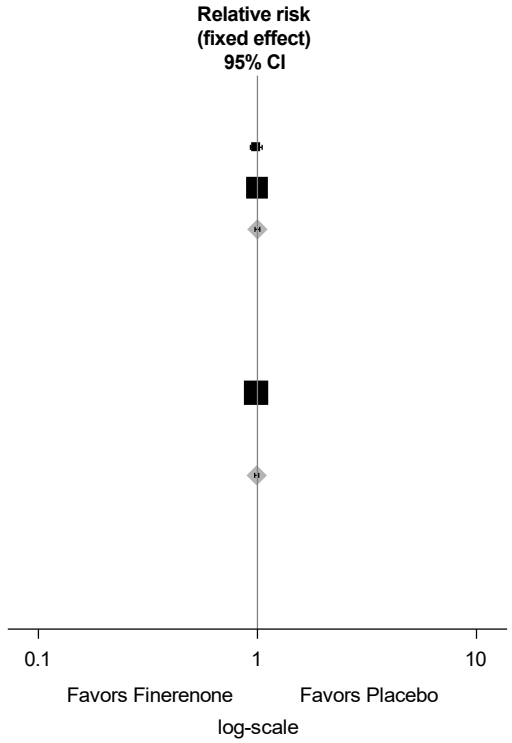
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	954 / 1103	955 / 1075	76.5	0.97 [0.94,1.00]	
FIGARO-DKD	290 / 336	298 / 335	23.5	0.97 [0.92,1.03]	
Total	1244 / 1439	1253 / 1410		0.97 [0.95,1.00]	Z=-1.96, p=0.0500
Heterogeneity:	Q=0.01 (df=1)	p=0.9176	I^2=0.0%		
>= 65					
FIDELIO-DKD	1333 / 1514	1345 / 1535	59.3	1.00 [0.98,1.03]	
FIGARO-DKD	905 / 1021	894 / 1021	40.7	1.01 [0.98,1.05]	
Total	2238 / 2535	2239 / 2556		1.01 [0.99,1.03]	Z=0.75, p=0.4504
Heterogeneity:	Q=0.12 (df=1)	p=0.7256	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.10 (df=1)	p=0.0428	I^2=75.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.1.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

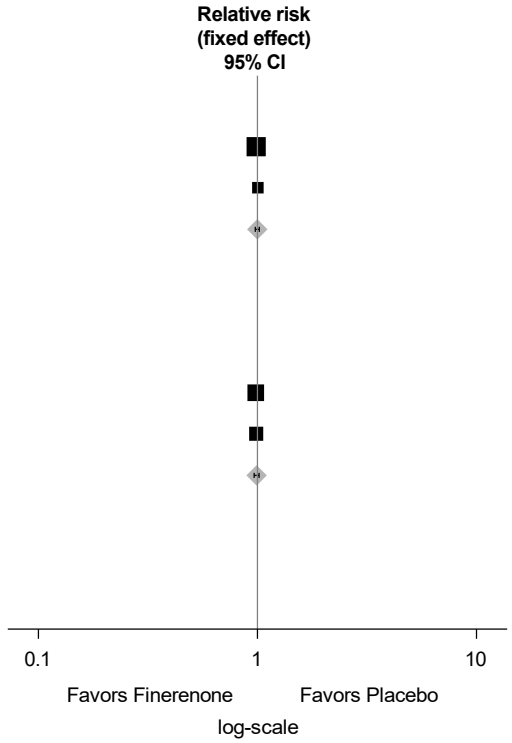
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	188 / 209	194 / 213	16.8	0.99 [0.93,1.05]	
FIGARO-DKD	1195 / 1357	1192 / 1356	83.2	1.00 [0.97,1.03]	
Total	1383 / 1566	1386 / 1569		1.00 [0.97,1.03]	Z=-0.05, p=0.9615
Heterogeneity:	Q=0.17 (df=1)	p=0.6806	I^2=0.0%		
Very High					
FIDELIO-DKD	2099 / 2408	2106 / 2397	100.0	0.99 [0.97,1.01]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	2099 / 2408	2106 / 2397		0.99 [0.97,1.01]	Z=-0.73, p=0.4681
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6668	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.1.9: Forestplot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

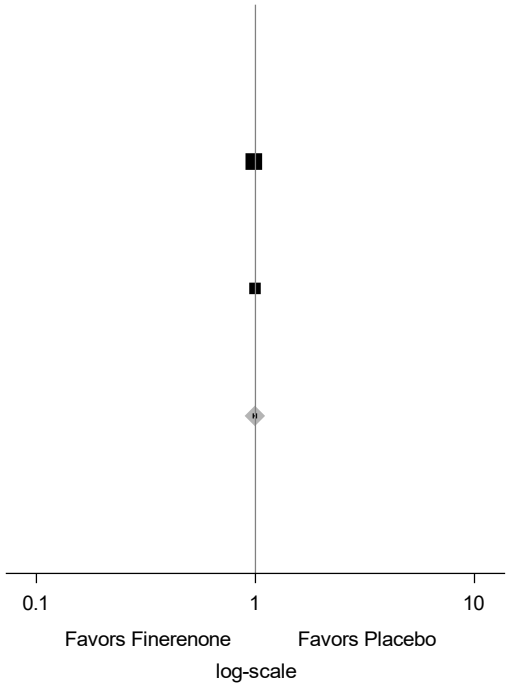
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	1381 / 1556	1377 / 1541	72.1	0.99 [0.97,1.02]	
FIGARO-DKD	567 / 637	552 / 627	27.9	1.01 [0.97,1.05]	
Total	1948 / 2193	1929 / 2168		1.00 [0.98,1.02]	Z=-0.17, p=0.8644
Heterogeneity:	Q=0.56 (df=1)	p=0.4563	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	906 / 1061	923 / 1069	56.0	0.99 [0.96,1.02]	
FIGARO-DKD	628 / 720	640 / 729	44.0	0.99 [0.96,1.03]	
Total	1534 / 1781	1563 / 1798		0.99 [0.97,1.02]	Z=-0.69, p=0.4909
Heterogeneity:	Q=0.03 (df=1)	p=0.8631	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6695	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

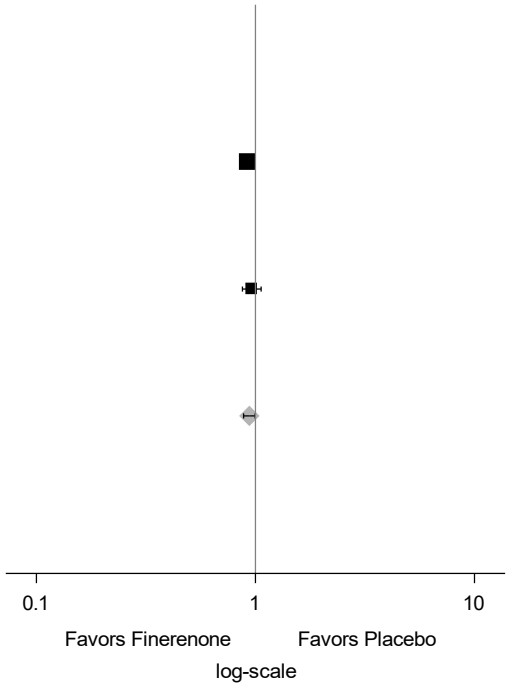
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2263 / 2617	2281 / 2610	65.0	0.99 [0.97,1.01]	
FIGARO-DKD	1186 / 1357	1183 / 1356	35.0	1.00 [0.97,1.03]	
Total	3449 / 3974	3464 / 3966		0.99 [0.98,1.01]	Z=-0.72, p=0.4686
Heterogeneity:	Q=0.47 (df=1)	p=0.4944	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

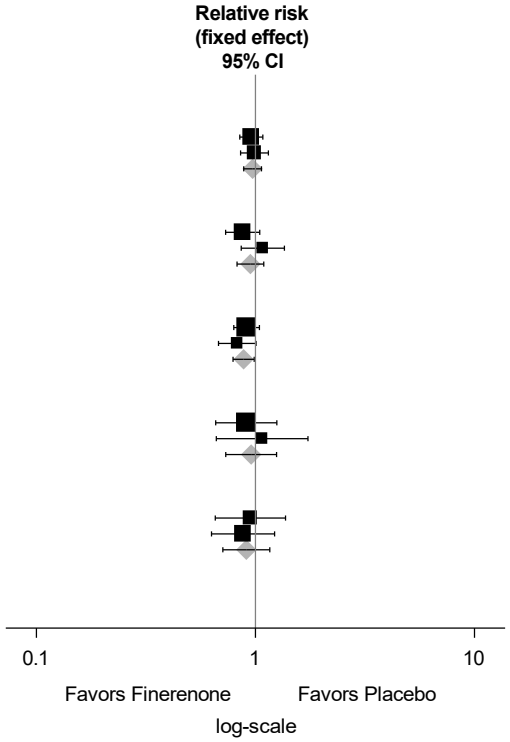
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	837 / 2617	904 / 2610	62.1	0.92 [0.86,1.00]	
FIGARO-DKD	492 / 1357	511 / 1356	37.9	0.96 [0.87,1.06]	
Total	1329 / 3974	1415 / 3966		0.94 [0.88,1.00]	Z=-2.08, p=0.0378
Heterogeneity:	Q=0.42 (df=1)	p=0.5189	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.3.1: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

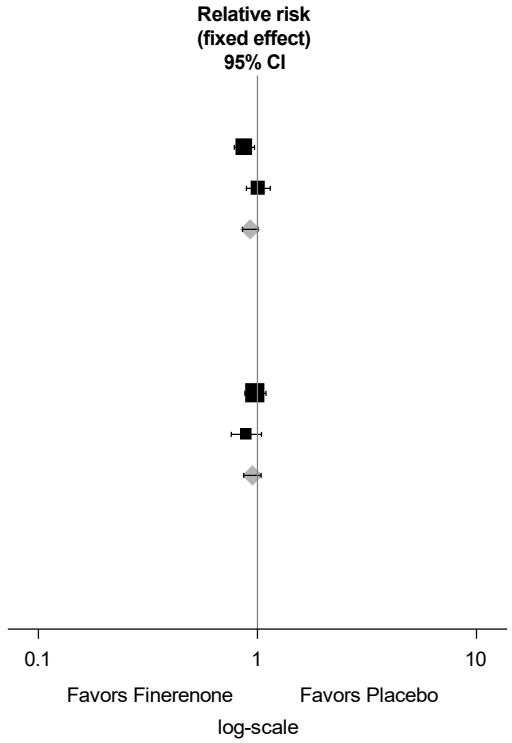
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	346 / 1075	357 / 1062	59.3	0.96 [0.85,1.08]	
FIGARO-DKD	229 / 638	231 / 637	40.7	0.99 [0.86,1.15]	
Total	575 / 1713	588 / 1699		0.97 [0.88,1.07]	Z=-0.63, p=0.5291
Heterogeneity:	Q=0.12 (df=1)	p=0.7317	I^2=0.0%		
North America					
FIDELIO-DKD	142 / 424	167 / 436	61.6	0.87 [0.73,1.05]	
FIGARO-DKD	99 / 267	93 / 271	38.4	1.08 [0.86,1.36]	
Total	241 / 691	260 / 707		0.95 [0.82,1.09]	Z=-0.74, p=0.4580
Heterogeneity:	Q=2.06 (df=1)	p=0.1517	I^2=51.3%		
Asia					
FIDELIO-DKD	259 / 751	282 / 745	68.2	0.91 [0.80,1.04]	
FIGARO-DKD	107 / 289	130 / 290	31.8	0.83 [0.68,1.01]	
Total	366 / 1040	412 / 1035		0.88 [0.79,0.99]	Z=-2.19, p=0.0282
Heterogeneity:	Q=0.65 (df=1)	p=0.4208	I^2=0.0%		
Latin America					
FIDELIO-DKD	56 / 273	61 / 270	69.2	0.91 [0.66,1.25]	
FIGARO-DKD	26 / 102	24 / 101	30.8	1.07 [0.66,1.74]	
Total	82 / 375	85 / 371		0.96 [0.73,1.25]	Z=-0.33, p=0.7401
Heterogeneity:	Q=0.32 (df=1)	p=0.5725	I^2=0.0%		
Others					
FIDELIO-DKD	34 / 94	37 / 97	44.6	0.95 [0.66,1.37]	
FIGARO-DKD	31 / 61	33 / 57	55.4	0.88 [0.63,1.22]	
Total	65 / 155	70 / 154		0.91 [0.71,1.16]	Z=-0.76, p=0.4459
Heterogeneity:	Q=0.09 (df=1)	p=0.7604	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.75 (df=4)	p=0.7816	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.3.2: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

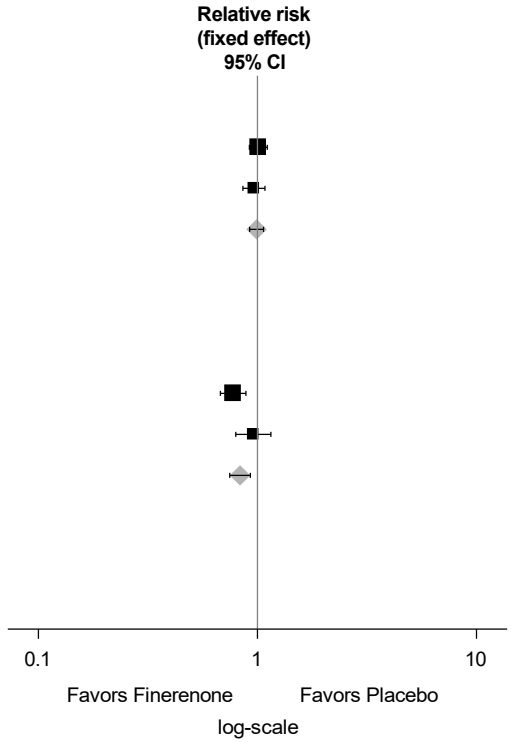
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	410 / 1213	469 / 1210	58.4	0.87 [0.78,0.97]	
FIGARO-DKD	315 / 862	307 / 848	41.6	1.01 [0.89,1.14]	
Total	725 / 2075	776 / 2058		0.93 [0.85,1.00]	Z=-1.85, p=0.0647
Heterogeneity:	Q=3.05 (df=1)	p=0.0807	I^2=67.2%		
Absent					
FIDELIO-DKD	427 / 1404	435 / 1400	67.1	0.98 [0.88,1.09]	
FIGARO-DKD	177 / 495	204 / 508	32.9	0.89 [0.76,1.04]	
Total	604 / 1899	639 / 1908		0.95 [0.87,1.04]	Z=-1.13, p=0.2568
Heterogeneity:	Q=0.92 (df=1)	p=0.3385	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7044	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.3.3: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

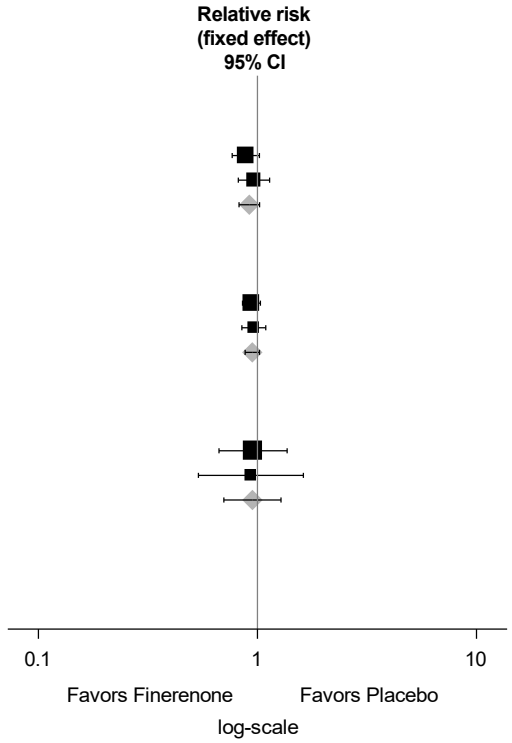
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	584 / 1735	567 / 1700	60.2	1.01 [0.92,1.11]	
FIGARO-DKD	346 / 924	361 / 929	39.8	0.96 [0.86,1.08]	
Total	930 / 2659	928 / 2629		0.99 [0.92,1.07]	Z=-0.25, p=0.8049
Heterogeneity:	Q=0.37 (df=1)	p=0.5445	I^2=0.0%		
> 4.5					
FIDELIO-DKD	253 / 882	337 / 910	65.4	0.77 [0.68,0.89]	
FIGARO-DKD	146 / 433	150 / 426	34.6	0.96 [0.80,1.15]	
Total	399 / 1315	487 / 1336		0.83 [0.75,0.93]	Z=-3.31, p=0.0009
Heterogeneity:	Q=3.32 (df=1)	p=0.0684	I^2=69.9%		
Subgroup Heterogeneity:	Q=6.79 (df=1)	p=0.0092	I^2=85.3%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.3.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

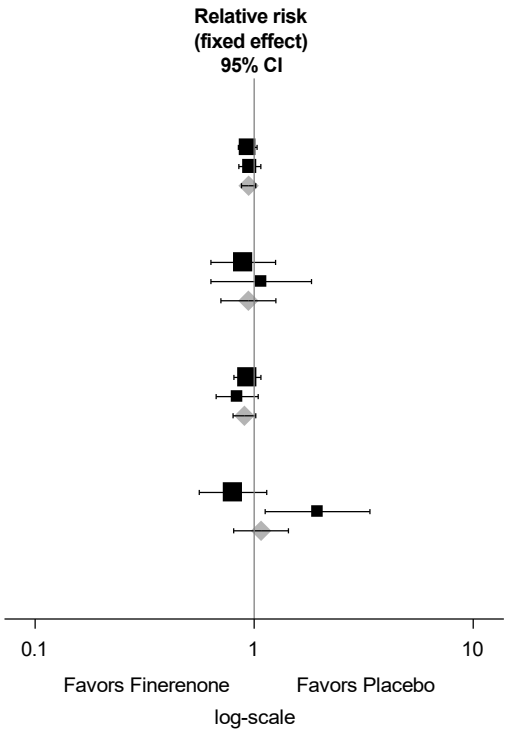
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	233 / 724	263 / 723	56.9	0.88 [0.77,1.02]	
FIGARO-DKD	177 / 494	184 / 495	43.1	0.96 [0.82,1.14]	
Total	410 / 1218	447 / 1218		0.92 [0.82,1.02]	Z=-1.56, p=0.1199
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	563 / 1759	600 / 1760	64.1	0.94 [0.85,1.03]	
FIGARO-DKD	301 / 829	312 / 827	35.9	0.96 [0.85,1.09]	
Total	864 / 2588	912 / 2587		0.95 [0.88,1.02]	Z=-1.41, p=0.1586
Heterogeneity:	Q=0.10 (df=1)	p=0.7571	I^2=0.0%		
>= 160					
FIDELIO-DKD	41 / 133	41 / 127	70.4	0.95 [0.67,1.37]	
FIGARO-DKD	14 / 34	15 / 34	29.6	0.93 [0.54,1.62]	
Total	55 / 167	56 / 161		0.95 [0.70,1.28]	Z=-0.35, p=0.7298
Heterogeneity:	Q=0.00 (df=1)	p=0.9458	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=2)	p=0.8936	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.3.5: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

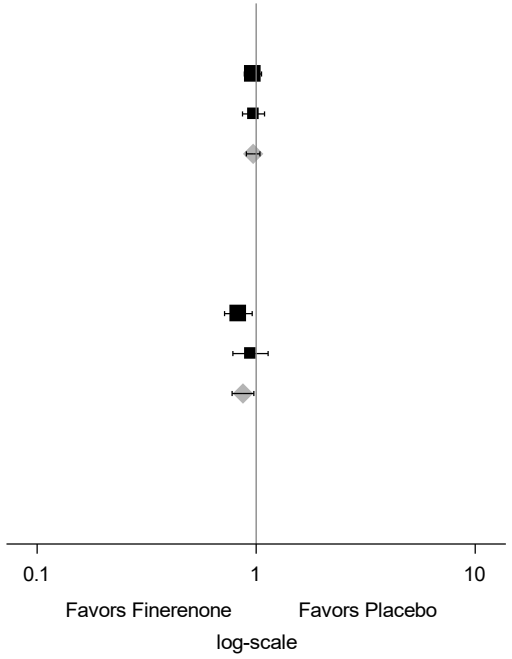
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	516 / 1634	560 / 1657	58.1	0.93 [0.85,1.03]	
FIGARO-DKD	361 / 1010	370 / 989	41.9	0.96 [0.85,1.07]	
Total	877 / 2644	930 / 2646		0.94 [0.88,1.02]	Z=-1.53, p=0.1250
Heterogeneity:	Q=0.08 (df=1)	p=0.7739	I^2=0.0%		
Black					
FIDELIO-DKD	43 / 129	43 / 115	70.8	0.89 [0.63,1.25]	
FIGARO-DKD	15 / 43	23 / 71	29.2	1.08 [0.63,1.83]	
Total	58 / 172	66 / 186		0.94 [0.70,1.26]	Z=-0.41, p=0.6795
Heterogeneity:	Q=0.35 (df=1)	p=0.5558	I^2=0.0%		
Asian					
FIDELIO-DKD	236 / 678	253 / 677	70.8	0.93 [0.81,1.07]	
FIGARO-DKD	89 / 252	106 / 251	29.2	0.84 [0.67,1.04]	
Total	325 / 930	359 / 928		0.90 [0.80,1.02]	Z=-1.69, p=0.0918
Heterogeneity:	Q=0.65 (df=1)	p=0.4213	I^2=0.0%		
Others					
FIDELIO-DKD	42 / 176	48 / 161	70.7	0.80 [0.56,1.14]	
FIGARO-DKD	27 / 52	12 / 45	29.3	1.95 [1.12,3.38]	
Total	69 / 228	60 / 206		1.08 [0.81,1.43]	Z=0.49, p=0.6219
Heterogeneity:	Q=7.13 (df=1)	p=0.0076	I^2=86.0%		
Subgroup Heterogeneity:	Q=1.29 (df=3)	p=0.7323	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.3.6: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

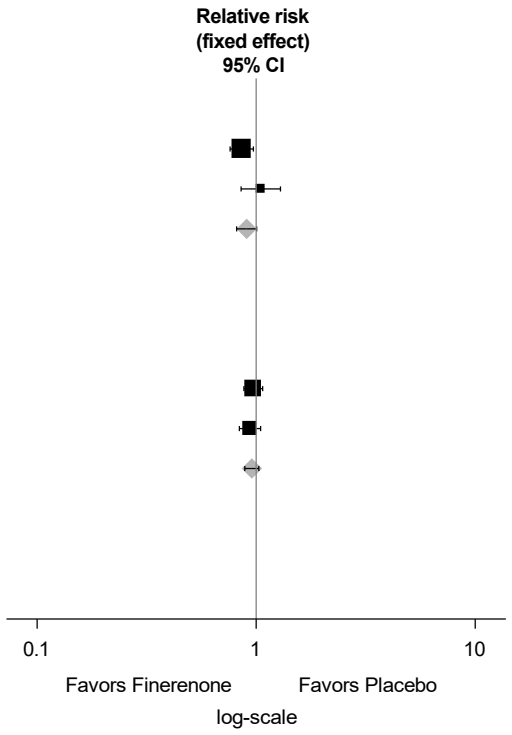
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	599 / 1797	645 / 1870	62.1	0.97 [0.88,1.06]	
FIGARO-DKD	346 / 917	362 / 933	37.9	0.97 [0.87,1.09]	
Total	945 / 2714	1007 / 2803		0.97 [0.90,1.04]	Z=-0.87, p=0.3819
Heterogeneity:	Q=0.01 (df=1)	p=0.9334	I^2=0.0%		
Female					
FIDELIO-DKD	238 / 820	259 / 740	61.9	0.83 [0.72,0.96]	
FIGARO-DKD	146 / 440	149 / 423	38.1	0.94 [0.78,1.13]	
Total	384 / 1260	408 / 1163		0.87 [0.78,0.98]	Z=-2.38, p=0.0173
Heterogeneity:	Q=1.13 (df=1)	p=0.2884	I^2=11.3%		
Subgroup Heterogeneity:	Q=2.42 (df=1)	p=0.1196	I^2=58.7%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.3.7: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

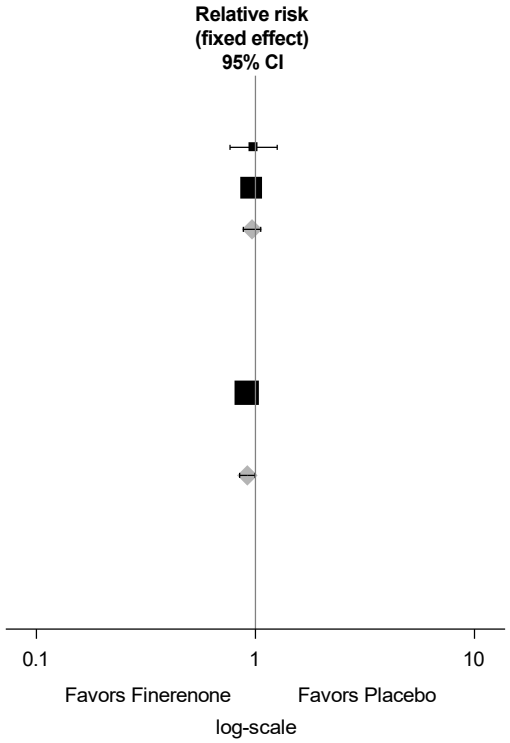
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	328 / 1103	372 / 1075	74.1	0.86 [0.76,0.97]	
FIGARO-DKD	120 / 336	114 / 335	25.9	1.05 [0.85,1.29]	
Total	448 / 1439	486 / 1410		0.90 [0.81,1.01]	Z=-1.86, p=0.0628
Heterogeneity:	Q=2.66 (df=1)	p=0.1031	I^2=62.4%		
>= 65					
FIDELIO-DKD	509 / 1514	532 / 1535	56.2	0.97 [0.88,1.07]	
FIGARO-DKD	372 / 1021	397 / 1021	43.8	0.94 [0.84,1.05]	
Total	881 / 2535	929 / 2556		0.96 [0.89,1.03]	Z=-1.21, p=0.2268
Heterogeneity:	Q=0.21 (df=1)	p=0.6488	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.69 (df=1)	p=0.4076	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.3.8: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

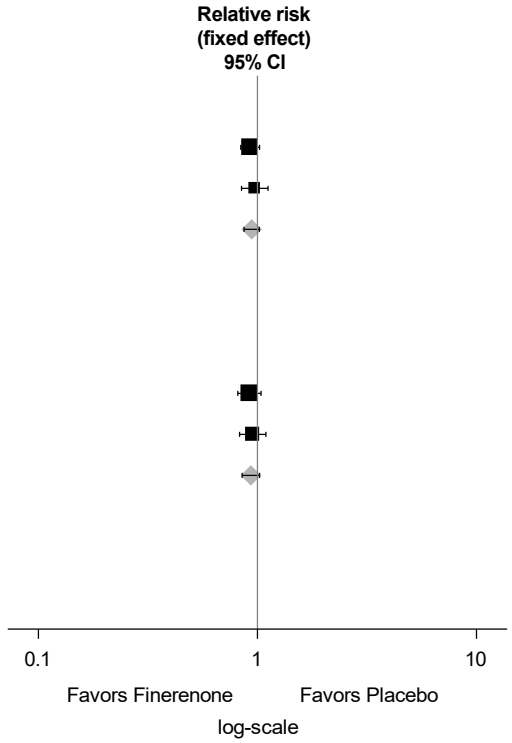
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 209	80 / 213	13.6	0.98 [0.77,1.26]	
FIGARO-DKD	492 / 1357	511 / 1356	86.4	0.96 [0.87,1.06]	
Total	569 / 1566	591 / 1569		0.96 [0.88,1.06]	Z=-0.77, p=0.4400
Heterogeneity:	Q=0.02 (df=1)	p=0.8869	I^2=0.0%		
Very High					
FIDELIO-DKD	760 / 2408	824 / 2397	100.0	0.92 [0.85,1.00]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	760 / 2408	824 / 2397		0.92 [0.85,1.00]	Z=-2.07, p=0.0381
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=1)	p=0.4269	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.3.9: Forestplot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

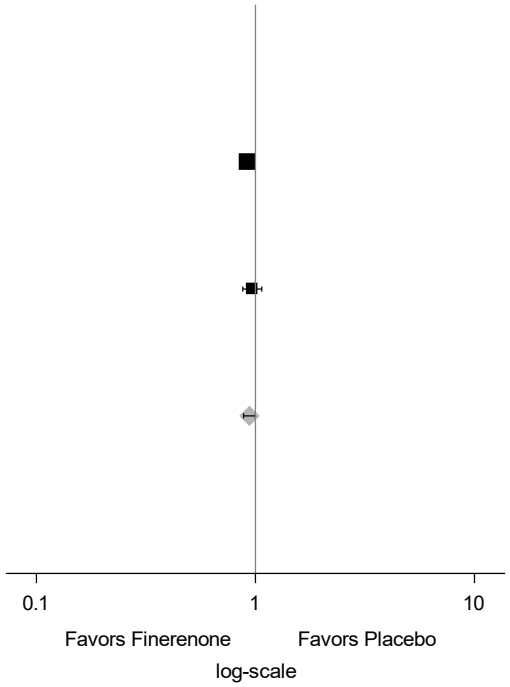
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	505 / 1556	540 / 1541	66.5	0.93 [0.84,1.02]	
FIGARO-DKD	242 / 637	245 / 627	33.5	0.97 [0.85,1.12]	
Total	747 / 2193	785 / 2168		0.94 [0.87,1.02]	Z=-1.47, p=0.1414
Heterogeneity:	Q=0.31 (df=1)	p=0.5773	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	332 / 1061	364 / 1069	56.3	0.92 [0.81,1.04]	
FIGARO-DKD	250 / 720	266 / 729	43.7	0.95 [0.83,1.09]	
Total	582 / 1781	630 / 1798		0.93 [0.85,1.02]	Z=-1.48, p=0.1384
Heterogeneity:	Q=0.14 (df=1)	p=0.7112	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8874	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.4: Forestplot for Relative Risk of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

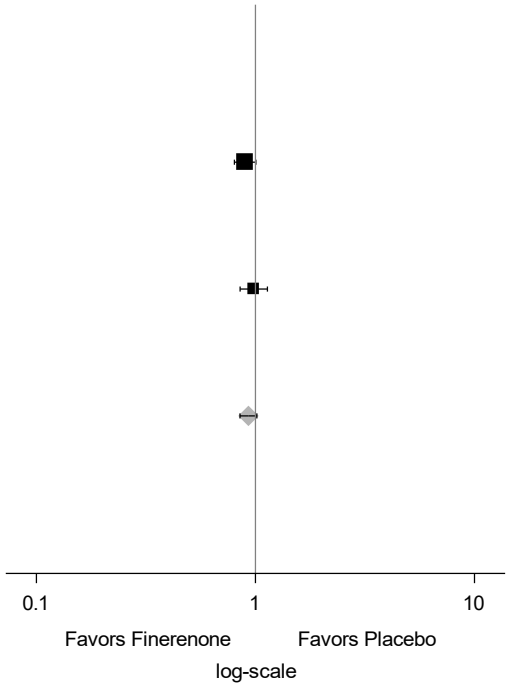
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	814 / 2617	881 / 2610	61.9	0.92 [0.85,1.00]	
FIGARO-DKD	484 / 1357	500 / 1356	38.1	0.97 [0.88,1.07]	
Total	1298 / 3974	1381 / 3966		0.94 [0.88,1.00]	Z=-2.01, p=0.0441
Heterogeneity:	Q=0.56 (df=1)	p=0.4536	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

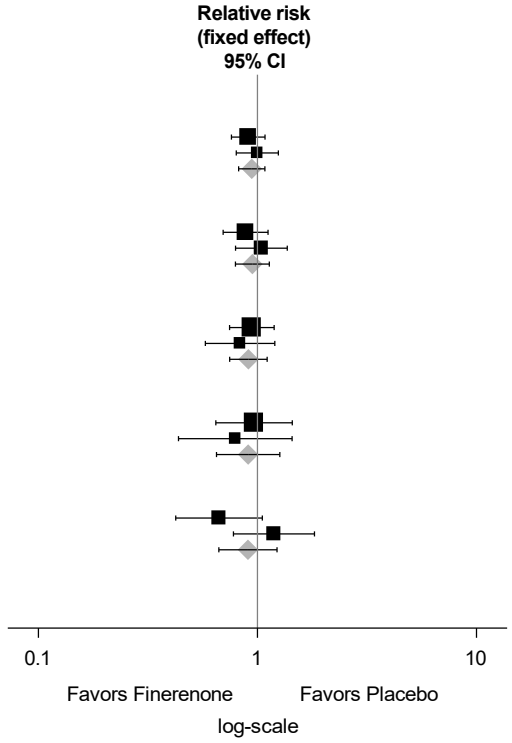
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	466 / 2617	518 / 2610	61.8	0.90 [0.80,1.00]	
FIGARO-DKD	290 / 1357	295 / 1356	38.2	0.98 [0.85,1.13]	
Total	756 / 3974	813 / 3966		0.93 [0.85,1.01]	Z=-1.63, p=0.1023
Heterogeneity:	Q=0.95 (df=1)	p=0.3305	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.5.1: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

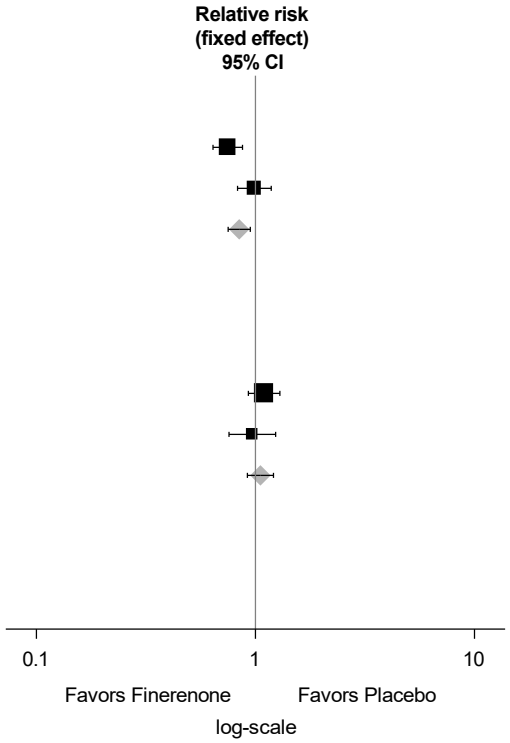
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	192 / 1075	209 / 1062	61.1	0.91 [0.76,1.08]	
FIGARO-DKD	126 / 638	126 / 637	38.9	1.00 [0.80,1.25]	
Total	318 / 1713	335 / 1699		0.94 [0.82,1.08]	Z=-0.85, p=0.3950
Heterogeneity:	Q=0.44 (df=1)	p=0.5087	I^2=0.0%		
North America					
FIDELIO-DKD	97 / 424	113 / 436	57.0	0.88 [0.70,1.12]	
FIGARO-DKD	76 / 267	74 / 271	43.0	1.04 [0.79,1.37]	
Total	173 / 691	187 / 707		0.95 [0.79,1.13]	Z=-0.59, p=0.5562
Heterogeneity:	Q=0.82 (df=1)	p=0.3653	I^2=0.0%		
Asia					
FIDELIO-DKD	115 / 751	121 / 745	70.8	0.94 [0.75,1.19]	
FIGARO-DKD	44 / 289	53 / 290	29.2	0.83 [0.58,1.20]	
Total	159 / 1040	174 / 1035		0.91 [0.75,1.11]	Z=-0.95, p=0.3440
Heterogeneity:	Q=0.31 (df=1)	p=0.5760	I^2=0.0%		
Latin America					
FIDELIO-DKD	40 / 273	41 / 270	68.8	0.96 [0.65,1.44]	
FIGARO-DKD	16 / 102	20 / 101	31.2	0.79 [0.44,1.44]	
Total	56 / 375	61 / 371		0.91 [0.65,1.27]	Z=-0.57, p=0.5654
Heterogeneity:	Q=0.29 (df=1)	p=0.5911	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 94	34 / 97	46.7	0.67 [0.42,1.05]	
FIGARO-DKD	28 / 61	22 / 57	53.3	1.19 [0.78,1.82]	
Total	50 / 155	56 / 154		0.90 [0.67,1.23]	Z=-0.64, p=0.5214
Heterogeneity:	Q=3.29 (df=1)	p=0.0695	I^2=69.6%		
Subgroup Heterogeneity:	Q=0.18 (df=4)	p=0.9962	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.5.2: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

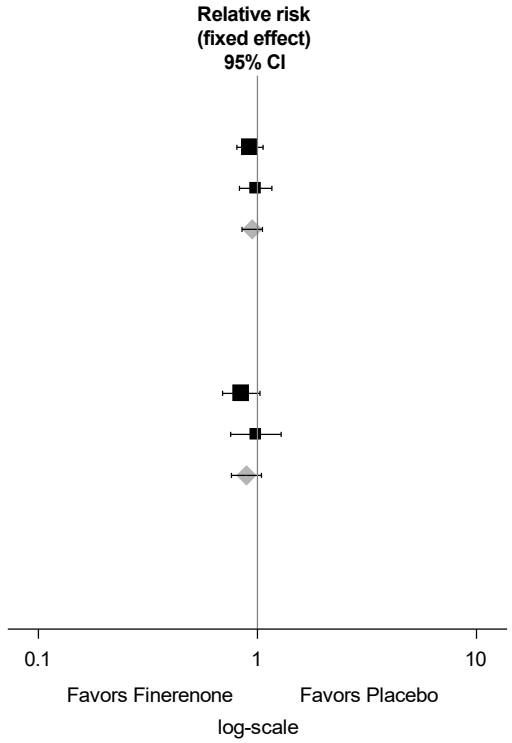
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	221 / 1213	295 / 1210	56.6	0.75 [0.64,0.87]	
FIGARO-DKD	191 / 862	190 / 848	43.4	0.99 [0.83,1.18]	
Total	412 / 2075	485 / 2058		0.84 [0.75,0.95]	Z=-2.88, p=0.0040
Heterogeneity:	Q=5.44 (df=1)	p=0.0197	I^2=81.6%		
Absent					
FIDELIO-DKD	245 / 1404	223 / 1400	68.7	1.10 [0.93,1.29]	
FIGARO-DKD	99 / 495	105 / 508	31.3	0.97 [0.76,1.24]	
Total	344 / 1899	328 / 1908		1.05 [0.92,1.21]	Z=0.75, p=0.4545
Heterogeneity:	Q=0.68 (df=1)	p=0.4107	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.91 (df=1)	p=0.0151	I^2=83.1%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.5.3: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

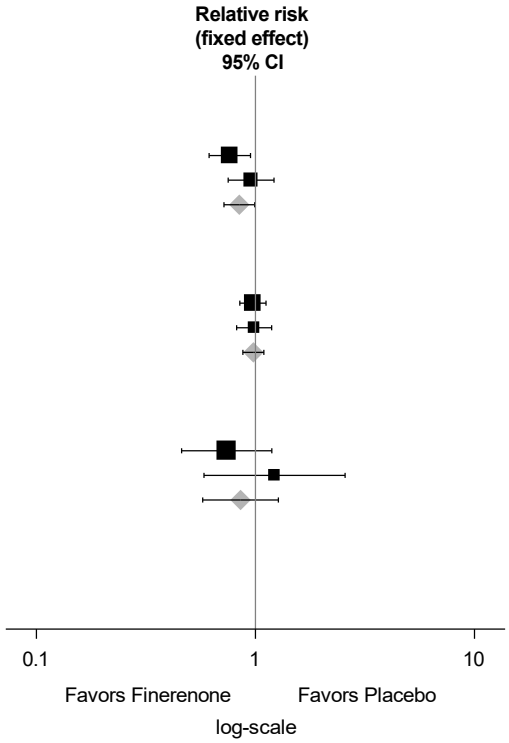
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	318 / 1735	337 / 1700	60.5	0.92 [0.81,1.06]	
FIGARO-DKD	203 / 924	208 / 929	39.5	0.98 [0.83,1.16]	
Total	521 / 2659	545 / 2629		0.95 [0.85,1.05]	Z=-1.00, p=0.3154
Heterogeneity:	Q=0.28 (df=1)	p=0.5951	I^2=0.0%		
> 4.5					
FIDELIO-DKD	148 / 882	181 / 910	64.6	0.84 [0.69,1.03]	
FIGARO-DKD	87 / 433	87 / 426	35.4	0.98 [0.75,1.28]	
Total	235 / 1315	268 / 1336		0.89 [0.76,1.04]	Z=-1.44, p=0.1501
Heterogeneity:	Q=0.83 (df=1)	p=0.3615	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.39 (df=1)	p=0.5317	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.5.4: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

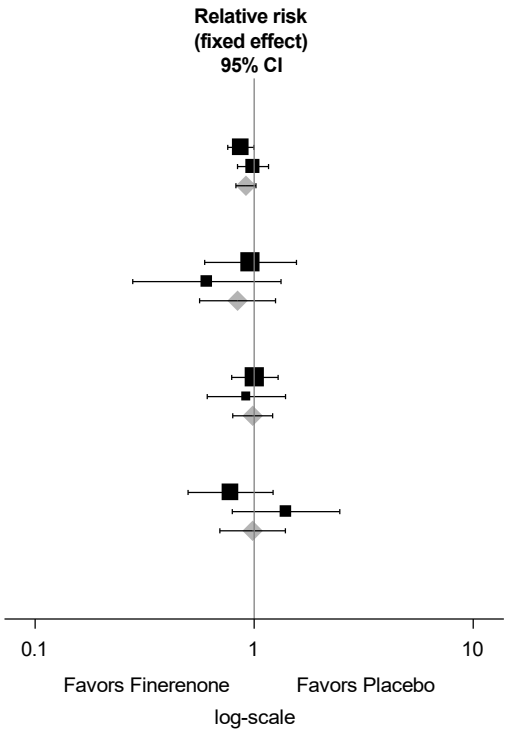
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	117 / 724	153 / 723	55.1	0.76 [0.61,0.95]	
FIGARO-DKD	102 / 494	107 / 495	44.9	0.96 [0.75,1.22]	
Total	219 / 1218	260 / 1218		0.84 [0.72,0.99]	Z=-2.07, p=0.0389
Heterogeneity:	Q=1.83 (df=1)	p=0.1765	I^2=45.3%		
130 - < 160					
FIDELIO-DKD	325 / 1759	334 / 1760	64.1	0.97 [0.85,1.12]	
FIGARO-DKD	177 / 829	179 / 827	35.9	0.99 [0.82,1.19]	
Total	502 / 2588	513 / 2587		0.98 [0.88,1.09]	Z=-0.39, p=0.6951
Heterogeneity:	Q=0.01 (df=1)	p=0.9111	I^2=0.0%		
>= 160					
FIDELIO-DKD	24 / 133	31 / 127	71.0	0.74 [0.46,1.19]	
FIGARO-DKD	11 / 34	9 / 34	29.0	1.22 [0.58,2.57]	
Total	35 / 167	40 / 161		0.85 [0.57,1.27]	Z=-0.77, p=0.4399
Heterogeneity:	Q=1.25 (df=1)	p=0.2630	I^2=20.2%		
Subgroup Heterogeneity:	Q=2.38 (df=2)	p=0.3046	I^2=15.9%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.5.5: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

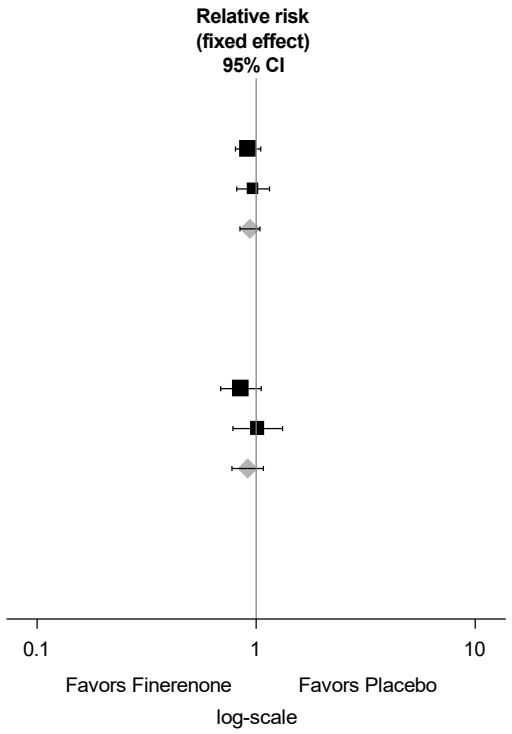
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	301 / 1634	351 / 1657	58.3	0.87 [0.76,1.00]	
FIGARO-DKD	225 / 1010	223 / 989	41.7	0.99 [0.84,1.16]	
Total	526 / 2644	574 / 2646		0.92 [0.83,1.02]	Z=-1.61, p=0.1069
Heterogeneity:	Q=1.37 (df=1)	p=0.2417	I^2=27.0%		
Black					
FIDELIO-DKD	27 / 129	25 / 115	72.3	0.96 [0.59,1.56]	
FIGARO-DKD	7 / 43	19 / 71	27.7	0.61 [0.28,1.33]	
Total	34 / 172	44 / 186		0.84 [0.56,1.25]	Z=-0.86, p=0.3914
Heterogeneity:	Q=0.97 (df=1)	p=0.3257	I^2=0.0%		
Asian					
FIDELIO-DKD	109 / 678	108 / 677	74.0	1.01 [0.79,1.29]	
FIGARO-DKD	37 / 252	40 / 251	26.0	0.92 [0.61,1.39]	
Total	146 / 930	148 / 928		0.98 [0.80,1.21]	Z=-0.15, p=0.8842
Heterogeneity:	Q=0.14 (df=1)	p=0.7133	I^2=0.0%		
Others					
FIDELIO-DKD	29 / 176	34 / 161	61.5	0.78 [0.50,1.22]	
FIGARO-DKD	21 / 52	13 / 45	38.5	1.40 [0.79,2.46]	
Total	50 / 228	47 / 206		0.98 [0.70,1.39]	Z=-0.09, p=0.9258
Heterogeneity:	Q=2.52 (df=1)	p=0.1125	I^2=60.3%		
Subgroup Heterogeneity:	Q=0.70 (df=3)	p=0.8722	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.5.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

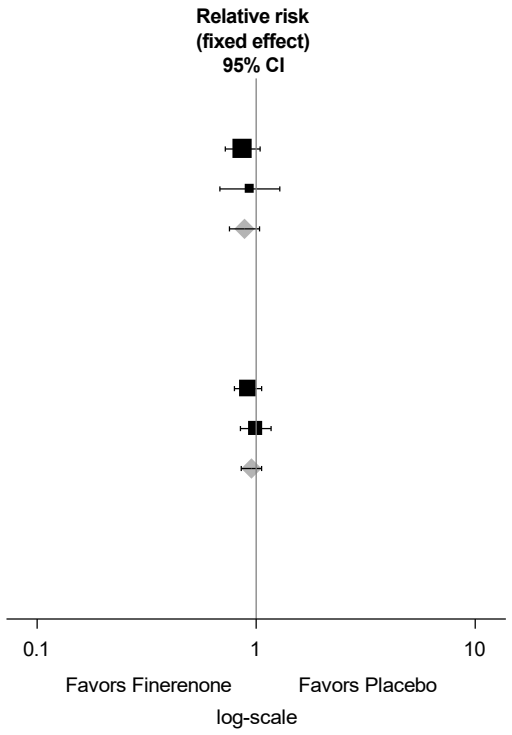
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	331 / 1797	375 / 1870	62.6	0.92 [0.80,1.05]	
FIGARO-DKD	198 / 917	208 / 933	37.4	0.97 [0.82,1.15]	
Total	529 / 2714	583 / 2803		0.94 [0.84,1.04]	Z=-1.22, p=0.2242
Heterogeneity:	Q=0.23 (df=1)	p=0.6325	I^2=0.0%		
Female					
FIDELIO-DKD	135 / 820	143 / 740	60.0	0.85 [0.69,1.05]	
FIGARO-DKD	92 / 440	87 / 423	40.0	1.02 [0.78,1.32]	
Total	227 / 1260	230 / 1163		0.91 [0.78,1.08]	Z=-1.06, p=0.2878
Heterogeneity:	Q=1.06 (df=1)	p=0.3040	I^2=5.3%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8075	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.5.7: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

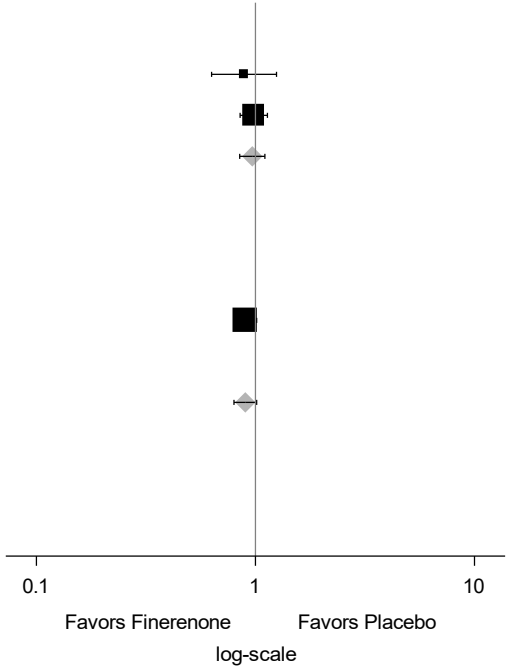
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	179 / 1103	201 / 1075	74.7	0.87 [0.72,1.04]	
FIGARO-DKD	61 / 336	65 / 335	25.3	0.94 [0.68,1.28]	
Total	240 / 1439	266 / 1410		0.88 [0.76,1.04]	Z=-1.52, p=0.1287
Heterogeneity:	Q=0.16 (df=1)	p=0.6860	I^2=0.0%		
>= 65					
FIDELIO-DKD	287 / 1514	317 / 1535	55.9	0.92 [0.80,1.06]	
FIGARO-DKD	229 / 1021	230 / 1021	44.1	1.00 [0.85,1.17]	
Total	516 / 2535	547 / 2556		0.95 [0.85,1.06]	Z=-0.91, p=0.3610
Heterogeneity:	Q=0.55 (df=1)	p=0.4596	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=1)	p=0.4547	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.5.8: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

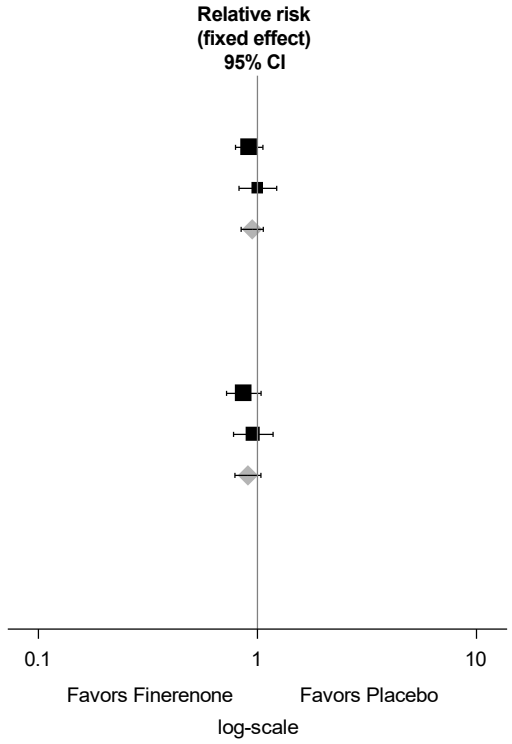
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	54 / 213	15.0	0.89 [0.63,1.25]	
FIGARO-DKD	290 / 1357	295 / 1356	85.0	0.98 [0.85,1.13]	
Total	337 / 1566	349 / 1569		0.97 [0.85,1.10]	Z=-0.49, p=0.6225
Heterogeneity:	Q=0.29 (df=1)	p=0.5890	I^2=0.0%		
Very High					
FIDELIO-DKD	419 / 2408	464 / 2397	100.0	0.90 [0.80,1.01]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	419 / 2408	464 / 2397		0.90 [0.80,1.01]	Z=-1.75, p=0.0801
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4196	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.5.9: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

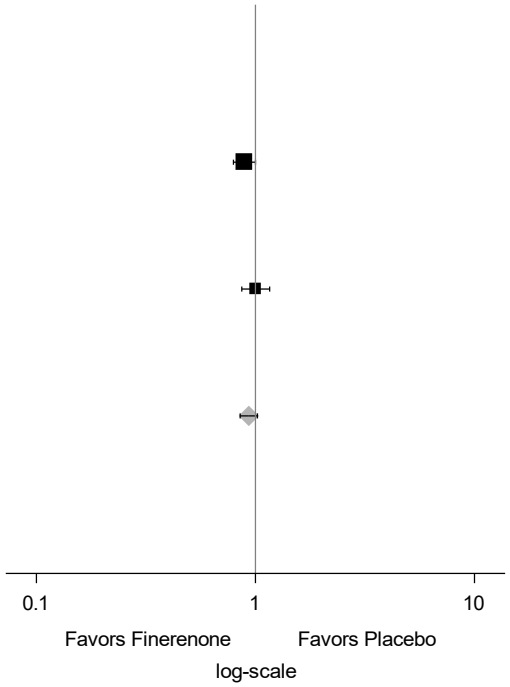
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	288 / 1556	311 / 1541	65.4	0.92 [0.79,1.06]	
FIGARO-DKD	151 / 637	148 / 627	34.6	1.00 [0.82,1.22]	
Total	439 / 2193	459 / 2168		0.95 [0.84,1.06]	Z=-0.93, p=0.3531
Heterogeneity:	Q=0.53 (df=1)	p=0.4676	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	178 / 1061	207 / 1069	56.7	0.87 [0.72,1.04]	
FIGARO-DKD	139 / 720	147 / 729	43.3	0.96 [0.78,1.18]	
Total	317 / 1781	354 / 1798		0.90 [0.79,1.04]	Z=-1.44, p=0.1502
Heterogeneity:	Q=0.50 (df=1)	p=0.4779	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6222	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.6: Forestplot for Relative Risk of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

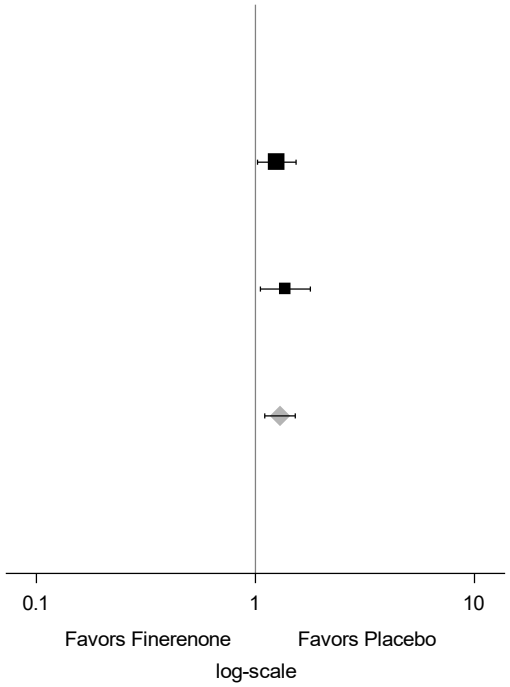
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	444 / 2617	497 / 2610	61.5	0.89 [0.79,1.00]	
FIGARO-DKD	284 / 1357	283 / 1356	38.5	1.00 [0.87,1.16]	
Total	728 / 3974	780 / 3966		0.93 [0.85,1.02]	Z=-1.51, p=0.1313
Heterogeneity:	Q=1.54 (df=1)	p=0.2147	I^2=35.1%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

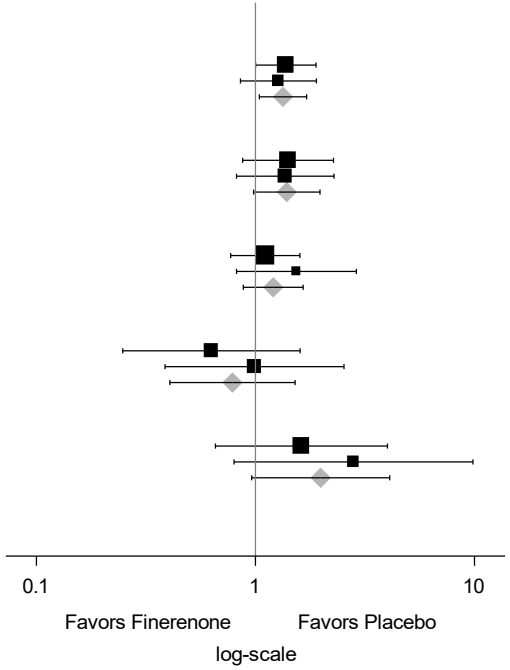
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	197 / 2617	157 / 2610	62.7	1.25 [1.02,1.53]	
FIGARO-DKD	122 / 1357	89 / 1356	37.3	1.37 [1.05,1.78]	
Total	319 / 3974	246 / 3966		1.29 [1.10,1.52]	Z=3.16, p=0.0016
Heterogeneity:	Q=0.29 (df=1)	p=0.5933	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.7.1: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

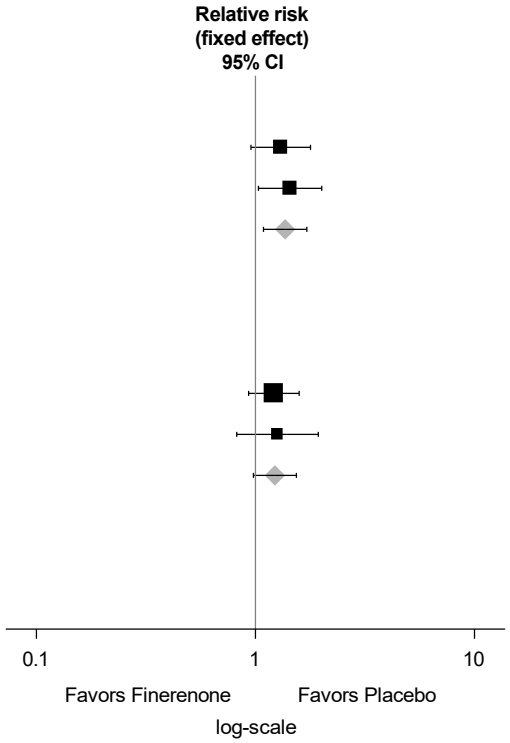
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	85 / 1075	61 / 1062	61.2	1.38 [1.00,1.89]	
FIGARO-DKD	51 / 638	40 / 637	38.8	1.27 [0.85,1.90]	
Total	136 / 1713	101 / 1699		1.34 [1.04,1.71]	Z=2.28, p=0.0225
Heterogeneity:	Q=0.09 (df=1)	p=0.7638	I^2=0.0%		
North America					
FIDELIO-DKD	37 / 424	27 / 436	53.5	1.41 [0.87,2.27]	
FIGARO-DKD	31 / 267	23 / 271	46.5	1.37 [0.82,2.28]	
Total	68 / 691	50 / 707		1.39 [0.98,1.97]	Z=1.85, p=0.0648
Heterogeneity:	Q=0.01 (df=1)	p=0.9339	I^2=0.0%		
Asia					
FIDELIO-DKD	57 / 751	51 / 745	75.0	1.11 [0.77,1.60]	
FIGARO-DKD	23 / 289	15 / 290	25.0	1.54 [0.82,2.89]	
Total	80 / 1040	66 / 1035		1.21 [0.88,1.65]	Z=1.17, p=0.2438
Heterogeneity:	Q=0.78 (df=1)	p=0.3772	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 273	11 / 270	50.4	0.63 [0.25,1.60]	
FIGARO-DKD	8 / 102	8 / 101	49.6	0.99 [0.39,2.54]	
Total	15 / 375	19 / 371		0.79 [0.41,1.52]	Z=-0.72, p=0.4721
Heterogeneity:	Q=0.45 (df=1)	p=0.5024	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 94	7 / 97	65.9	1.62 [0.66,4.01]	
FIGARO-DKD	9 / 61	3 / 57	34.1	2.80 [0.80,9.84]	
Total	20 / 155	10 / 154		1.99 [0.96,4.10]	Z=1.85, p=0.0639
Heterogeneity:	Q=0.48 (df=1)	p=0.4873	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.96 (df=4)	p=0.4108	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.7.2: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

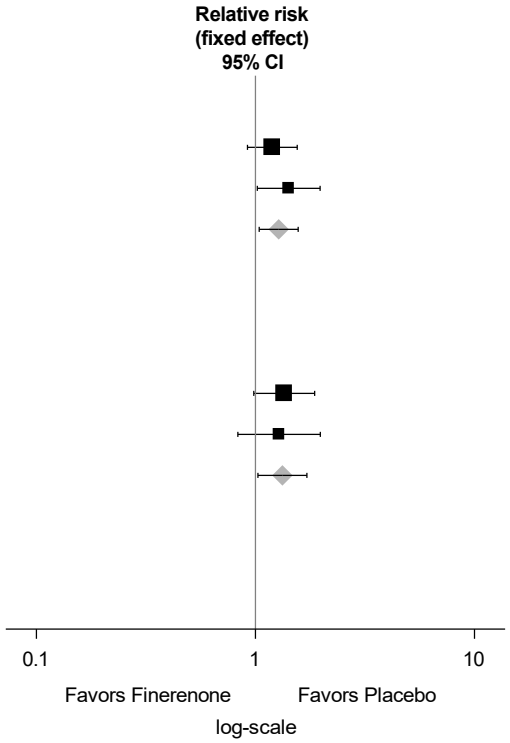
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	85 / 1213	65 / 1210	53.1	1.30 [0.95,1.78]	
FIGARO-DKD	79 / 862	54 / 848	46.9	1.44 [1.03,2.01]	
Total	164 / 2075	119 / 2058		1.37 [1.09,1.72]	Z=2.68, p=0.0073
Heterogeneity:	Q=0.18 (df=1)	p=0.6732	I^2=0.0%		
Absent					
FIDELIO-DKD	112 / 1404	92 / 1400	72.3	1.21 [0.93,1.58]	
FIGARO-DKD	43 / 495	35 / 508	27.7	1.26 [0.82,1.94]	
Total	155 / 1899	127 / 1908		1.23 [0.98,1.54]	Z=1.77, p=0.0761
Heterogeneity:	Q=0.02 (df=1)	p=0.8828	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5104	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.7.3: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

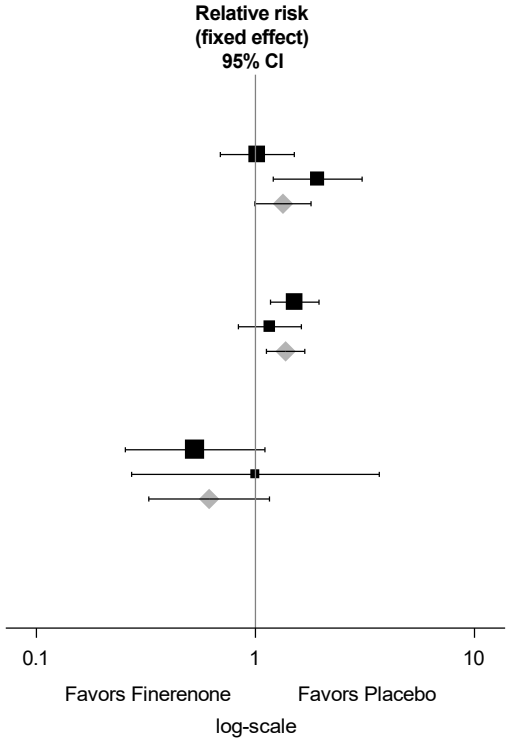
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	117 / 1735	96 / 1700	61.4	1.19 [0.92,1.55]	
FIGARO-DKD	79 / 924	56 / 929	38.6	1.42 [1.02,1.97]	
Total	196 / 2659	152 / 2629		1.28 [1.04,1.57]	Z=2.34, p=0.0194
Heterogeneity:	Q=0.64 (df=1)	p=0.4232	I^2=0.0%		
> 4.5					
FIDELIO-DKD	80 / 882	61 / 910	64.7	1.35 [0.98,1.86]	
FIGARO-DKD	43 / 433	33 / 426	35.3	1.28 [0.83,1.98]	
Total	123 / 1315	94 / 1336		1.33 [1.03,1.72]	Z=2.16, p=0.0310
Heterogeneity:	Q=0.04 (df=1)	p=0.8442	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8160	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.7.4: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

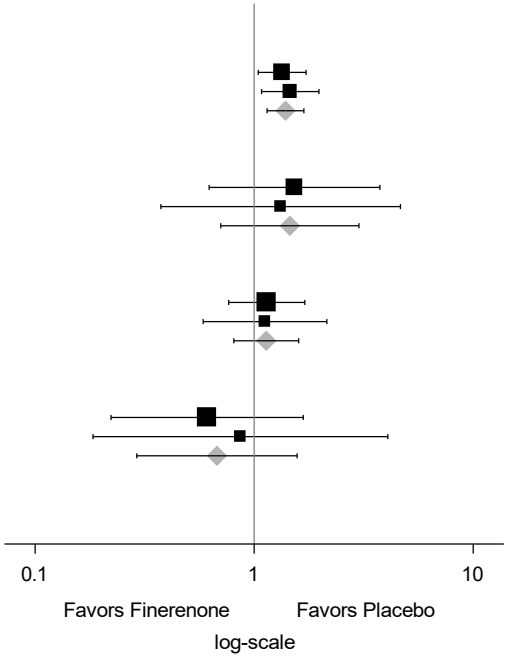
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	48 / 724	47 / 723	59.1	1.02 [0.69,1.50]	
FIGARO-DKD	48 / 494	25 / 495	40.9	1.92 [1.21,3.07]	
Total	96 / 1218	72 / 1218		1.34 [0.99,1.79]	Z=1.92, p=0.0548
Heterogeneity:	Q=4.19 (df=1)	p=0.0406	I^2=76.2%		
130 - < 160					
FIDELIO-DKD	139 / 1759	92 / 1760	62.8	1.51 [1.17,1.95]	
FIGARO-DKD	70 / 829	60 / 827	37.2	1.16 [0.84,1.62]	
Total	209 / 2588	152 / 2587		1.37 [1.12,1.68]	Z=3.08, p=0.0021
Heterogeneity:	Q=1.50 (df=1)	p=0.2200	I^2=33.5%		
>= 160					
FIDELIO-DKD	10 / 133	18 / 127	75.9	0.53 [0.25,1.10]	
FIGARO-DKD	4 / 34	4 / 34	24.1	1.00 [0.27,3.68]	
Total	14 / 167	22 / 161		0.61 [0.33,1.16]	Z=-1.50, p=0.1324
Heterogeneity:	Q=0.69 (df=1)	p=0.4056	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.67 (df=2)	p=0.0587	I^2=64.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.7.5: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

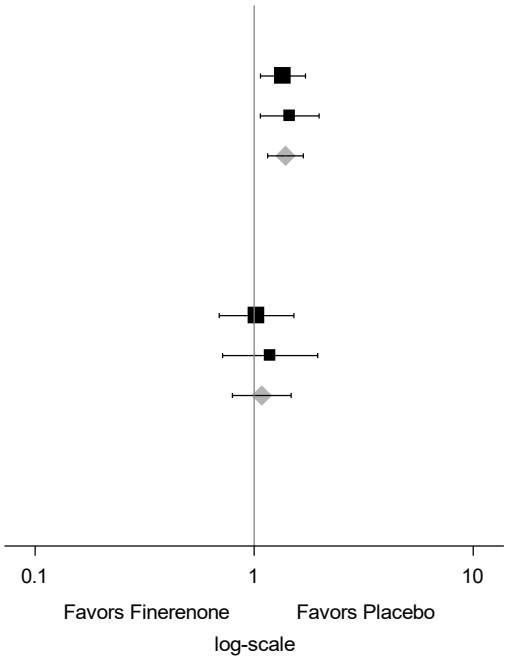
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	131 / 1634	99 / 1657	58.9	1.34 [1.04,1.73]	
FIGARO-DKD	97 / 1010	65 / 989	41.1	1.46 [1.08,1.98]	
Total	228 / 2644	164 / 2646		1.39 [1.15,1.69]	Z=3.34, p=0.0008
Heterogeneity:	Q=0.18 (df=1)	p=0.6707	I^2=0.0%		
Black					
FIDELIO-DKD	12 / 129	7 / 115	66.3	1.53 [0.62,3.75]	
FIGARO-DKD	4 / 43	5 / 71	33.7	1.32 [0.38,4.65]	
Total	16 / 172	12 / 186		1.46 [0.70,3.01]	Z=1.01, p=0.3115
Heterogeneity:	Q=0.03 (df=1)	p=0.8534	I^2=0.0%		
Asian					
FIDELIO-DKD	48 / 678	42 / 677	72.5	1.14 [0.76,1.70]	
FIGARO-DKD	18 / 252	16 / 251	27.5	1.12 [0.58,2.15]	
Total	66 / 930	58 / 928		1.14 [0.81,1.60]	Z=0.73, p=0.4650
Heterogeneity:	Q=0.00 (df=1)	p=0.9626	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 176	9 / 161	70.2	0.61 [0.22,1.68]	
FIGARO-DKD	3 / 52	3 / 45	29.8	0.87 [0.18,4.08]	
Total	9 / 228	12 / 206		0.68 [0.29,1.57]	Z=-0.91, p=0.3629
Heterogeneity:	Q=0.14 (df=1)	p=0.7108	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.47 (df=3)	p=0.3250	I^2=13.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.7.6: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

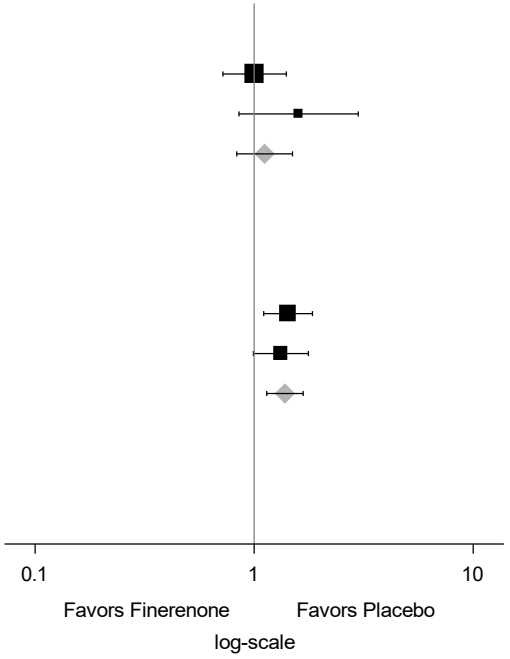
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	147 / 1797	113 / 1870	63.0	1.35 [1.07,1.71]	
FIGARO-DKD	90 / 917	63 / 933	37.0	1.45 [1.07,1.98]	
Total	237 / 2714	176 / 2803		1.39 [1.15,1.68]	Z=3.44, p=0.0006
Heterogeneity:	Q=0.13 (df=1)	p=0.7201	I^2=0.0%		
Female					
FIDELIO-DKD	50 / 820	44 / 740	61.8	1.03 [0.69,1.52]	
FIGARO-DKD	32 / 440	26 / 423	38.2	1.18 [0.72,1.95]	
Total	82 / 1260	70 / 1163		1.08 [0.80,1.48]	Z=0.51, p=0.6117
Heterogeneity:	Q=0.19 (df=1)	p=0.6592	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1764	I^2=45.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.7.7: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

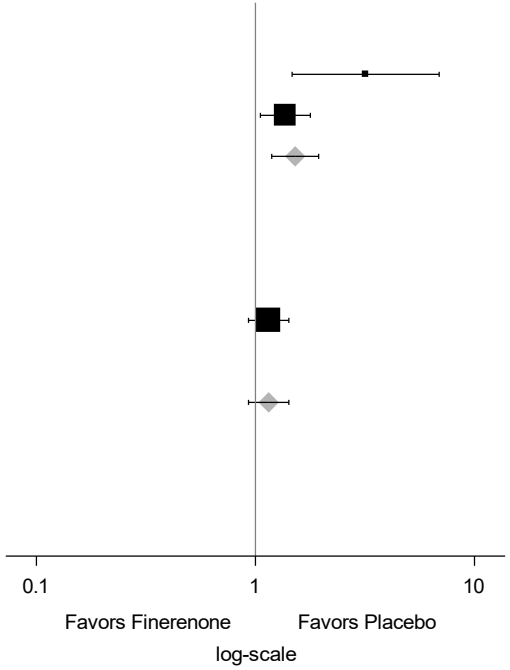
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	66 / 1103	64 / 1075	78.0	1.01 [0.72,1.40]	
FIGARO-DKD	24 / 336	15 / 335	22.0	1.60 [0.85,2.99]	
Total	90 / 1439	79 / 1410		1.12 [0.83,1.50]	Z=0.73, p=0.4630
Heterogeneity:	Q=1.63 (df=1)	p=0.2023	I^2=38.5%		
>= 65					
FIDELIO-DKD	131 / 1514	93 / 1535	56.0	1.43 [1.11,1.84]	
FIGARO-DKD	98 / 1021	74 / 1021	44.0	1.32 [0.99,1.77]	
Total	229 / 2535	167 / 2556		1.38 [1.14,1.67]	Z=3.31, p=0.0009
Heterogeneity:	Q=0.15 (df=1)	p=0.7017	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.43 (df=1)	p=0.2321	I^2=30.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.7.8: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

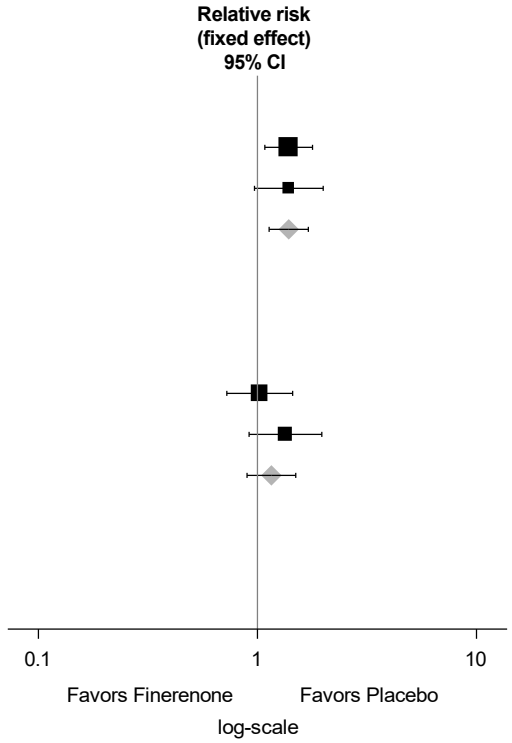
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	25 / 209	8 / 213	10.4	3.18 [1.47,6.90]	
FIGARO-DKD	122 / 1357	89 / 1356	89.6	1.37 [1.05,1.78]	
Total	147 / 1566	97 / 1569		1.52 [1.19,1.94]	Z=3.32, p=0.0009
Heterogeneity:	Q=4.12 (df=1)	p=0.0424	I^2=75.7%		
Very High					
FIDELIO-DKD	172 / 2408	149 / 2397	100.0	1.15 [0.93,1.42]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	172 / 2408	149 / 2397		1.15 [0.93,1.42]	Z=1.29, p=0.1987
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.82 (df=1)	p=0.0929	I^2=64.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.7.9: Forestplot for Relative Risk of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

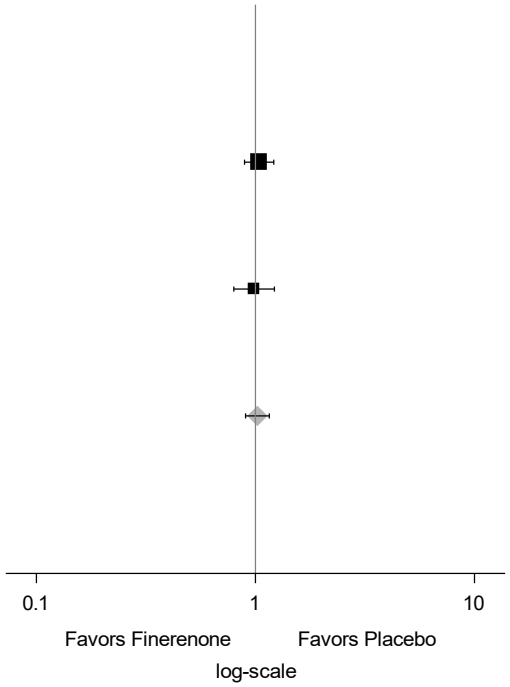
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	136 / 1556	97 / 1541	67.5	1.39 [1.08,1.78]	
FIGARO-DKD	65 / 637	46 / 627	32.5	1.39 [0.97,2.00]	
Total	201 / 2193	143 / 2168		1.39 [1.13,1.71]	Z=3.13, p=0.0018
Heterogeneity:	Q=0.00 (df=1)	p=0.9941	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	61 / 1061	60 / 1069	55.0	1.02 [0.72,1.45]	
FIGARO-DKD	57 / 720	43 / 729	45.0	1.34 [0.92,1.97]	
Total	118 / 1781	103 / 1798		1.16 [0.90,1.50]	Z=1.12, p=0.2618
Heterogeneity:	Q=1.05 (df=1)	p=0.3044	I^2=5.2%		
Subgroup Heterogeneity:	Q=1.18 (df=1)	p=0.2770	I^2=15.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

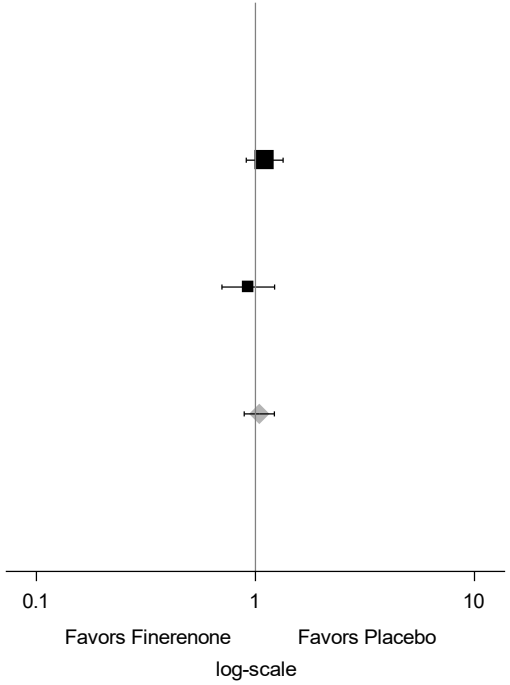
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	295 / 2617	283 / 2610	65.8	1.04 [0.89,1.21]	
FIGARO-DKD	149 / 1357	151 / 1356	34.2	0.99 [0.80,1.22]	
Total	444 / 3974	434 / 3966		1.02 [0.90,1.16]	Z=0.33, p=0.7443
Heterogeneity:	Q=0.16 (df=1)	p=0.6934	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

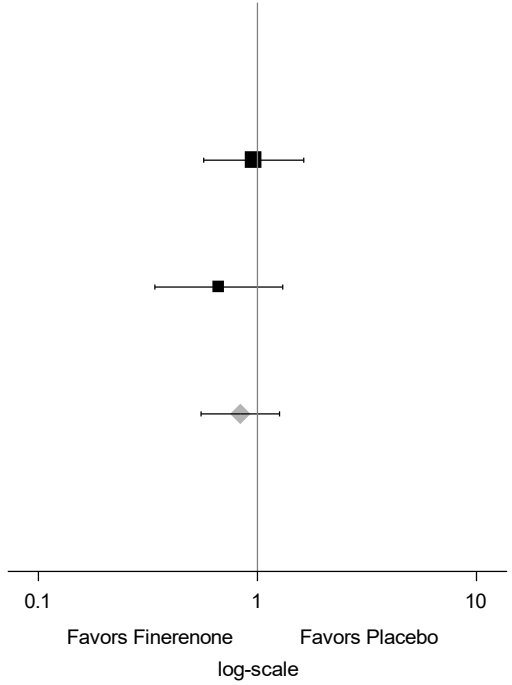
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	200 / 2617	181 / 2610	67.1	1.10 [0.91,1.34]	
FIGARO-DKD	90 / 1357	97 / 1356	32.9	0.93 [0.70,1.22]	
Total	290 / 3974	278 / 3966		1.04 [0.89,1.22]	Z=0.50, p=0.6176
Heterogeneity:	Q=1.00 (df=1)	p=0.3161	I^2=0.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.10: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

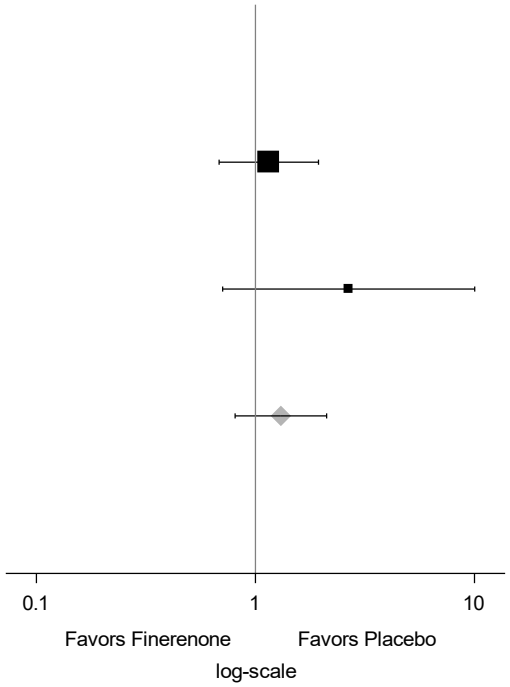
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	28 / 2610	62.0	0.96 [0.57,1.63]	
FIGARO-DKD	14 / 1357	21 / 1356	38.0	0.67 [0.34,1.30]	
Total	41 / 3974	49 / 3966		0.83 [0.55,1.26]	Z=-0.86, p=0.3914
Heterogeneity:	Q=0.71 (df=1)	p=0.3990	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.11: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nephrogenic anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

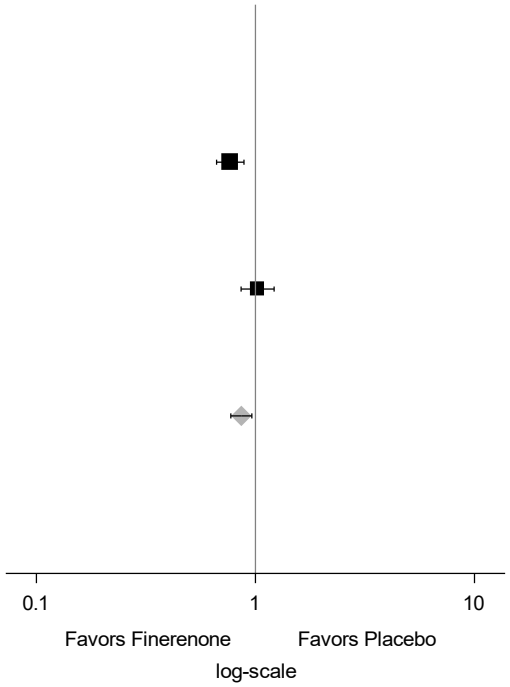
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	26 / 2610	86.5	1.15 [0.68,1.94]	
FIGARO-DKD	8 / 1357	3 / 1356	13.5	2.66 [0.71,10.02]	
Total	38 / 3974	29 / 3966		1.31 [0.81,2.11]	Z=1.09, p=0.2762
Heterogeneity:	Q=1.34 (df=1)	p=0.2473	I^2=25.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.12: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

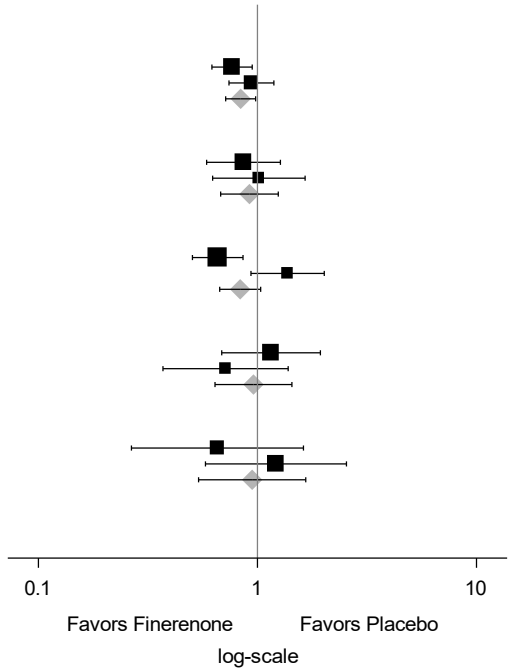
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	287 / 2617	373 / 2610	59.2	0.77 [0.66,0.89]	
FIGARO-DKD	217 / 1357	212 / 1356	40.8	1.02 [0.86,1.22]	
Total	504 / 3974	585 / 3966		0.86 [0.77,0.96]	Z=-2.63, p=0.0085
Heterogeneity:	Q=6.23 (df=1)	p=0.0126	I^2=84.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.12.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

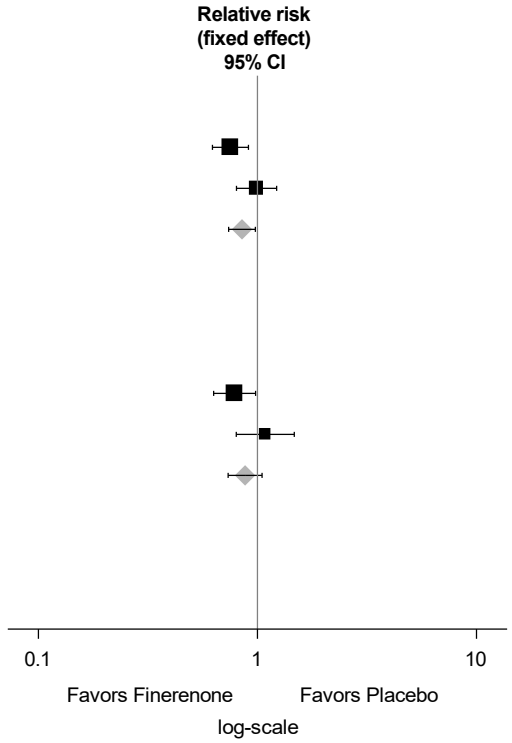
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	131 / 1075	169 / 1062	55.4	0.77 [0.62,0.95]	
FIGARO-DKD	110 / 638	117 / 637	44.6	0.94 [0.74,1.19]	
Total	241 / 1713	286 / 1699		0.84 [0.72,0.98]	Z=-2.20, p=0.0280
Heterogeneity:	Q=1.58 (df=1)	p=0.2082	I^2=36.9%		
North America					
FIDELIO-DKD	42 / 424	50 / 436	61.1	0.86 [0.59,1.27]	
FIGARO-DKD	29 / 267	29 / 271	38.9	1.01 [0.62,1.65]	
Total	71 / 691	79 / 707		0.92 [0.68,1.24]	Z=-0.54, p=0.5873
Heterogeneity:	Q=0.26 (df=1)	p=0.6112	I^2=0.0%		
Asia					
FIDELIO-DKD	79 / 751	119 / 745	67.8	0.66 [0.50,0.86]	
FIGARO-DKD	52 / 289	38 / 290	32.2	1.37 [0.93,2.02]	
Total	131 / 1040	157 / 1035		0.83 [0.67,1.03]	Z=-1.65, p=0.0987
Heterogeneity:	Q=9.47 (df=1)	p=0.0021	I^2=89.4%		
Latin America					
FIDELIO-DKD	28 / 273	24 / 270	61.7	1.15 [0.69,1.94]	
FIGARO-DKD	13 / 102	18 / 101	38.3	0.72 [0.37,1.38]	
Total	41 / 375	42 / 371		0.96 [0.64,1.44]	Z=-0.20, p=0.8386
Heterogeneity:	Q=1.25 (df=1)	p=0.2632	I^2=20.1%		
Others					
FIDELIO-DKD	7 / 94	11 / 97	40.2	0.66 [0.27,1.62]	
FIGARO-DKD	13 / 61	10 / 57	59.8	1.21 [0.58,2.55]	
Total	20 / 155	21 / 154		0.95 [0.54,1.66]	Z=-0.19, p=0.8467
Heterogeneity:	Q=1.06 (df=1)	p=0.3024	I^2=6.0%		
Subgroup Heterogeneity:	Q=0.76 (df=4)	p=0.9442	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.12.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

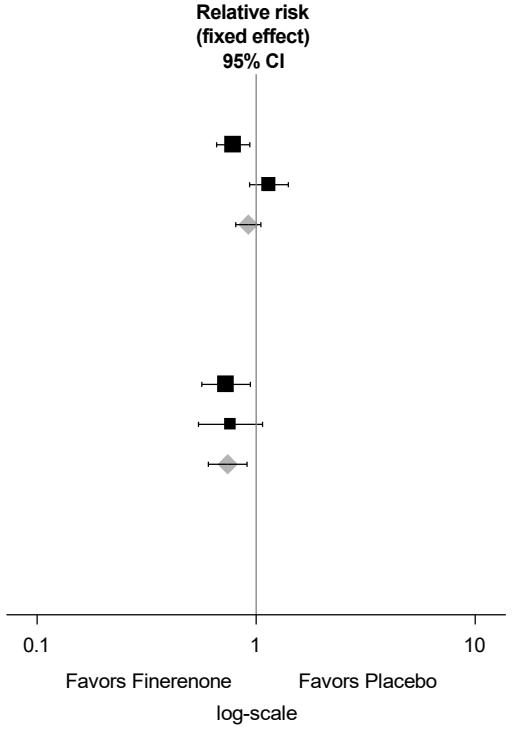
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	160 / 1213	212 / 1210	55.5	0.75 [0.62,0.91]	
FIGARO-DKD	144 / 862	143 / 848	44.5	0.99 [0.80,1.22]	
Total	304 / 2075	355 / 2058		0.85 [0.74,0.98]	Z=-2.27, p=0.0234
Heterogeneity:	Q=3.60 (df=1)	p=0.0577	I^2=72.2%		
Absent					
FIDELIO-DKD	127 / 1404	161 / 1400	65.7	0.79 [0.63,0.98]	
FIGARO-DKD	73 / 495	69 / 508	34.3	1.09 [0.80,1.47]	
Total	200 / 1899	230 / 1908		0.88 [0.73,1.05]	Z=-1.43, p=0.1530
Heterogeneity:	Q=2.82 (df=1)	p=0.0932	I^2=64.5%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7790	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.12.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

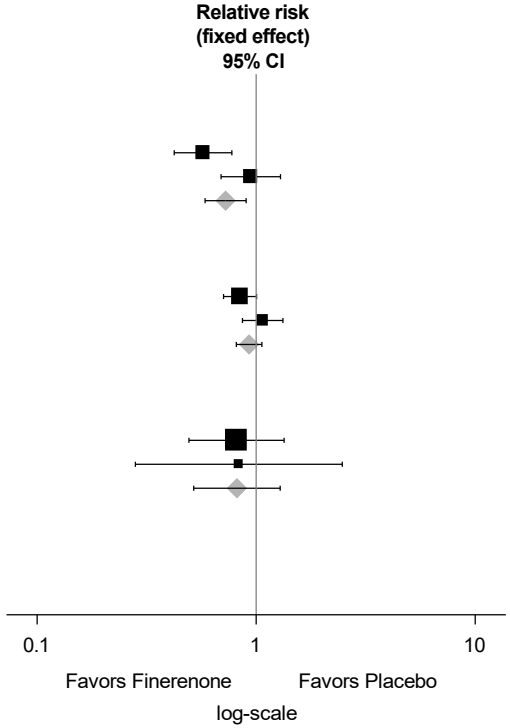
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	198 / 1735	247 / 1700	57.6	0.79 [0.66,0.94]	
FIGARO-DKD	165 / 924	145 / 929	42.4	1.14 [0.93,1.40]	
Total	363 / 2659	392 / 2629		0.92 [0.81,1.05]	Z=-1.23, p=0.2198
Heterogeneity:	Q=7.55 (df=1)	p=0.0060	I^2=86.8%		
> 4.5					
FIDELIO-DKD	89 / 882	126 / 910	63.5	0.73 [0.56,0.94]	
FIGARO-DKD	52 / 433	67 / 426	36.5	0.76 [0.55,1.07]	
Total	141 / 1315	193 / 1336		0.74 [0.60,0.91]	Z=-2.89, p=0.0039
Heterogeneity:	Q=0.05 (df=1)	p=0.8286	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.07 (df=1)	p=0.0796	I^2=67.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.12.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

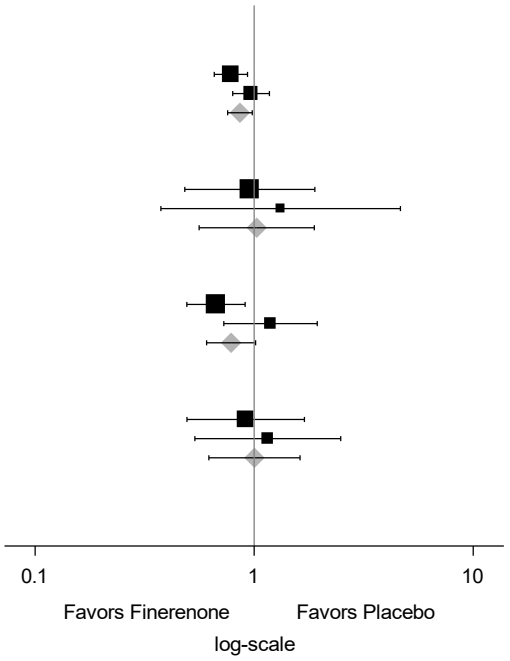
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	59 / 724	103 / 723	51.5	0.57 [0.42,0.77]	
FIGARO-DKD	66 / 494	70 / 495	48.5	0.94 [0.69,1.29]	
Total	125 / 1218	173 / 1218		0.73 [0.58,0.90]	Z=-2.92, p=0.0035
Heterogeneity:	Q=5.11 (df=1)	p=0.0238	I^2=80.4%		
130 - < 160					
FIDELIO-DKD	205 / 1759	243 / 1760	60.0	0.84 [0.71,1.00]	
FIGARO-DKD	146 / 829	136 / 827	40.0	1.07 [0.87,1.32]	
Total	351 / 2588	379 / 2587		0.93 [0.81,1.06]	Z=-1.09, p=0.2771
Heterogeneity:	Q=2.88 (df=1)	p=0.0895	I^2=65.3%		
>= 160					
FIDELIO-DKD	23 / 133	27 / 127	82.5	0.81 [0.49,1.34]	
FIGARO-DKD	5 / 34	6 / 34	17.5	0.83 [0.28,2.47]	
Total	28 / 167	33 / 161		0.82 [0.52,1.29]	Z=-0.87, p=0.3829
Heterogeneity:	Q=0.00 (df=1)	p=0.9684	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.68 (df=2)	p=0.1584	I^2=45.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.12.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

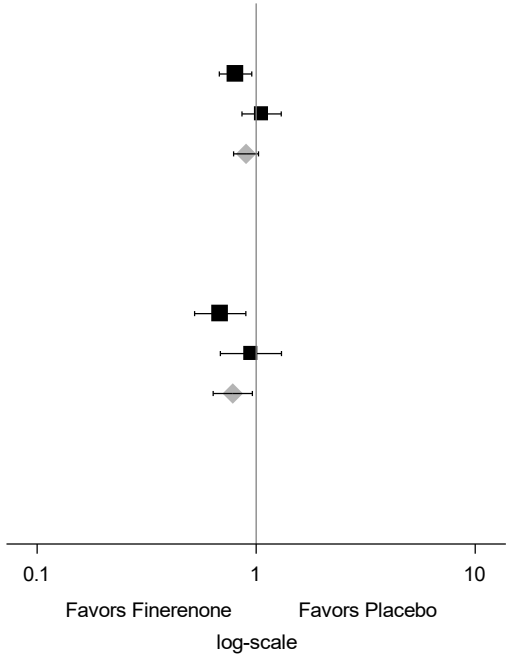
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	193 / 1634	250 / 1657	54.9	0.78 [0.66,0.93]	
FIGARO-DKD	170 / 1010	172 / 989	45.1	0.97 [0.80,1.17]	
Total	363 / 2644	422 / 2646		0.86 [0.76,0.98]	Z=-2.27, p=0.0234
Heterogeneity:	Q=2.55 (df=1)	p=0.1105	I^2=60.7%		
Black					
FIDELIO-DKD	15 / 129	14 / 115	77.2	0.96 [0.48,1.89]	
FIGARO-DKD	4 / 43	5 / 71	22.8	1.32 [0.38,4.65]	
Total	19 / 172	19 / 186		1.03 [0.56,1.88]	Z=0.09, p=0.9310
Heterogeneity:	Q=0.20 (df=1)	p=0.6574	I^2=0.0%		
Asian					
FIDELIO-DKD	61 / 678	91 / 677	72.0	0.67 [0.49,0.91]	
FIGARO-DKD	31 / 252	26 / 251	28.0	1.19 [0.73,1.94]	
Total	92 / 930	117 / 928		0.78 [0.61,1.02]	Z=-1.85, p=0.0650
Heterogeneity:	Q=3.77 (df=1)	p=0.0522	I^2=73.5%		
Others					
FIDELIO-DKD	18 / 176	18 / 161	60.7	0.91 [0.49,1.70]	
FIGARO-DKD	12 / 52	9 / 45	39.3	1.15 [0.54,2.48]	
Total	30 / 228	27 / 206		1.00 [0.62,1.62]	Z=0.01, p=0.9902
Heterogeneity:	Q=0.21 (df=1)	p=0.6438	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.21 (df=3)	p=0.7502	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.12.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

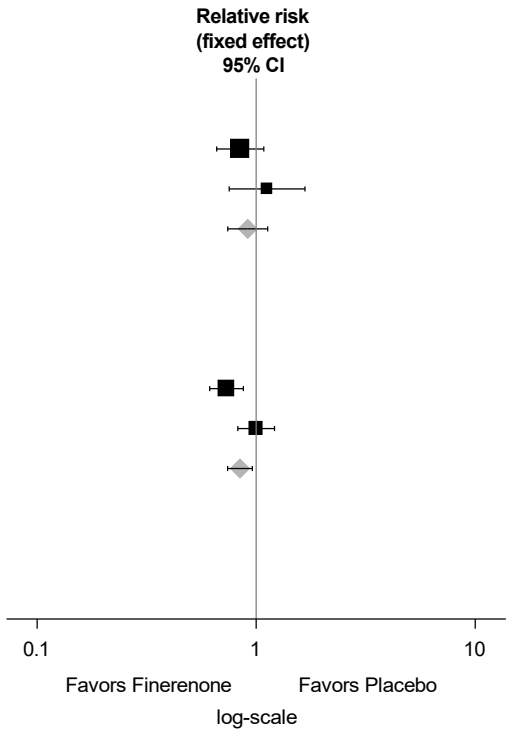
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	205 / 1797	265 / 1870	59.5	0.81 [0.68,0.95]	
FIGARO-DKD	154 / 917	148 / 933	40.5	1.06 [0.86,1.30]	
Total	359 / 2714	413 / 2803		0.90 [0.79,1.02]	Z=-1.59, p=0.1114
Heterogeneity:	Q=4.02 (df=1)	p=0.0449	I^2=75.1%		
Female					
FIDELIO-DKD	82 / 820	108 / 740	58.7	0.69 [0.52,0.90]	
FIGARO-DKD	63 / 440	64 / 423	41.3	0.95 [0.69,1.30]	
Total	145 / 1260	172 / 1163		0.78 [0.64,0.96]	Z=-2.34, p=0.0193
Heterogeneity:	Q=2.28 (df=1)	p=0.1311	I^2=56.1%		
Subgroup Heterogeneity:	Q=1.25 (df=1)	p=0.2627	I^2=20.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.12.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

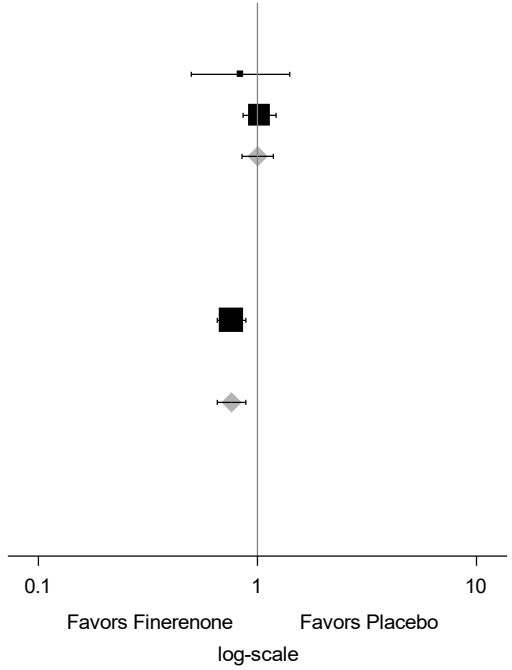
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	105 / 1103	121 / 1075	72.1	0.85 [0.66,1.08]	
FIGARO-DKD	45 / 336	40 / 335	27.9	1.12 [0.75,1.67]	
Total	150 / 1439	161 / 1410		0.92 [0.74,1.13]	Z=-0.83, p=0.4067
Heterogeneity:	Q=1.39 (df=1)	p=0.2378	I^2=28.2%		
>= 65					
FIDELIO-DKD	182 / 1514	252 / 1535	54.3	0.73 [0.61,0.87]	
FIGARO-DKD	172 / 1021	172 / 1021	45.7	1.00 [0.82,1.21]	
Total	354 / 2535	424 / 2556		0.84 [0.74,0.96]	Z=-2.57, p=0.0101
Heterogeneity:	Q=5.45 (df=1)	p=0.0196	I^2=81.7%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5170	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.12.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

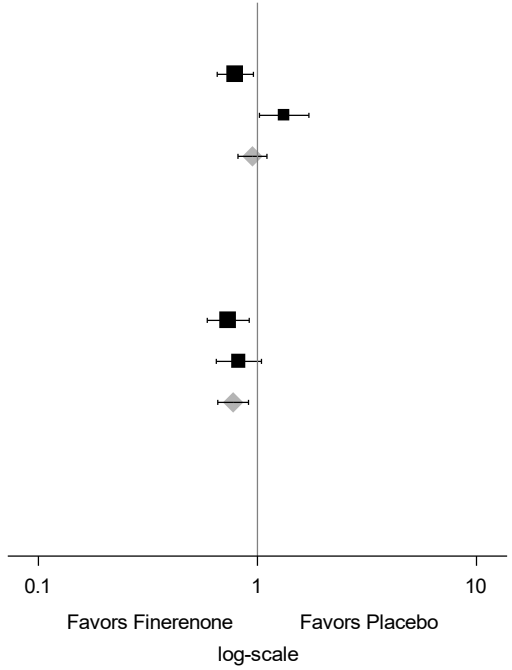
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	23 / 209	28 / 213	10.1	0.84 [0.50,1.40]	
FIGARO-DKD	217 / 1357	212 / 1356	89.9	1.02 [0.86,1.22]	
Total	240 / 1566	240 / 1569		1.00 [0.85,1.18]	Z=0.03, p=0.9794
Heterogeneity:	Q=0.52 (df=1)	p=0.4720	I^2=0.0%		
Very High					
FIDELIO-DKD	264 / 2408	345 / 2397	100.0	0.76 [0.66,0.88]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	264 / 2408	345 / 2397		0.76 [0.66,0.88]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.83 (df=1)	p=0.0157	I^2=82.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.12.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

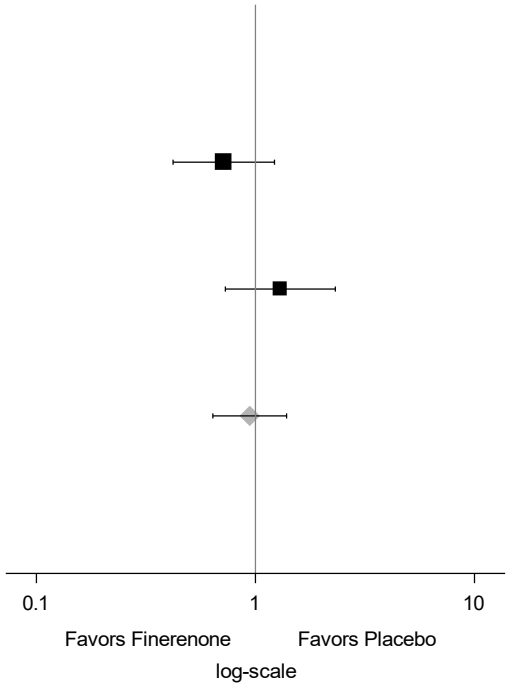
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	168 / 1556	210 / 1541	65.1	0.79 [0.66,0.96]	
FIGARO-DKD	113 / 637	84 / 627	34.9	1.32 [1.02,1.72]	
Total	281 / 2193	294 / 2168		0.95 [0.81,1.10]	Z=-0.68, p=0.4991
Heterogeneity:	Q=9.76 (df=1)	p=0.0018	I^2=89.8%		
45 - < 60					
FIDELIO-DKD	119 / 1061	163 / 1069	53.7	0.74 [0.59,0.92]	
FIGARO-DKD	104 / 720	128 / 729	46.3	0.82 [0.65,1.04]	
Total	223 / 1781	291 / 1798		0.77 [0.66,0.91]	Z=-3.10, p=0.0019
Heterogeneity:	Q=0.46 (df=1)	p=0.4985	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.22 (df=1)	p=0.0729	I^2=68.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.13: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

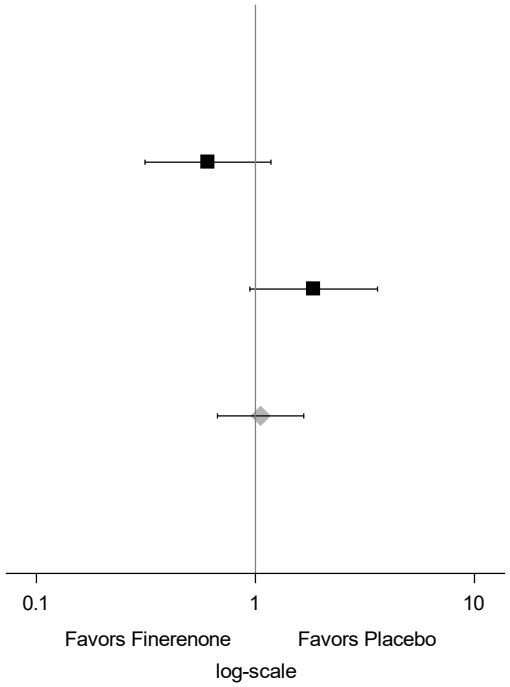
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	32 / 2610	54.0	0.72 [0.42,1.22]	
FIGARO-DKD	26 / 1357	20 / 1356	46.0	1.30 [0.73,2.32]	
Total	49 / 3974	52 / 3966		0.94 [0.64,1.39]	Z=-0.30, p=0.7606
Heterogeneity:	Q=2.20 (df=1)	p=0.1383	I^2=54.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.14: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Bradycardia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

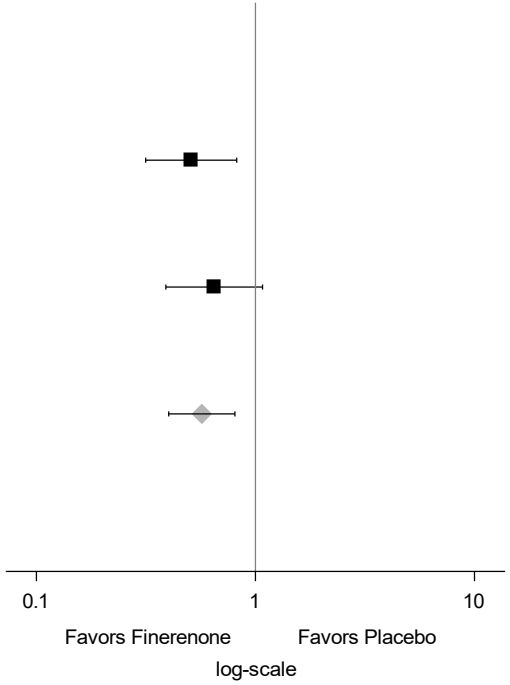
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 2617	23 / 2610	50.6	0.61 [0.31,1.18]	
FIGARO-DKD	24 / 1357	13 / 1356	49.4	1.84 [0.94,3.61]	
Total	38 / 3974	36 / 3966		1.06 [0.67,1.66]	Z=0.23, p=0.8149
Heterogeneity:	Q=5.34 (df=1)	p=0.0208	I^2=81.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.15: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

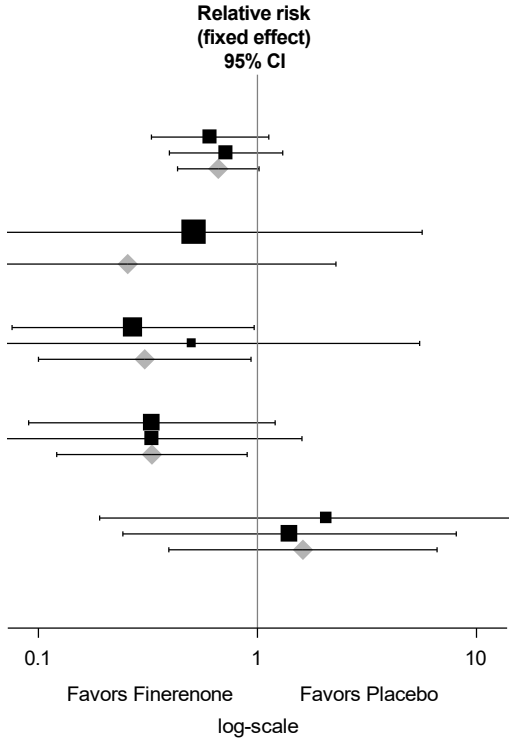
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	49 / 2610	53.0	0.51 [0.32,0.82]	
FIGARO-DKD	24 / 1357	37 / 1356	47.0	0.65 [0.39,1.08]	
Total	49 / 3974	86 / 3966		0.57 [0.40,0.81]	Z=-3.18, p=0.0015
Heterogeneity:	Q=0.46 (df=1)	p=0.4968	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.15.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

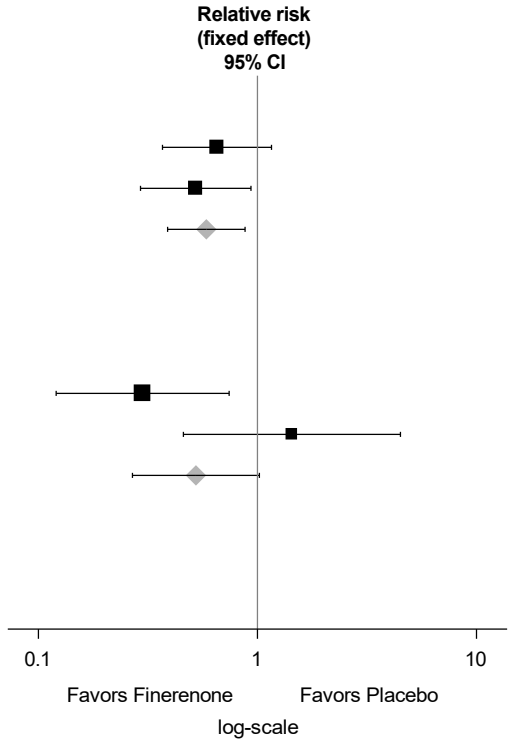
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	26 / 1062	48.3	0.61 [0.33,1.13]	
FIGARO-DKD	18 / 638	25 / 637	51.7	0.72 [0.40,1.30]	
Total	34 / 1713	51 / 1699		0.66 [0.43,1.02]	Z=-1.88, p=0.0596
Heterogeneity:	Q=0.15 (df=1)	p=0.7017	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 424	2 / 436	100.0	0.51 [0.05,5.65]	
FIGARO-DKD	0 / 267	2 / 271	0.0	0.00 [0.00,17E296]	
Total	1 / 691	4 / 707		0.26 [0.03,2.28]	Z=-1.22, p=0.2220
Heterogeneity:	Q=0.33 (df=1)	p=0.5679	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 751	11 / 745	78.0	0.27 [0.08,0.97]	
FIGARO-DKD	1 / 289	2 / 290	22.0	0.50 [0.05,5.50]	
Total	4 / 1040	13 / 1035		0.31 [0.10,0.93]	Z=-2.08, p=0.0376
Heterogeneity:	Q=0.20 (df=1)	p=0.6549	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 273	9 / 270	59.7	0.33 [0.09,1.20]	
FIGARO-DKD	2 / 102	6 / 101	40.3	0.33 [0.07,1.60]	
Total	5 / 375	15 / 371		0.33 [0.12,0.90]	Z=-2.17, p=0.0299
Heterogeneity:	Q=0.00 (df=1)	p=0.9991	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	1 / 97	35.1	2.06 [0.19,22.38]	
FIGARO-DKD	3 / 61	2 / 57	64.9	1.40 [0.24,8.09]	
Total	5 / 155	3 / 154		1.61 [0.39,6.61]	Z=0.66, p=0.5062
Heterogeneity:	Q=0.07 (df=1)	p=0.7976	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.41 (df=4)	p=0.2475	I^2=26.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.15.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

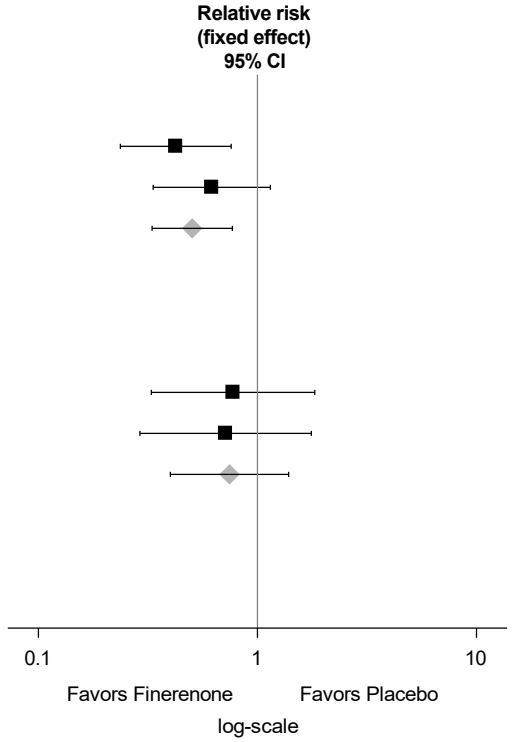
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 1213	29 / 1210	50.7	0.65 [0.37,1.16]	
FIGARO-DKD	17 / 862	32 / 848	49.3	0.52 [0.29,0.93]	
Total	36 / 2075	61 / 2058		0.58 [0.39,0.88]	Z=-2.59, p=0.0097
Heterogeneity:	Q=0.29 (df=1)	p=0.5911	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 1404	20 / 1400	61.2	0.30 [0.12,0.74]	
FIGARO-DKD	7 / 495	5 / 508	38.8	1.44 [0.46,4.50]	
Total	13 / 1899	25 / 1908		0.52 [0.27,1.02]	Z=-1.90, p=0.0574
Heterogeneity:	Q=4.46 (df=1)	p=0.0346	I^2=77.6%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7835	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.15.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1735	37 / 1700	52.8	0.42 [0.24,0.76]	
FIGARO-DKD	16 / 924	26 / 929	47.2	0.62 [0.33,1.15]	
Total	32 / 2659	63 / 2629		0.50 [0.33,0.77]	Z=-3.19, p=0.0014
Heterogeneity:	Q=0.77 (df=1)	p=0.3813	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 882	12 / 910	52.4	0.77 [0.33,1.83]	
FIGARO-DKD	8 / 433	11 / 426	47.6	0.72 [0.29,1.76]	
Total	17 / 1315	23 / 1336		0.75 [0.40,1.39]	Z=-0.93, p=0.3543
Heterogeneity:	Q=0.02 (df=1)	p=0.9019	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3066	I^2=4.3%		

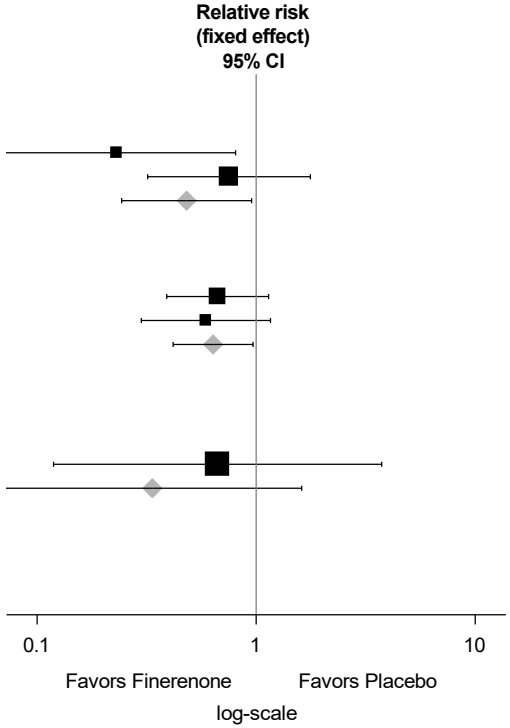


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.15.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

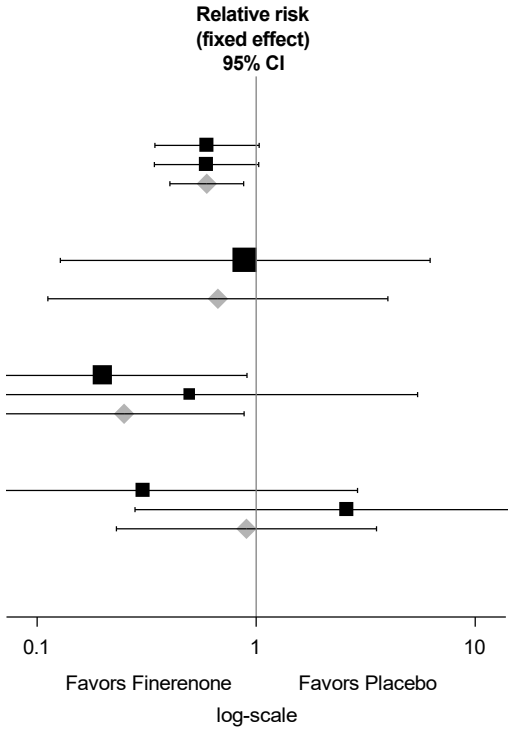
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 724	13 / 723	31.8	0.23 [0.07,0.81]	
FIGARO-DKD	9 / 494	12 / 495	68.2	0.75 [0.32,1.77]	
Total	12 / 1218	25 / 1218		0.48 [0.24,0.95]	Z=-2.10, p=0.0360
Heterogeneity:	Q=2.37 (df=1)	p=0.1234	I^2=57.9%		
130 - < 160					
FIDELIO-DKD	22 / 1759	33 / 1760	61.7	0.67 [0.39,1.14]	
FIGARO-DKD	13 / 829	22 / 827	38.3	0.59 [0.30,1.16]	
Total	35 / 2588	55 / 2587		0.64 [0.42,0.97]	Z=-2.11, p=0.0347
Heterogeneity:	Q=0.08 (df=1)	p=0.7793	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	3 / 127	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	2 / 34	3 / 34	100.0	0.67 [0.12,3.74]	
Total	2 / 167	6 / 161		0.34 [0.07,1.61]	Z=-1.36, p=0.1729
Heterogeneity:	Q=0.61 (df=1)	p=0.4352	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=2)	p=0.6276	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.15.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

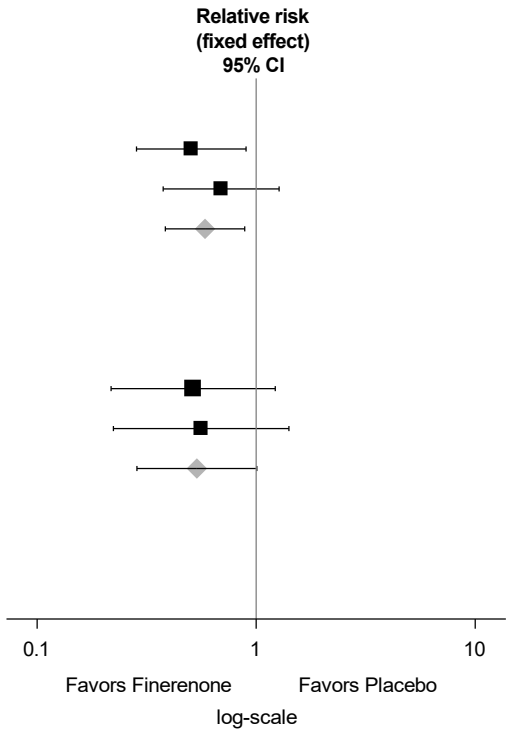
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	20 / 1634	34 / 1657	50.0	0.60 [0.34,1.03]	
FIGARO-DKD	20 / 1010	33 / 989	50.0	0.59 [0.34,1.03]	
Total	40 / 2644	67 / 2646		0.59 [0.40,0.88]	Z=-2.62, p=0.0087
Heterogeneity:	Q=0.00 (df=1)	p=0.9896	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	2 / 115	100.0	0.89 [0.13,6.23]	
FIGARO-DKD	0 / 43	1 / 71	0.0	0.00 [0.00,25E296]	
Total	2 / 172	3 / 186		0.67 [0.11,3.99]	Z=-0.44, p=0.6588
Heterogeneity:	Q=0.08 (df=1)	p=0.7717	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 678	10 / 677	71.4	0.20 [0.04,0.91]	
FIGARO-DKD	1 / 252	2 / 251	28.6	0.50 [0.05,5.46]	
Total	3 / 930	12 / 928		0.25 [0.07,0.88]	Z=-2.16, p=0.0310
Heterogeneity:	Q=0.40 (df=1)	p=0.5254	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	3 / 161	49.4	0.30 [0.03,2.90]	
FIGARO-DKD	3 / 52	1 / 45	50.6	2.60 [0.28,24.09]	
Total	4 / 228	4 / 206		0.90 [0.23,3.54]	Z=-0.15, p=0.8836
Heterogeneity:	Q=1.76 (df=1)	p=0.1852	I^2=43.0%		
Subgroup Heterogeneity:	Q=2.16 (df=3)	p=0.5401	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.15.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

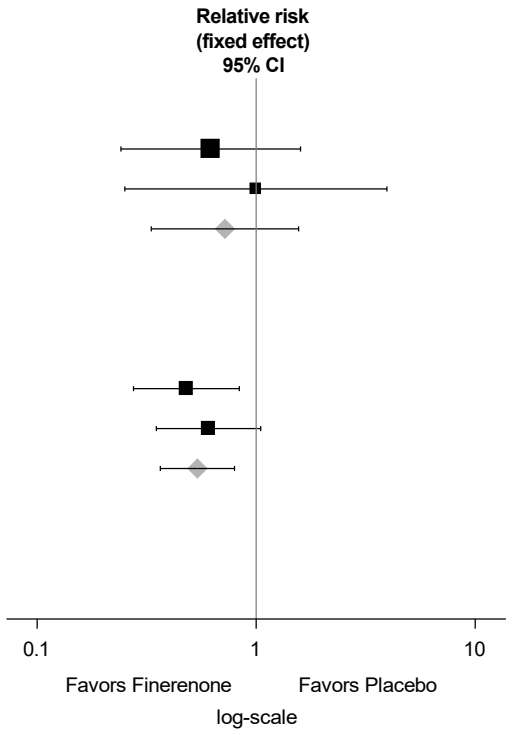
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	35 / 1870	52.8	0.51 [0.28,0.90]	
FIGARO-DKD	17 / 917	25 / 933	47.2	0.69 [0.38,1.27]	
Total	34 / 2714	60 / 2803		0.58 [0.38,0.89]	Z=-2.53, p=0.0116
Heterogeneity:	Q=0.54 (df=1)	p=0.4629	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 820	14 / 740	53.3	0.52 [0.22,1.22]	
FIGARO-DKD	7 / 440	12 / 423	46.7	0.56 [0.22,1.41]	
Total	15 / 1260	26 / 1163		0.54 [0.29,1.01]	Z=-1.94, p=0.0526
Heterogeneity:	Q=0.02 (df=1)	p=0.8965	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8240	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.15.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

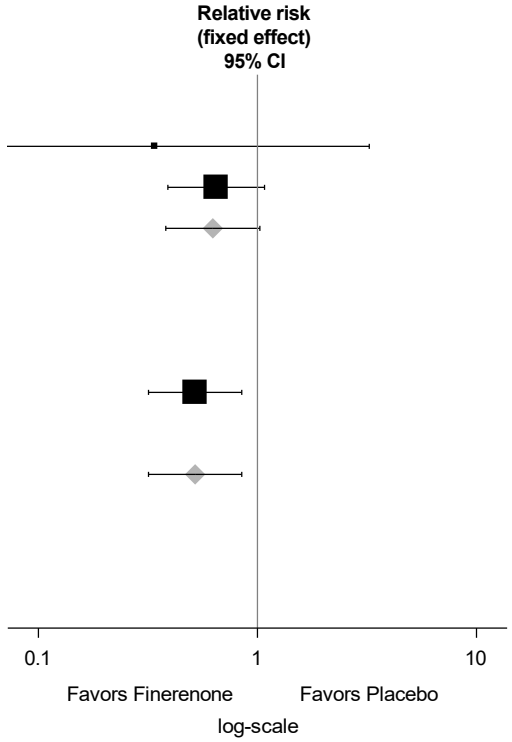
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	7 / 1103	11 / 1075	68.1	0.62 [0.24,1.59]	
FIGARO-DKD	4 / 336	4 / 335	31.9	1.00 [0.25,3.95]	
Total	11 / 1439	15 / 1410		0.72 [0.33,1.56]	Z=-0.83, p=0.4058
Heterogeneity:	Q=0.31 (df=1)	p=0.5774	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 1514	38 / 1535	49.3	0.48 [0.28,0.84]	
FIGARO-DKD	20 / 1021	33 / 1021	50.7	0.61 [0.35,1.05]	
Total	38 / 2535	71 / 2556		0.54 [0.37,0.80]	Z=-3.10, p=0.0019
Heterogeneity:	Q=0.34 (df=1)	p=0.5594	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5135	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.15.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

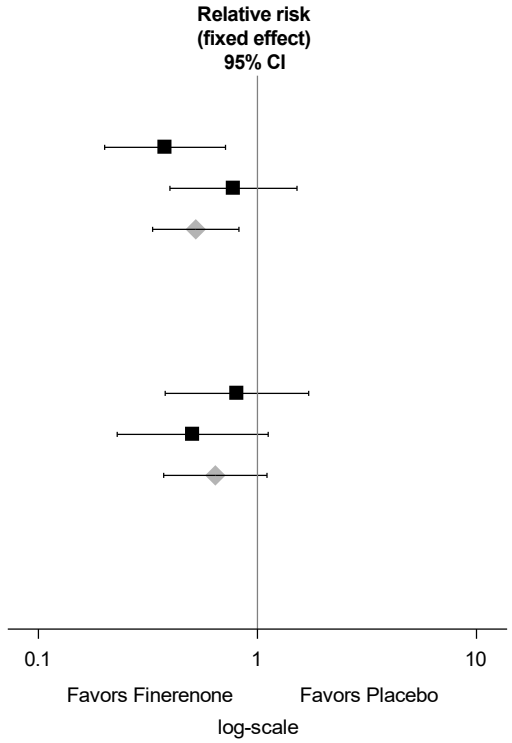
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	3 / 213	4.8	0.34 [0.04,3.24]	
FIGARO-DKD	24 / 1357	37 / 1356	95.2	0.65 [0.39,1.08]	
Total	25 / 1566	40 / 1569		0.63 [0.38,1.03]	Z=-1.86, p=0.0630
Heterogeneity:	Q=0.30 (df=1)	p=0.5837	I^2=0.0%		
Very High					
FIDELIO-DKD	24 / 2408	46 / 2397	100.0	0.52 [0.32,0.85]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	24 / 2408	46 / 2397		0.52 [0.32,0.85]	Z=-2.62, p=0.0088
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6005	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.15.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

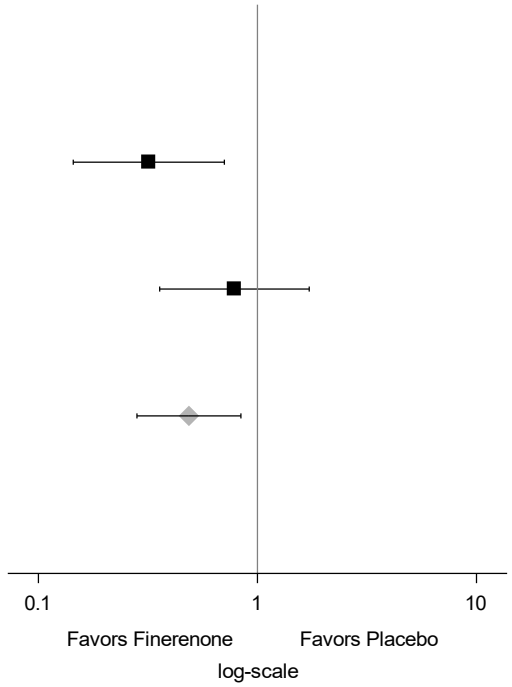
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	34 / 1541	52.5	0.38 [0.20,0.71]	
FIGARO-DKD	15 / 637	19 / 627	47.5	0.78 [0.40,1.52]	
Total	28 / 2193	53 / 2168		0.52 [0.33,0.82]	Z=-2.80, p=0.0051
Heterogeneity:	Q=2.34 (df=1)	p=0.1258	I^2=57.3%		
45 - < 60					
FIDELIO-DKD	12 / 1061	15 / 1069	52.5	0.81 [0.38,1.71]	
FIGARO-DKD	9 / 720	18 / 729	47.5	0.51 [0.23,1.12]	
Total	21 / 1781	33 / 1798		0.64 [0.37,1.11]	Z=-1.60, p=0.1101
Heterogeneity:	Q=0.69 (df=1)	p=0.4049	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.32 (df=1)	p=0.5687	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

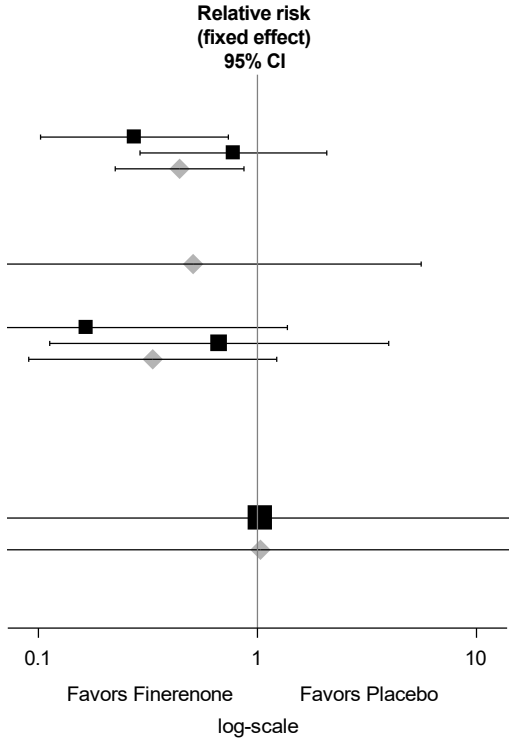
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 2617	25 / 2610	49.5	0.32 [0.14,0.71]	
FIGARO-DKD	11 / 1357	14 / 1356	50.5	0.79 [0.36,1.72]	
Total	19 / 3974	39 / 3966		0.49 [0.28,0.84]	Z=-2.58, p=0.0098
Heterogeneity:	Q=2.51 (df=1)	p=0.1134	I^2=60.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.16.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

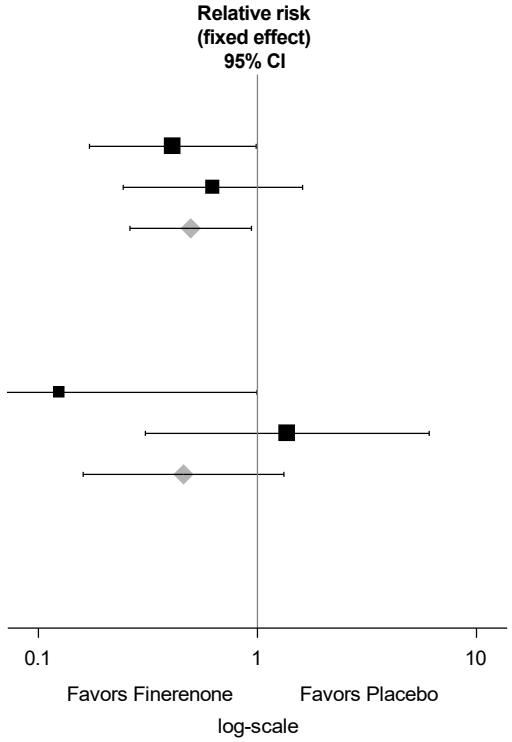
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	5 / 1075	18 / 1062	49.7	0.27 [0.10,0.74]	
FIGARO-DKD	7 / 638	9 / 637	50.3	0.78 [0.29,2.07]	
Total	12 / 1713	27 / 1699		0.44 [0.22,0.87]	Z=-2.37, p=0.0178
Heterogeneity:	Q=2.16 (df=1)	p=0.1413	I^2=53.8%		
North America					
FIDELIO-DKD	1 / 424	0 / 436	0.0	908E8 [908E8,908E8]	
FIGARO-DKD	0 / 267	2 / 271	0.0	0.00 [0.00,17E296]	
Total	1 / 691	2 / 707		0.51 [0.05,5.59]	Z=-0.55, p=0.5804
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	1 / 751	6 / 745	41.5	0.17 [0.02,1.37]	
FIGARO-DKD	2 / 289	3 / 290	58.5	0.67 [0.11,3.97]	
Total	3 / 1040	9 / 1035		0.33 [0.09,1.22]	Z=-1.66, p=0.0979
Heterogeneity:	Q=1.01 (df=1)	p=0.3147	I^2=1.1%		
Latin America					
FIDELIO-DKD	0 / 273	0 / 270	0.0	-	
FIGARO-DKD	2 / 102	0 / 101	0.0	102E9 [102E9,102E9]	
Total	2 / 375	0 / 371		1.91E7 [1.91E7,1.91E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	1 / 97	100.0	1.03 [0.07,16.26]	
FIGARO-DKD	0 / 61	0 / 57	0.0	-	
Total	1 / 155	1 / 154		1.03 [0.07,16.26]	Z=0.02, p=0.9822
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=4)	p=0.9676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	7 / 1213	17 / 1210	53.6	0.41 [0.17,0.99]	
FIGARO-DKD	7 / 862	11 / 848	46.4	0.63 [0.24,1.61]	
Total	14 / 2075	28 / 2058		0.50 [0.26,0.94]	Z=-2.15, p=0.0313
Heterogeneity:	Q=0.41 (df=1)	p=0.5209	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 1404	8 / 1400	34.0	0.12 [0.02,1.00]	
FIGARO-DKD	4 / 495	3 / 508	66.0	1.37 [0.31,6.08]	
Total	5 / 1899	11 / 1908		0.46 [0.16,1.32]	Z=-1.44, p=0.1488
Heterogeneity:	Q=3.57 (df=1)	p=0.0588	I^2=72.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9045	I^2=0.0%		

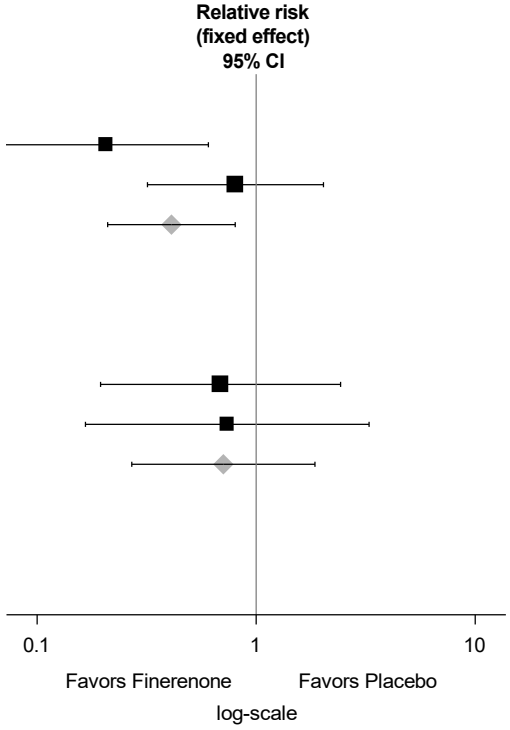


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure chronic (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

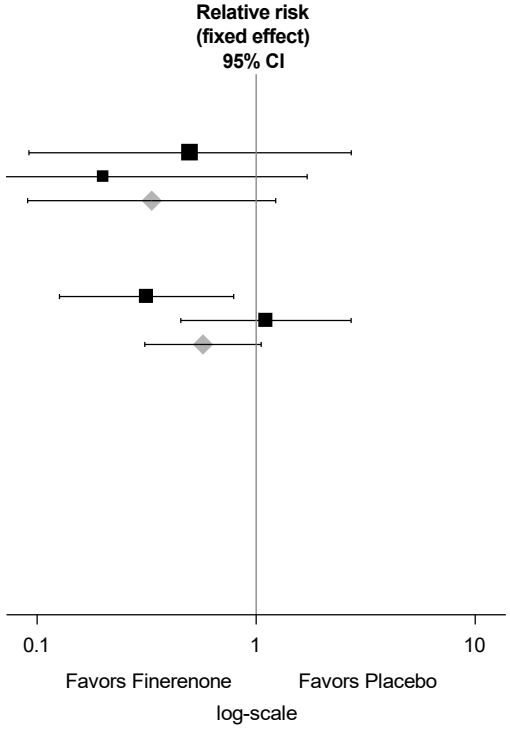
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	4 / 1735	19 / 1700	42.5	0.21 [0.07,0.61]	
FIGARO-DKD	8 / 924	10 / 929	57.5	0.80 [0.32,2.03]	
Total	12 / 2659	29 / 2629		0.41 [0.21,0.80]	Z=-2.60, p=0.0092
Heterogeneity:	Q=3.60 (df=1)	p=0.0577	I^2=72.2%		
> 4.5					
FIDELIO-DKD	4 / 882	6 / 910	58.3	0.69 [0.19,2.43]	
FIGARO-DKD	3 / 433	4 / 426	41.7	0.74 [0.17,3.28]	
Total	7 / 1315	10 / 1336		0.71 [0.27,1.85]	Z=-0.70, p=0.4825
Heterogeneity:	Q=0.00 (df=1)	p=0.9438	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3620	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

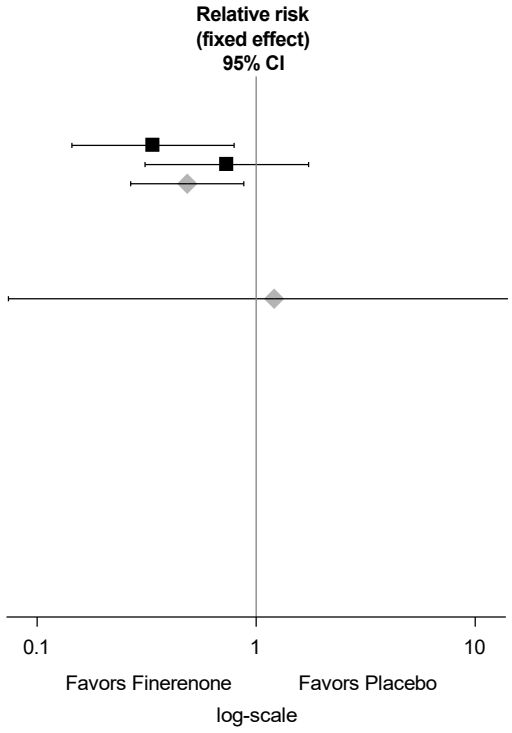
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	2 / 724	4 / 723	61.5	0.50 [0.09,2.72]	
FIGARO-DKD	1 / 494	5 / 495	38.5	0.20 [0.02,1.71]	
Total	3 / 1218	9 / 1218		0.33 [0.09,1.23]	Z=-1.65, p=0.0987
Heterogeneity:	Q=0.43 (df=1)	p=0.5096	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	6 / 1759	19 / 1760	48.9	0.32 [0.13,0.79]	
FIGARO-DKD	10 / 829	9 / 827	51.1	1.11 [0.45,2.71]	
Total	16 / 2588	28 / 2587		0.57 [0.31,1.05]	Z=-1.79, p=0.0732
Heterogeneity:	Q=3.71 (df=1)	p=0.0540	I^2=73.1%		
>= 160					
FIDELIO-DKD	0 / 133	2 / 127	0.0	0.00 [0.00,81E295]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	2 / 161		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.54 (df=2)	p=0.7638	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

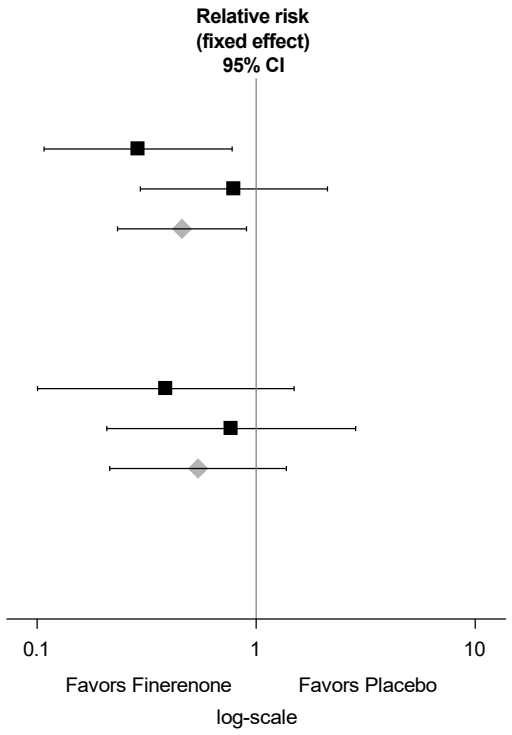
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	7 / 1634	21 / 1657	50.4	0.34 [0.14,0.79]	
FIGARO-DKD	9 / 1010	12 / 989	49.6	0.73 [0.31,1.74]	
Total	16 / 2644	33 / 2646		0.48 [0.27,0.88]	Z=-2.39, p=0.0169
Heterogeneity:	Q=1.58 (df=1)	p=0.2082	I^2=36.9%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	11E10 [11E10,11E10]	
FIGARO-DKD	0 / 43	1 / 71	0.0	0.00 [0.00,25E296]	
Total	1 / 172	1 / 186		1.21 [0.07,19.73]	Z=0.13, p=0.8946
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 678	4 / 677	0.0	0.00 [0.00,21E296]	
FIGARO-DKD	0 / 252	1 / 251	0.0	0.00 [0.00,11E296]	
Total	0 / 930	5 / 928		0.00 [0.00,24E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 176	0 / 161	0.0	-	
FIGARO-DKD	2 / 52	0 / 45	0.0	2E11 [2E11,2E11]	
Total	2 / 228	0 / 206		2.81E7 [2.81E7,2.81E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.39 (df=3)	p=0.9417	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.16.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

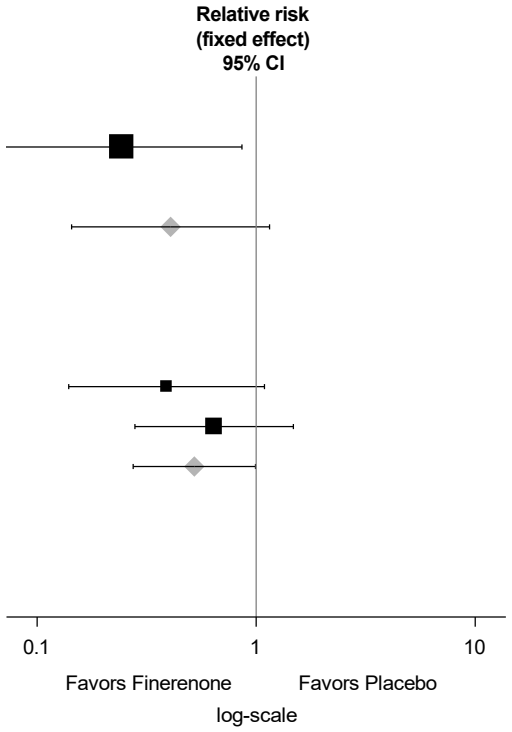
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	5 / 1797	18 / 1870	49.7	0.29 [0.11,0.78]	
FIGARO-DKD	7 / 917	9 / 933	50.3	0.79 [0.30,2.12]	
Total	12 / 2714	27 / 2803		0.46 [0.23,0.90]	Z=-2.25, p=0.0241
Heterogeneity:	Q=2.02 (df=1)	p=0.1553	I^2=50.5%		
Female					
FIDELIO-DKD	3 / 820	7 / 740	48.5	0.39 [0.10,1.49]	
FIGARO-DKD	4 / 440	5 / 423	51.5	0.77 [0.21,2.84]	
Total	7 / 1260	12 / 1163		0.54 [0.21,1.37]	Z=-1.29, p=0.1971
Heterogeneity:	Q=0.52 (df=1)	p=0.4729	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7737	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.16.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

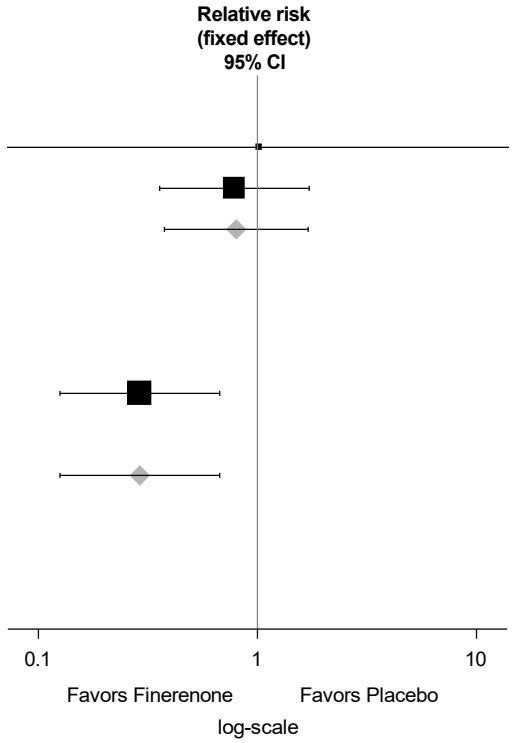
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 1103	12 / 1075	100.0	0.24 [0.07,0.86]	
FIGARO-DKD	2 / 336	0 / 335	0.0	843E8 [843E8,843E8]	
Total	5 / 1439	12 / 1410		0.41 [0.14,1.15]	Z=-1.70, p=0.0901
Heterogeneity:	Q=0.63 (df=1)	p=0.4265	I^2=0.0%		
>= 65					
FIDELIO-DKD	5 / 1514	13 / 1535	39.6	0.39 [0.14,1.09]	
FIGARO-DKD	9 / 1021	14 / 1021	60.4	0.64 [0.28,1.48]	
Total	14 / 2535	27 / 2556		0.52 [0.27,0.99]	Z=-1.98, p=0.0475
Heterogeneity:	Q=0.55 (df=1)	p=0.4588	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6891	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.16.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	1 / 213	7.5	1.02 [0.06,16.19]	
FIGARO-DKD	11 / 1357	14 / 1356	92.5	0.79 [0.36,1.72]	
Total	12 / 1566	15 / 1569		0.80 [0.38,1.70]	Z=-0.58, p=0.5639
Heterogeneity:	Q=0.03 (df=1)	p=0.8588	I^2=0.0%		
Very High					
FIDELIO-DKD	7 / 2408	24 / 2397	100.0	0.29 [0.13,0.67]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	7 / 2408	24 / 2397		0.29 [0.13,0.67]	Z=-2.89, p=0.0039
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.09 (df=1)	p=0.0785	I^2=67.7%		

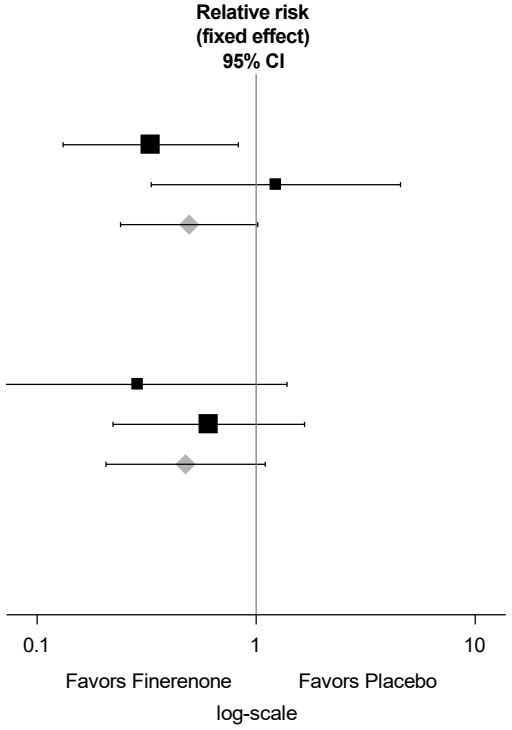


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.16.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure chronic (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

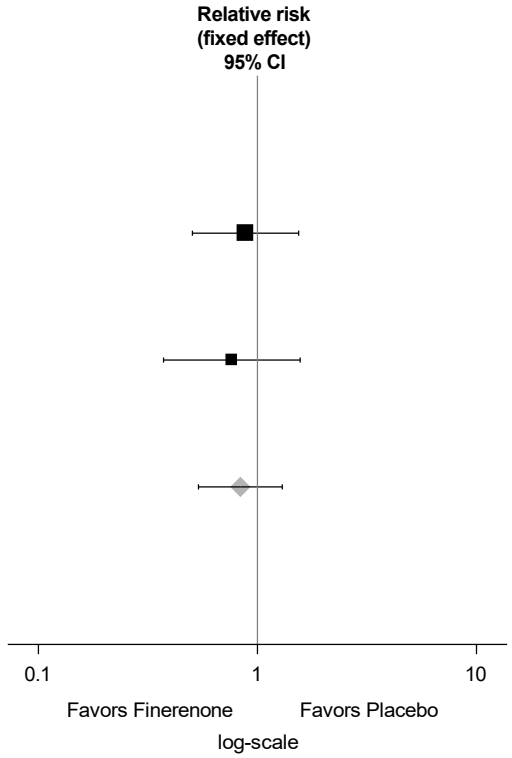
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	6 / 1556	18 / 1541	66.9	0.33 [0.13,0.83]	
FIGARO-DKD	5 / 637	4 / 627	33.1	1.23 [0.33,4.56]	
Total	11 / 2193	22 / 2168		0.49 [0.24,1.02]	Z=-1.91, p=0.0555
Heterogeneity:	Q=2.60 (df=1)	p=0.1069	I^2=61.5%		
45 - < 60					
FIDELIO-DKD	2 / 1061	7 / 1069	29.2	0.29 [0.06,1.38]	
FIGARO-DKD	6 / 720	10 / 729	70.8	0.61 [0.22,1.66]	
Total	8 / 1781	17 / 1798		0.48 [0.21,1.10]	Z=-1.74, p=0.0823
Heterogeneity:	Q=0.62 (df=1)	p=0.4310	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9470	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.17: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

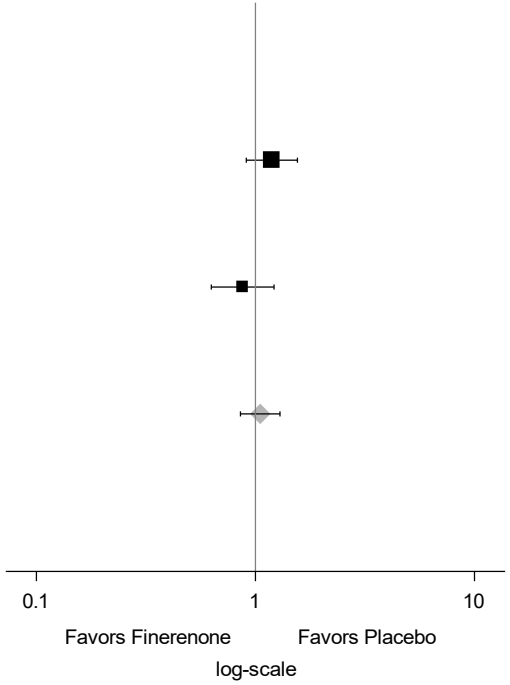
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	26 / 2610	62.3	0.88 [0.50,1.54]	
FIGARO-DKD	13 / 1357	17 / 1356	37.7	0.76 [0.37,1.57]	
Total	36 / 3974	43 / 3966		0.84 [0.54,1.30]	Z=-0.80, p=0.4241
Heterogeneity:	Q=0.10 (df=1)	p=0.7568	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.18: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

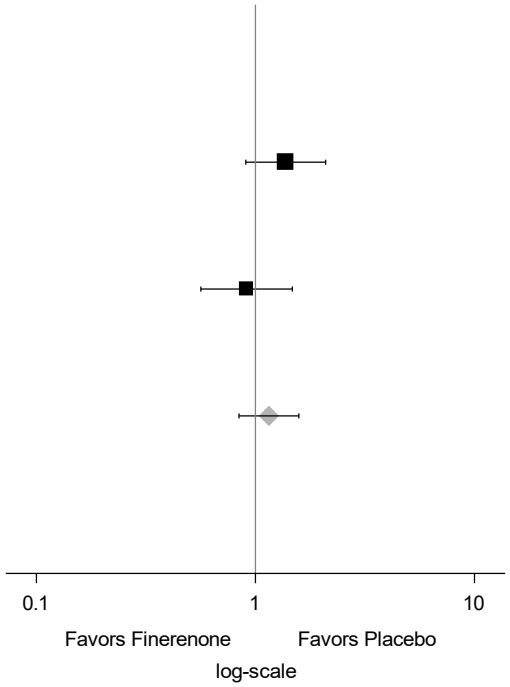
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	112 / 2617	94 / 2610	60.1	1.19 [0.91,1.55]	
FIGARO-DKD	63 / 1357	72 / 1356	39.9	0.87 [0.63,1.22]	
Total	175 / 3974	166 / 3966		1.05 [0.85,1.29]	Z=0.47, p=0.6364
Heterogeneity:	Q=2.00 (df=1)	p=0.1574	I^2=50.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.19: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

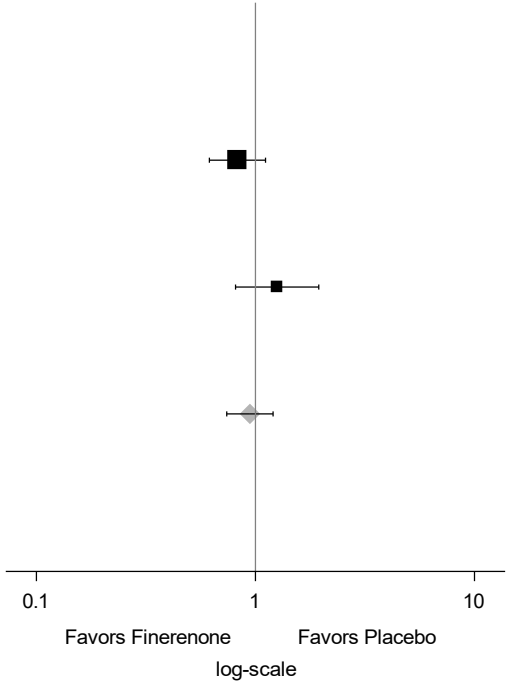
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2617	37 / 2610	56.8	1.37 [0.90,2.09]	
FIGARO-DKD	31 / 1357	34 / 1356	43.2	0.91 [0.56,1.47]	
Total	82 / 3974	71 / 3966		1.15 [0.84,1.58]	Z=0.88, p=0.3781
Heterogeneity:	Q=1.60 (df=1)	p=0.2066	I^2=37.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.20: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

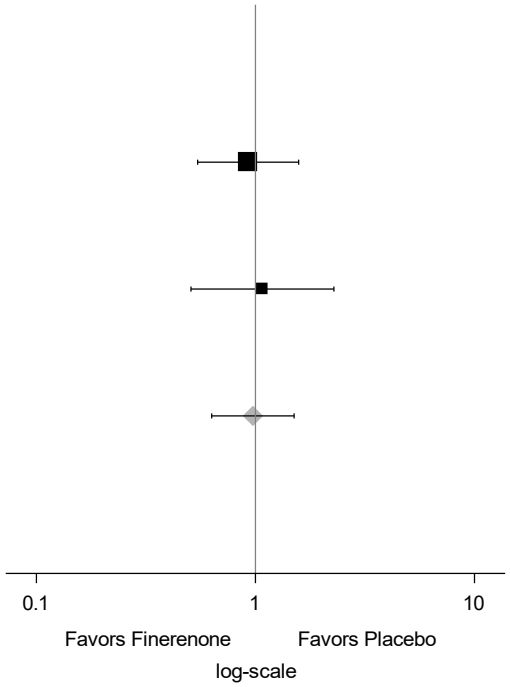
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	78 / 2617	94 / 2610	68.7	0.83 [0.62,1.11]	
FIGARO-DKD	44 / 1357	35 / 1356	31.3	1.26 [0.81,1.95]	
Total	122 / 3974	129 / 3966		0.94 [0.74,1.20]	Z=-0.47, p=0.6395
Heterogeneity:	Q=2.40 (df=1)	p=0.1212	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.21: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypothyroidism (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

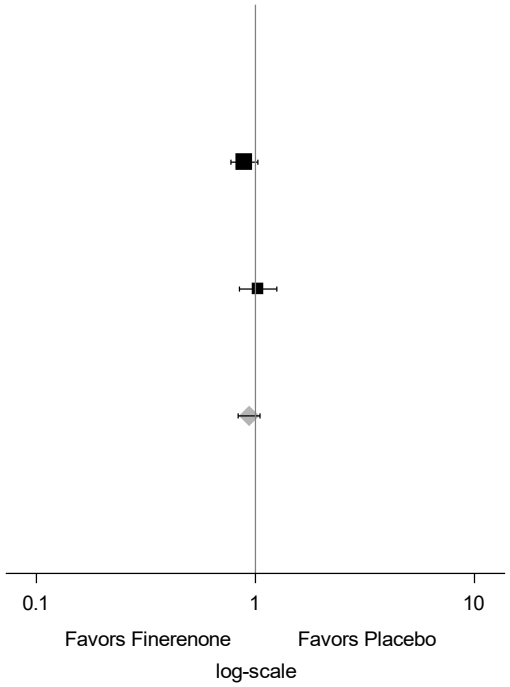
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	28 / 2610	66.7	0.93 [0.54,1.57]	
FIGARO-DKD	14 / 1357	13 / 1356	33.3	1.08 [0.51,2.28]	
Total	40 / 3974	41 / 3966		0.97 [0.63,1.50]	Z=-0.12, p=0.9038
Heterogeneity:	Q=0.10 (df=1)	p=0.7490	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.22: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

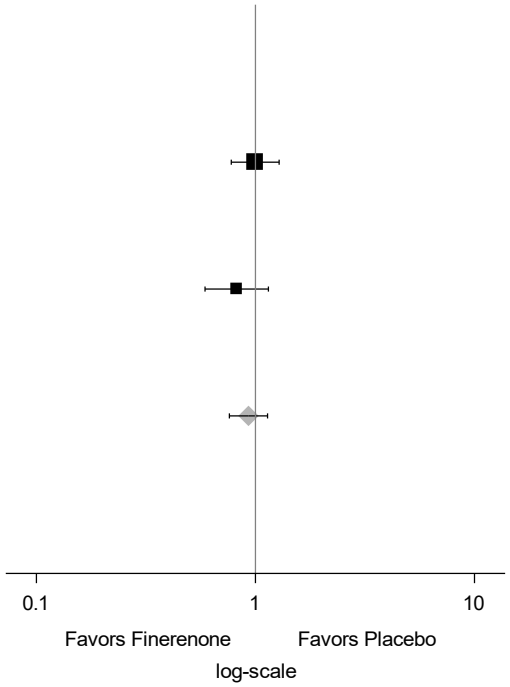
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	316 / 2617	354 / 2610	65.8	0.89 [0.77,1.03]	
FIGARO-DKD	176 / 1357	171 / 1356	34.2	1.03 [0.84,1.25]	
Total	492 / 3974	525 / 3966		0.94 [0.83,1.05]	Z=-1.14, p=0.2532
Heterogeneity:	Q=1.36 (df=1)	p=0.2430	I^2=26.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.23: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

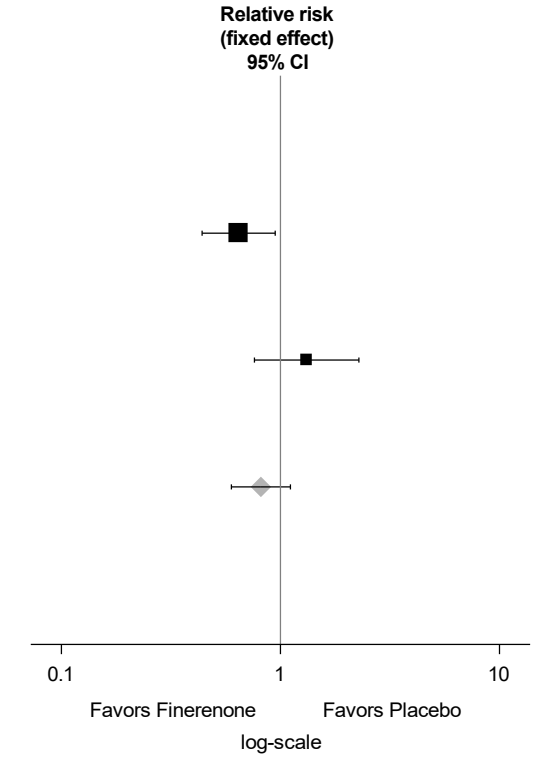
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	116 / 2617	116 / 2610	63.7	1.00 [0.78,1.28]	
FIGARO-DKD	60 / 1357	73 / 1356	36.3	0.82 [0.59,1.15]	
Total	176 / 3974	189 / 3966		0.93 [0.76,1.14]	Z=-0.72, p=0.4728
Heterogeneity:	Q=0.83 (df=1)	p=0.3620	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.24: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

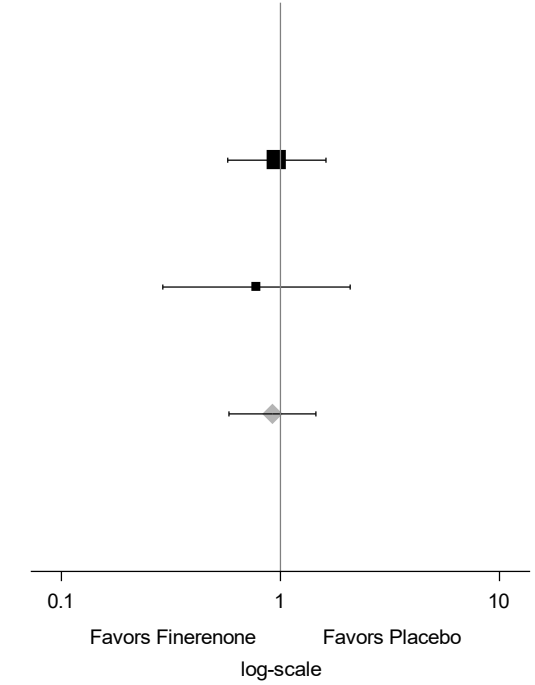
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2617	65 / 2610	67.1	0.64 [0.44,0.95]	
FIGARO-DKD	29 / 1357	22 / 1356	32.9	1.32 [0.76,2.28]	
Total	71 / 3974	87 / 3966		0.81 [0.60,1.11]	Z=-1.30, p=0.1943
Heterogeneity:	Q=4.37 (df=1)	p=0.0365	I^2=77.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.25: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

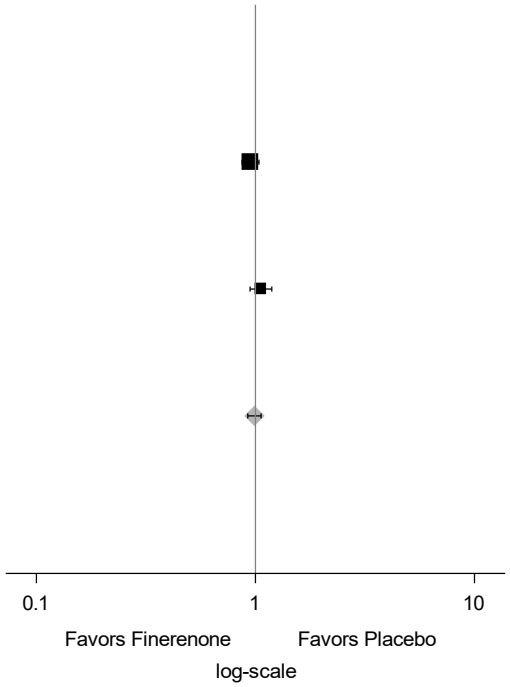
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	29 / 2610	78.4	0.96 [0.57,1.61]	
FIGARO-DKD	7 / 1357	9 / 1356	21.6	0.78 [0.29,2.08]	
Total	35 / 3974	38 / 3966		0.92 [0.58,1.45]	Z=-0.36, p=0.7176
Heterogeneity:	Q=0.14 (df=1)	p=0.7057	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.26: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

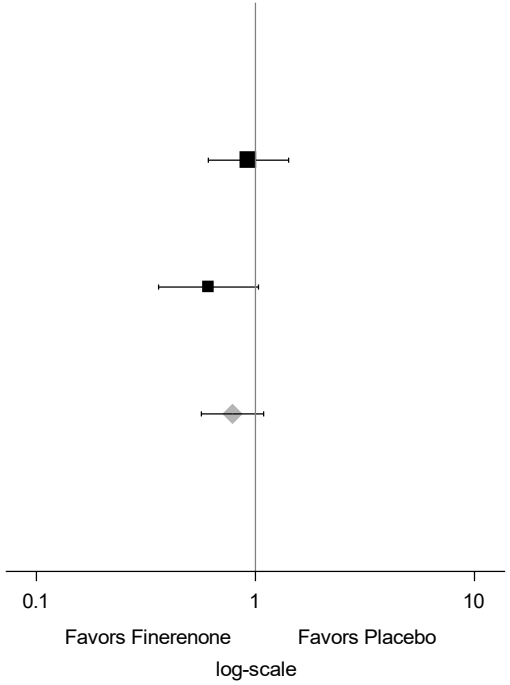
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	693 / 2617	728 / 2610	62.3	0.95 [0.87,1.04]	
FIGARO-DKD	423 / 1357	399 / 1356	37.7	1.06 [0.95,1.19]	
Total	1116 / 3974	1127 / 3966		0.99 [0.92,1.06]	Z=-0.30, p=0.7656
Heterogeneity:	Q=2.21 (df=1)	p=0.1375	I^2=54.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.27: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

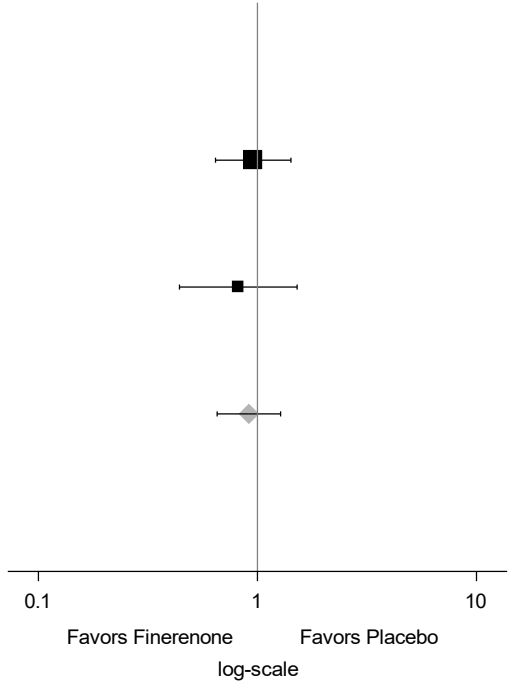
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2617	44 / 2610	60.8	0.93 [0.61,1.42]	
FIGARO-DKD	22 / 1357	36 / 1356	39.2	0.61 [0.36,1.03]	
Total	63 / 3974	80 / 3966		0.79 [0.57,1.09]	Z=-1.45, p=0.1483
Heterogeneity:	Q=1.49 (df=1)	p=0.2217	I^2=33.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.28: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

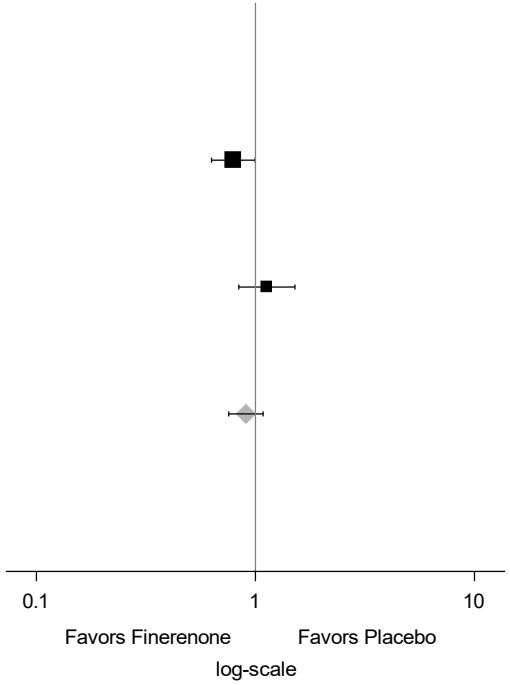
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2617	49 / 2610	70.9	0.96 [0.64,1.42]	
FIGARO-DKD	18 / 1357	22 / 1356	29.1	0.82 [0.44,1.52]	
Total	65 / 3974	71 / 3966		0.91 [0.65,1.28]	Z=-0.53, p=0.5958
Heterogeneity:	Q=0.18 (df=1)	p=0.6752	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.29: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

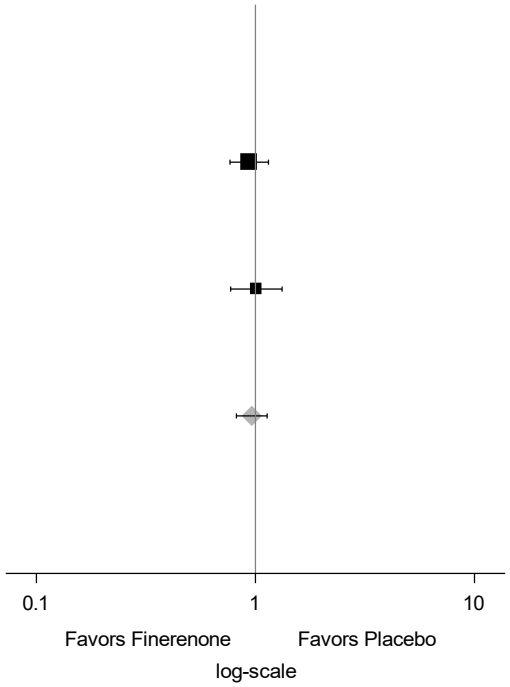
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	124 / 2617	156 / 2610	62.4	0.79 [0.63,1.00]	
FIGARO-DKD	88 / 1357	78 / 1356	37.6	1.13 [0.84,1.51]	
Total	212 / 3974	234 / 3966		0.90 [0.76,1.08]	Z=-1.09, p=0.2775
Heterogeneity:	Q=3.40 (df=1)	p=0.0650	I^2=70.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.30: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

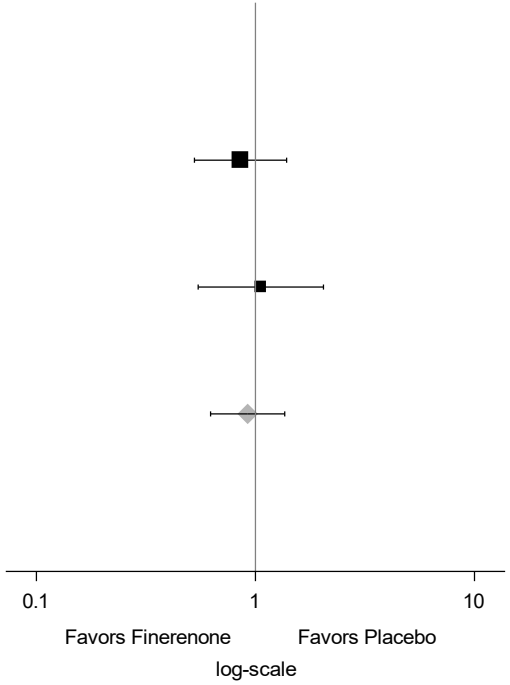
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	170 / 2617	181 / 2610	64.1	0.94 [0.77,1.15]	
FIGARO-DKD	98 / 1357	97 / 1356	35.9	1.01 [0.77,1.32]	
Total	268 / 3974	278 / 3966		0.96 [0.82,1.13]	Z=-0.47, p=0.6409
Heterogeneity:	Q=0.19 (df=1)	p=0.6638	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.31: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

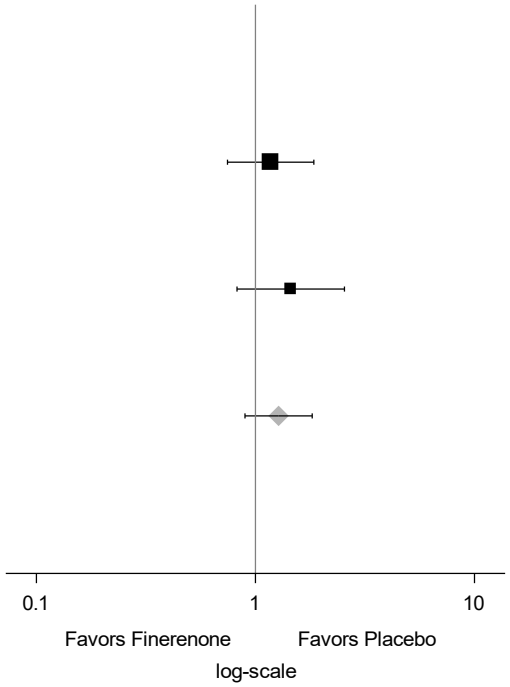
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	35 / 2610	64.9	0.85 [0.53,1.39]	
FIGARO-DKD	18 / 1357	17 / 1356	35.1	1.06 [0.55,2.04]	
Total	48 / 3974	52 / 3966		0.92 [0.62,1.36]	Z=-0.41, p=0.6801
Heterogeneity:	Q=0.26 (df=1)	p=0.6092	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.32: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

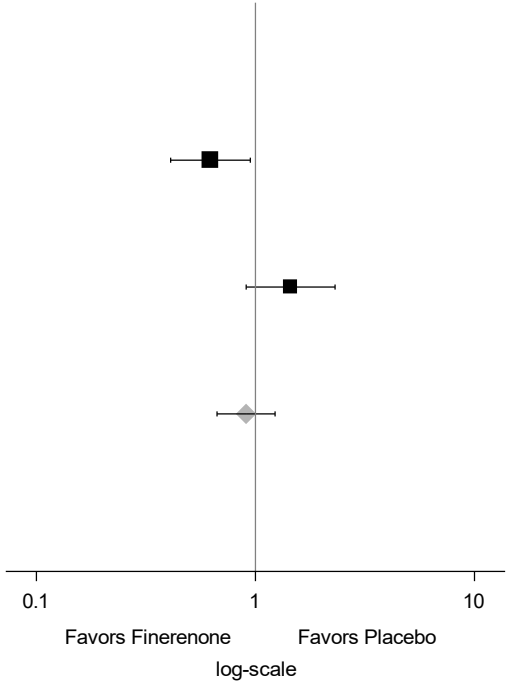
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2617	34 / 2610	60.7	1.17 [0.75,1.85]	
FIGARO-DKD	29 / 1357	20 / 1356	39.3	1.45 [0.82,2.55]	
Total	69 / 3974	54 / 3966		1.28 [0.90,1.82]	Z=1.35, p=0.1769
Heterogeneity:	Q=0.33 (df=1)	p=0.5682	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.33: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

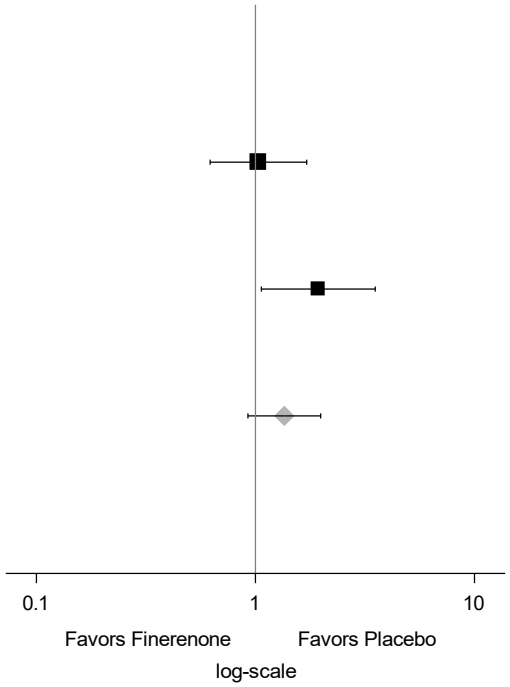
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	56 / 2610	55.4	0.62 [0.41,0.95]	
FIGARO-DKD	42 / 1357	29 / 1356	44.6	1.45 [0.91,2.31]	
Total	77 / 3974	85 / 3966		0.91 [0.67,1.23]	Z=-0.64, p=0.5254
Heterogeneity:	Q=6.92 (df=1)	p=0.0085	I^2=85.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.34: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

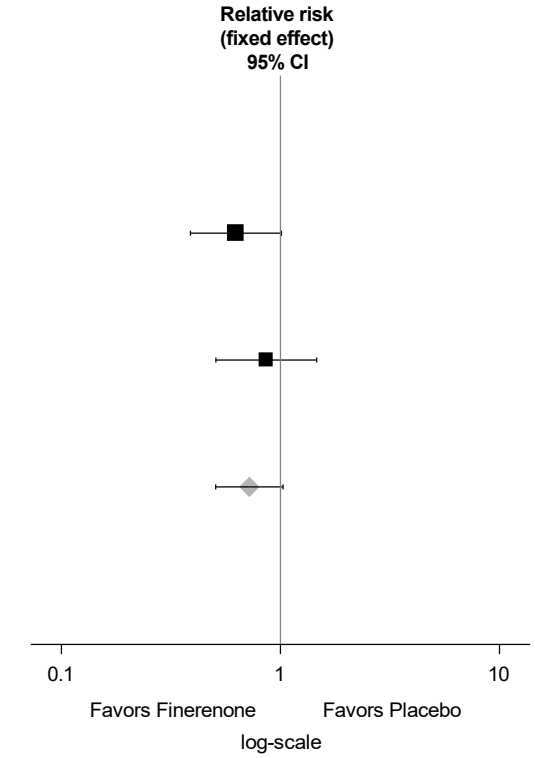
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	29 / 2610	58.2	1.03 [0.62,1.71]	
FIGARO-DKD	31 / 1357	16 / 1356	41.8	1.94 [1.06,3.52]	
Total	61 / 3974	45 / 3966		1.35 [0.92,1.99]	Z=1.55, p=0.1201
Heterogeneity:	Q=2.47 (df=1)	p=0.1158	I^2=59.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.35: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

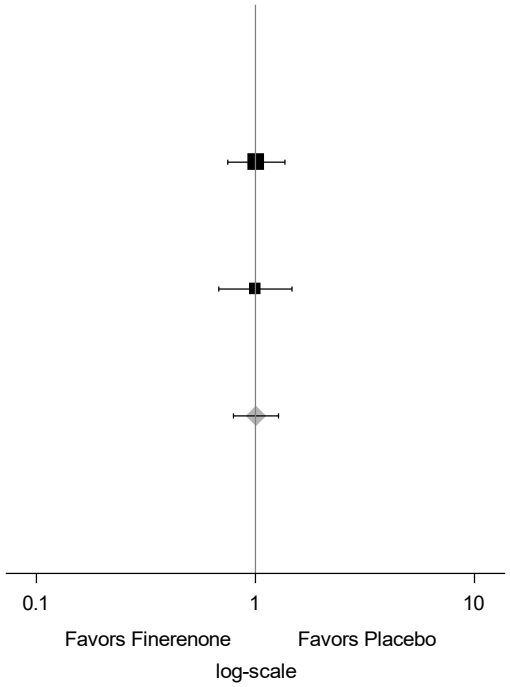
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	43 / 2610	55.1	0.63 [0.39,1.01]	
FIGARO-DKD	25 / 1357	29 / 1356	44.9	0.86 [0.51,1.46]	
Total	52 / 3974	72 / 3966		0.72 [0.51,1.03]	Z=-1.81, p=0.0703
Heterogeneity:	Q=0.77 (df=1)	p=0.3810	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.36: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

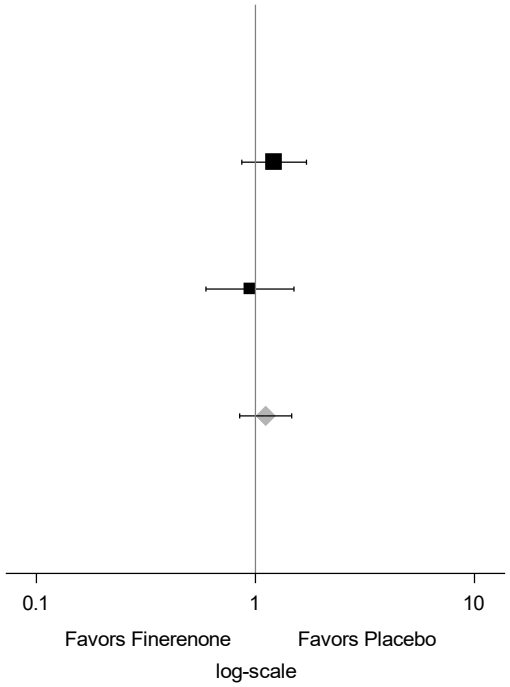
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	83 / 2617	82 / 2610	62.1	1.01 [0.75,1.36]	
FIGARO-DKD	50 / 1357	50 / 1356	37.9	1.00 [0.68,1.47]	
Total	133 / 3974	132 / 3966		1.01 [0.79,1.27]	Z=0.05, p=0.9631
Heterogeneity:	Q=0.00 (df=1)	p=0.9674	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.37: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

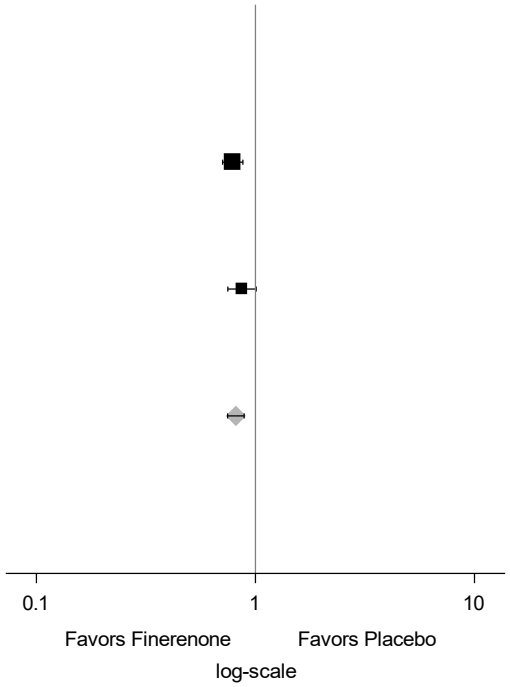
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	72 / 2617	59 / 2610	64.9	1.22 [0.87,1.71]	
FIGARO-DKD	34 / 1357	36 / 1356	35.1	0.94 [0.59,1.50]	
Total	106 / 3974	95 / 3966		1.11 [0.85,1.46]	Z=0.77, p=0.4408
Heterogeneity:	Q=0.75 (df=1)	p=0.3852	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.38: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

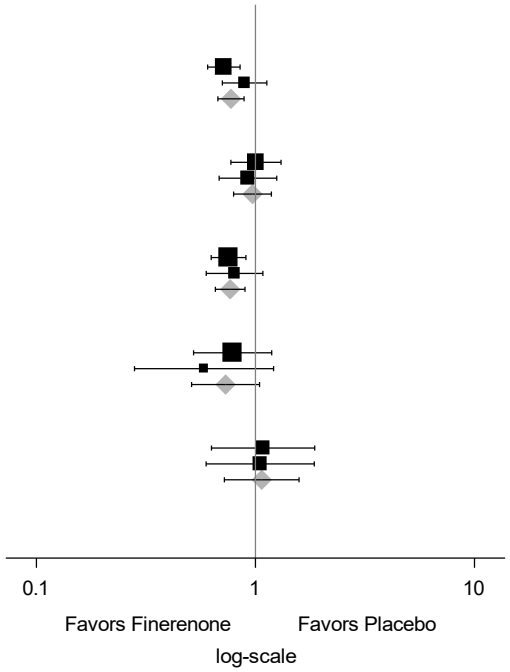
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	481 / 2617	609 / 2610	66.1	0.79 [0.71,0.88]	
FIGARO-DKD	258 / 1357	297 / 1356	33.9	0.87 [0.75,1.01]	
Total	739 / 3974	906 / 3966		0.81 [0.75,0.89]	Z=-4.66, p=<.0001
Heterogeneity:	Q=1.08 (df=1)	p=0.2984	I^2=7.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.38.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	183 / 1075	252 / 1062	65.3	0.72 [0.60,0.85]	
FIGARO-DKD	109 / 638	122 / 637	34.7	0.89 [0.71,1.13]	
Total	292 / 1713	374 / 1699		0.77 [0.67,0.89]	Z=-3.67, p=0.0002
Heterogeneity:	Q=2.18 (df=1)	p=0.1400	I^2=54.1%		
North America					
FIDELIO-DKD	87 / 424	89 / 436	56.9	1.01 [0.77,1.31]	
FIGARO-DKD	61 / 267	67 / 271	43.1	0.92 [0.68,1.25]	
Total	148 / 691	156 / 707		0.97 [0.79,1.18]	Z=-0.31, p=0.7591
Heterogeneity:	Q=0.17 (df=1)	p=0.6813	I^2=0.0%		
Asia					
FIDELIO-DKD	155 / 751	204 / 745	72.7	0.75 [0.63,0.90]	
FIGARO-DKD	60 / 289	75 / 290	27.3	0.80 [0.60,1.08]	
Total	215 / 1040	279 / 1035		0.77 [0.66,0.90]	Z=-3.34, p=0.0008
Heterogeneity:	Q=0.13 (df=1)	p=0.7236	I^2=0.0%		
Latin America					
FIDELIO-DKD	35 / 273	44 / 270	76.0	0.79 [0.52,1.19]	
FIGARO-DKD	10 / 102	17 / 101	24.0	0.58 [0.28,1.21]	
Total	45 / 375	61 / 371		0.73 [0.51,1.04]	Z=-1.72, p=0.0849
Heterogeneity:	Q=0.49 (df=1)	p=0.4823	I^2=0.0%		
Others					
FIDELIO-DKD	21 / 94	20 / 97	52.3	1.08 [0.63,1.86]	
FIGARO-DKD	18 / 61	16 / 57	47.7	1.05 [0.60,1.86]	
Total	39 / 155	36 / 154		1.07 [0.72,1.58]	Z=0.33, p=0.7426
Heterogeneity:	Q=0.01 (df=1)	p=0.9399	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.26 (df=4)	p=0.1802	I^2=36.2%		

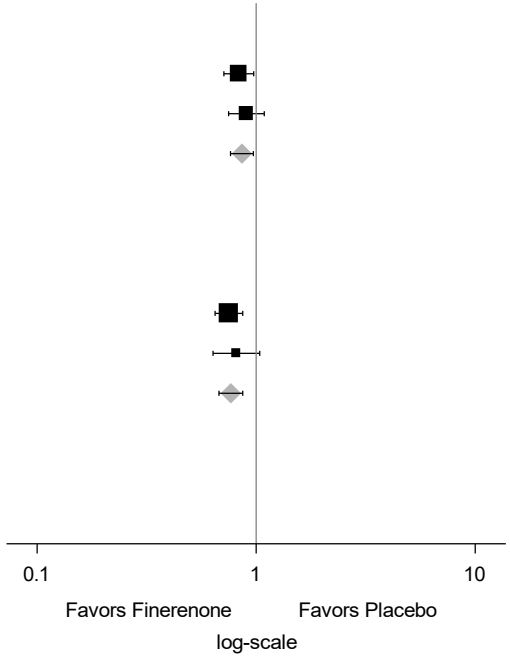


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.38.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

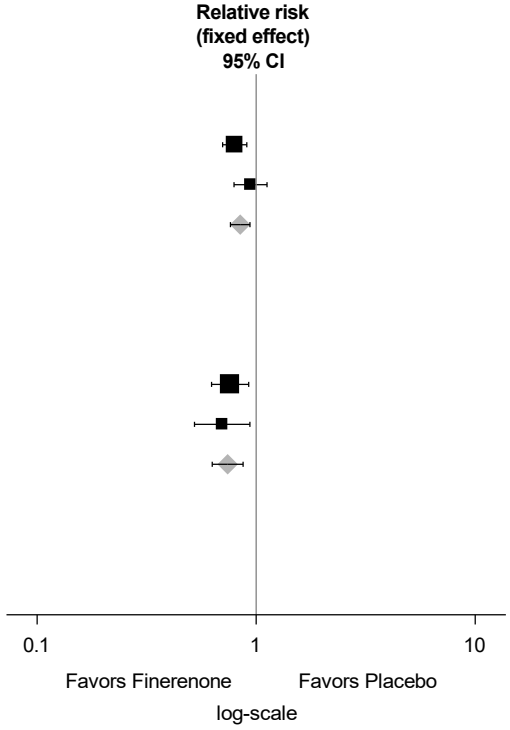
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	228 / 1213	273 / 1210	58.8	0.83 [0.71,0.97]	
FIGARO-DKD	167 / 862	182 / 848	41.2	0.90 [0.75,1.09]	
Total	395 / 2075	455 / 2058		0.86 [0.76,0.97]	Z=-2.44, p=0.0147
Heterogeneity:	Q=0.41 (df=1)	p=0.5199	I^2=0.0%		
Absent					
FIDELIO-DKD	253 / 1404	336 / 1400	74.0	0.75 [0.65,0.87]	
FIGARO-DKD	91 / 495	115 / 508	26.0	0.81 [0.64,1.04]	
Total	344 / 1899	451 / 1908		0.77 [0.68,0.87]	Z=-4.17, p=<.0001
Heterogeneity:	Q=0.29 (df=1)	p=0.5901	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.74 (df=1)	p=0.1875	I^2=42.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.38.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

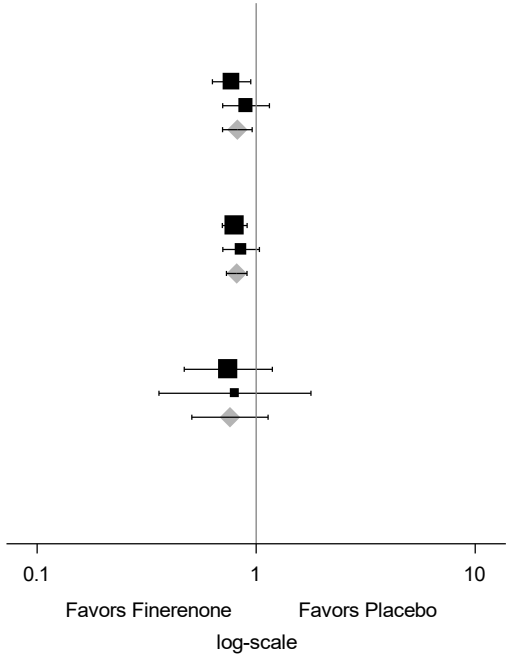
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	338 / 1735	415 / 1700	65.1	0.80 [0.70,0.91]	
FIGARO-DKD	194 / 924	207 / 929	34.9	0.94 [0.79,1.12]	
Total	532 / 2659	622 / 2629		0.85 [0.76,0.94]	Z=-3.21, p=0.0013
Heterogeneity:	Q=2.29 (df=1)	p=0.1298	I^2=56.4%		
> 4.5					
FIDELIO-DKD	143 / 882	194 / 910	69.0	0.76 [0.63,0.92]	
FIGARO-DKD	64 / 433	90 / 426	31.0	0.70 [0.52,0.94]	
Total	207 / 1315	284 / 1336		0.74 [0.63,0.87]	Z=-3.62, p=0.0003
Heterogeneity:	Q=0.22 (df=1)	p=0.6408	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.82 (df=1)	p=0.1777	I^2=45.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.38.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

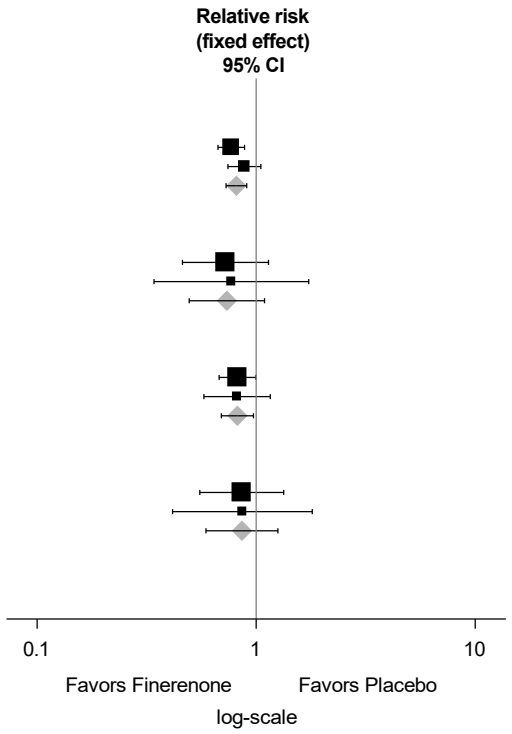
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	133 / 724	172 / 723	59.8	0.77 [0.63,0.94]	
FIGARO-DKD	96 / 494	107 / 495	40.2	0.90 [0.70,1.15]	
Total	229 / 1218	279 / 1218		0.82 [0.70,0.96]	Z=-2.49, p=0.0128
Heterogeneity:	Q=0.88 (df=1)	p=0.3483	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	323 / 1759	405 / 1760	68.5	0.80 [0.70,0.91]	
FIGARO-DKD	154 / 829	180 / 827	31.5	0.85 [0.70,1.03]	
Total	477 / 2588	585 / 2587		0.82 [0.73,0.91]	Z=-3.71, p=0.0002
Heterogeneity:	Q=0.32 (df=1)	p=0.5707	I^2=0.0%		
>= 160					
FIDELIO-DKD	25 / 133	32 / 127	74.8	0.75 [0.47,1.19]	
FIGARO-DKD	8 / 34	10 / 34	25.2	0.80 [0.36,1.78]	
Total	33 / 167	42 / 161		0.76 [0.51,1.13]	Z=-1.35, p=0.1779
Heterogeneity:	Q=0.02 (df=1)	p=0.8821	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=2)	p=0.9385	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.38.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

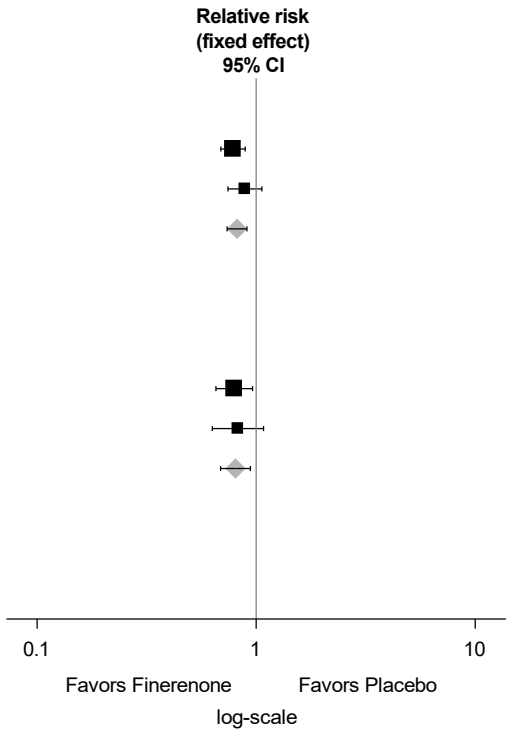
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	280 / 1634	369 / 1657	60.6	0.77 [0.67,0.88]	
FIGARO-DKD	194 / 1010	215 / 989	39.4	0.88 [0.74,1.05]	
Total	474 / 2644	584 / 2646		0.81 [0.73,0.91]	Z=-3.76, p=0.0002
Heterogeneity:	Q=1.48 (df=1)	p=0.2230	I^2=32.7%		
Black					
FIDELIO-DKD	26 / 129	32 / 115	76.4	0.72 [0.46,1.14]	
FIGARO-DKD	7 / 43	15 / 71	23.6	0.77 [0.34,1.74]	
Total	33 / 172	47 / 186		0.73 [0.49,1.09]	Z=-1.52, p=0.1274
Heterogeneity:	Q=0.02 (df=1)	p=0.8963	I^2=0.0%		
Asian					
FIDELIO-DKD	144 / 678	175 / 677	76.5	0.82 [0.68,1.00]	
FIGARO-DKD	46 / 252	56 / 251	23.5	0.82 [0.58,1.16]	
Total	190 / 930	231 / 928		0.82 [0.69,0.97]	Z=-2.29, p=0.0220
Heterogeneity:	Q=0.00 (df=1)	p=0.9834	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 176	33 / 161	73.5	0.86 [0.55,1.34]	
FIGARO-DKD	11 / 52	11 / 45	26.5	0.87 [0.42,1.80]	
Total	42 / 228	44 / 206		0.86 [0.59,1.26]	Z=-0.78, p=0.4377
Heterogeneity:	Q=0.00 (df=1)	p=0.9872	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.35 (df=3)	p=0.9502	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.38.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

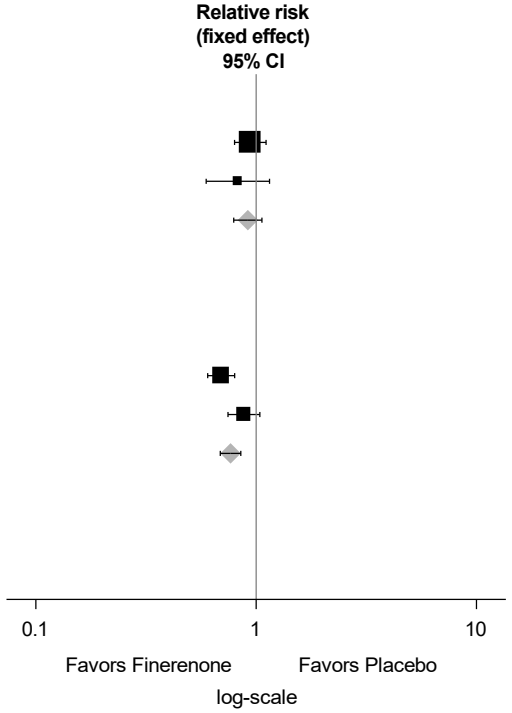
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	327 / 1797	434 / 1870	66.0	0.78 [0.69,0.89]	
FIGARO-DKD	179 / 917	205 / 933	34.0	0.89 [0.74,1.06]	
Total	506 / 2714	639 / 2803		0.82 [0.74,0.91]	Z=-3.79, p=0.0002
Heterogeneity:	Q=1.24 (df=1)	p=0.2652	I^2=19.5%		
Female					
FIDELIO-DKD	154 / 820	175 / 740	66.2	0.79 [0.66,0.96]	
FIGARO-DKD	79 / 440	92 / 423	33.8	0.83 [0.63,1.08]	
Total	233 / 1260	267 / 1163		0.80 [0.69,0.94]	Z=-2.72, p=0.0065
Heterogeneity:	Q=0.05 (df=1)	p=0.8186	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8649	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.38.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

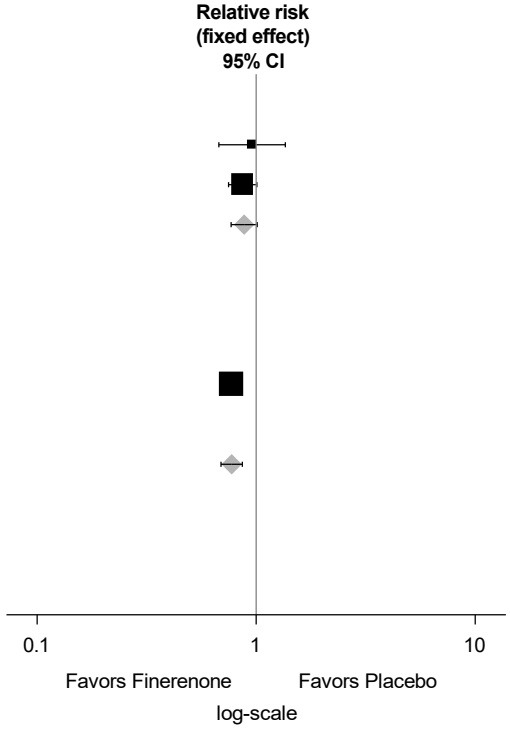
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	221 / 1103	229 / 1075	80.2	0.94 [0.80,1.11]	
FIGARO-DKD	53 / 336	64 / 335	19.8	0.83 [0.59,1.15]	
Total	274 / 1439	293 / 1410		0.92 [0.79,1.06]	Z=-1.16, p=0.2459
Heterogeneity:	Q=0.48 (df=1)	p=0.4897	I^2=0.0%		
>= 65					
FIDELIO-DKD	260 / 1514	380 / 1535	58.3	0.69 [0.60,0.80]	
FIGARO-DKD	205 / 1021	233 / 1021	41.7	0.88 [0.74,1.04]	
Total	465 / 2535	613 / 2556		0.77 [0.69,0.85]	Z=-4.89, p=<.0001
Heterogeneity:	Q=4.57 (df=1)	p=0.0326	I^2=78.1%		
Subgroup Heterogeneity:	Q=3.77 (df=1)	p=0.0521	I^2=73.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.38.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

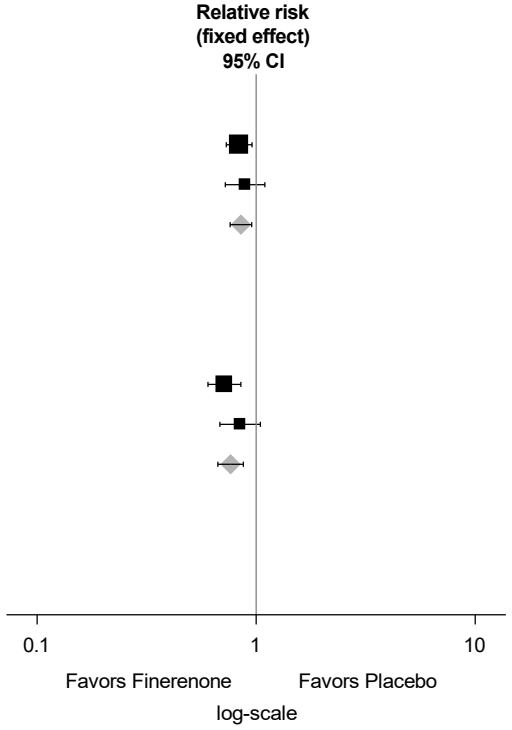
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	50 / 213	15.4	0.96 [0.68,1.36]	
FIGARO-DKD	258 / 1357	297 / 1356	84.6	0.87 [0.75,1.01]	
Total	305 / 1566	347 / 1569		0.88 [0.77,1.01]	Z=-1.81, p=0.0704
Heterogeneity:	Q=0.26 (df=1)	p=0.6110	I^2=0.0%		
Very High					
FIDELIO-DKD	434 / 2408	559 / 2397	100.0	0.77 [0.69,0.86]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	434 / 2408	559 / 2397		0.77 [0.69,0.86]	Z=-4.51, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.12 (df=1)	p=0.1458	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.38.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

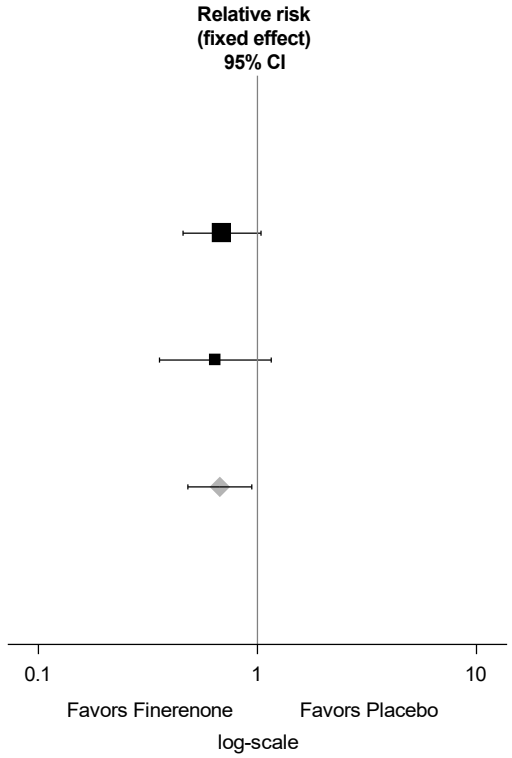
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	304 / 1556	360 / 1541	70.2	0.84 [0.73,0.96]	
FIGARO-DKD	132 / 637	146 / 627	29.8	0.89 [0.72,1.10]	
Total	436 / 2193	506 / 2168		0.85 [0.76,0.95]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.24 (df=1)	p=0.6237	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	177 / 1061	249 / 1069	60.2	0.72 [0.60,0.85]	
FIGARO-DKD	126 / 720	151 / 729	39.8	0.84 [0.68,1.05]	
Total	303 / 1781	400 / 1798		0.76 [0.67,0.87]	Z=-3.93, p=<.0001
Heterogeneity:	Q=1.39 (df=1)	p=0.2378	I^2=28.3%		
Subgroup Heterogeneity:	Q=1.46 (df=1)	p=0.2264	I^2=31.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

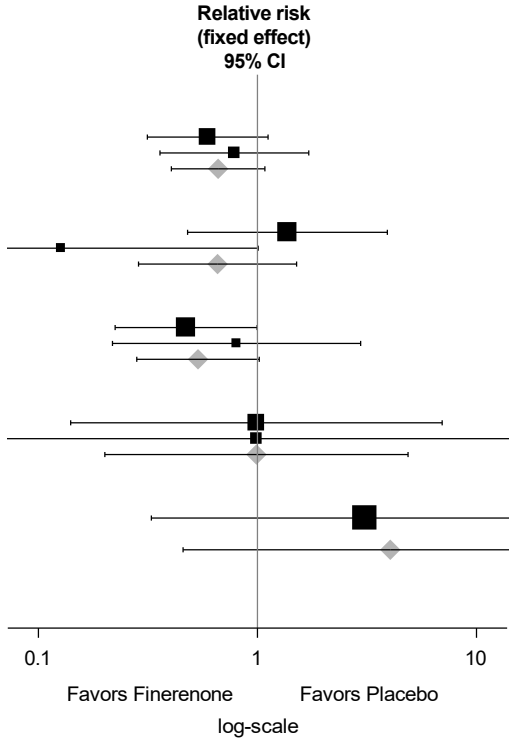
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	55 / 2610	67.2	0.69 [0.46,1.04]	
FIGARO-DKD	18 / 1357	28 / 1356	32.8	0.64 [0.36,1.16]	
Total	56 / 3974	83 / 3966		0.67 [0.48,0.94]	Z=-2.31, p=0.0211
Heterogeneity:	Q=0.04 (df=1)	p=0.8478	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.39.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

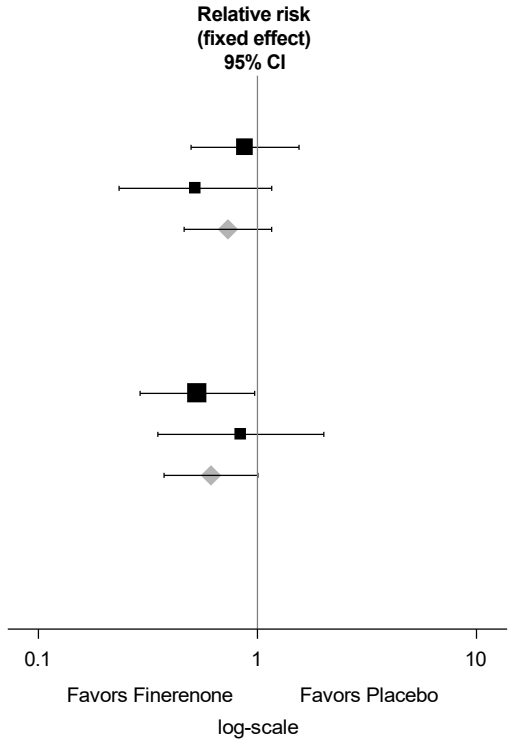
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	25 / 1062	60.3	0.59 [0.31,1.12]	
FIGARO-DKD	11 / 638	14 / 637	39.7	0.78 [0.36,1.71]	
Total	26 / 1713	39 / 1699		0.66 [0.40,1.08]	Z=-1.65, p=0.0993
Heterogeneity:	Q=0.30 (df=1)	p=0.5854	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	6 / 436	79.6	1.37 [0.48,3.92]	
FIGARO-DKD	1 / 267	8 / 271	20.4	0.13 [0.02,1.01]	
Total	9 / 691	14 / 707		0.66 [0.29,1.51]	Z=-0.99, p=0.3226
Heterogeneity:	Q=4.30 (df=1)	p=0.0380	I^2=76.8%		
Asia					
FIDELIO-DKD	10 / 751	21 / 745	75.4	0.47 [0.22,1.00]	
FIGARO-DKD	4 / 289	5 / 290	24.6	0.80 [0.22,2.96]	
Total	14 / 1040	26 / 1035		0.54 [0.28,1.02]	Z=-1.90, p=0.0571
Heterogeneity:	Q=0.48 (df=1)	p=0.4891	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	2 / 270	66.6	0.99 [0.14,6.97]	
FIGARO-DKD	1 / 102	1 / 101	33.4	0.99 [0.06,15.62]	
Total	3 / 375	3 / 371		0.99 [0.20,4.87]	Z=-0.01, p=0.9896
Heterogeneity:	Q=0.00 (df=1)	p=0.9994	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 94	1 / 97	100.0	3.10 [0.33,29.23]	
FIGARO-DKD	1 / 61	0 / 57	0.0	854E8 [854E8,854E8]	
Total	4 / 155	1 / 154		4.04 [0.46,35.69]	Z=1.26, p=0.2090
Heterogeneity:	Q=0.05 (df=1)	p=0.8162	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.31 (df=4)	p=0.5071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

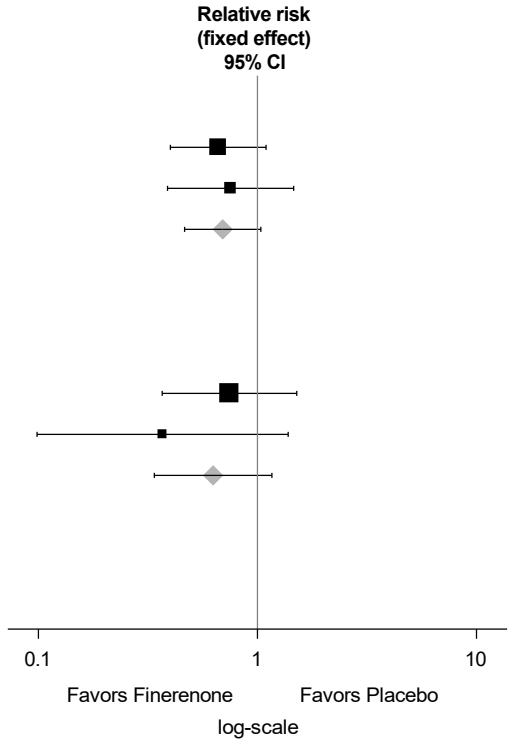
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	22 / 1213	25 / 1210	66.7	0.88 [0.50,1.55]	
FIGARO-DKD	9 / 862	17 / 848	33.3	0.52 [0.23,1.16]	
Total	31 / 2075	42 / 2058		0.73 [0.46,1.16]	Z=-1.32, p=0.1857
Heterogeneity:	Q=1.08 (df=1)	p=0.2976	I^2=7.8%		
Absent					
FIDELIO-DKD	16 / 1404	30 / 1400	67.7	0.53 [0.29,0.97]	
FIGARO-DKD	9 / 495	11 / 508	32.3	0.84 [0.35,2.01]	
Total	25 / 1899	41 / 1908		0.61 [0.37,1.00]	Z=-1.94, p=0.0522
Heterogeneity:	Q=0.71 (df=1)	p=0.3983	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6052	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

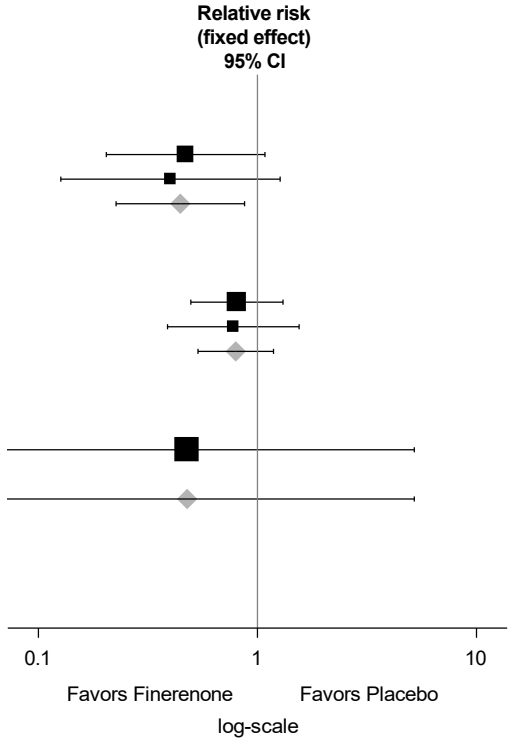
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1735	37 / 1700	63.5	0.66 [0.40,1.09]	
FIGARO-DKD	15 / 924	20 / 929	36.5	0.75 [0.39,1.46]	
Total	40 / 2659	57 / 2629		0.69 [0.46,1.04]	Z=-1.79, p=0.0740
Heterogeneity:	Q=0.09 (df=1)	p=0.7593	I^2=0.0%		
> 4.5					
FIDELIO-DKD	13 / 882	18 / 910	77.7	0.75 [0.37,1.51]	
FIGARO-DKD	3 / 433	8 / 426	22.3	0.37 [0.10,1.38]	
Total	16 / 1315	26 / 1336		0.63 [0.34,1.16]	Z=-1.48, p=0.1393
Heterogeneity:	Q=0.85 (df=1)	p=0.3570	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7882	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

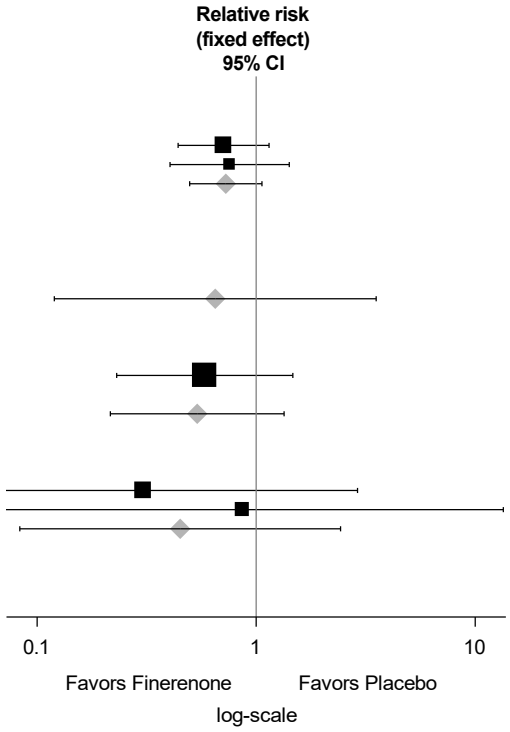
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 724	17 / 723	65.6	0.47 [0.20,1.08]	
FIGARO-DKD	4 / 494	10 / 495	34.4	0.40 [0.13,1.27]	
Total	12 / 1218	27 / 1218		0.44 [0.23,0.87]	Z=-2.35, p=0.0186
Heterogeneity:	Q=0.05 (df=1)	p=0.8265	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	29 / 1759	36 / 1760	67.1	0.81 [0.50,1.31]	
FIGARO-DKD	14 / 829	18 / 827	32.9	0.78 [0.39,1.55]	
Total	43 / 2588	54 / 2587		0.80 [0.54,1.18]	Z=-1.13, p=0.2597
Heterogeneity:	Q=0.01 (df=1)	p=0.9296	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	2 / 127	100.0	0.48 [0.04,5.20]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	1 / 167	2 / 161		0.48 [0.04,5.20]	Z=-0.61, p=0.5440
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.21 (df=2)	p=0.3307	I^2=9.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

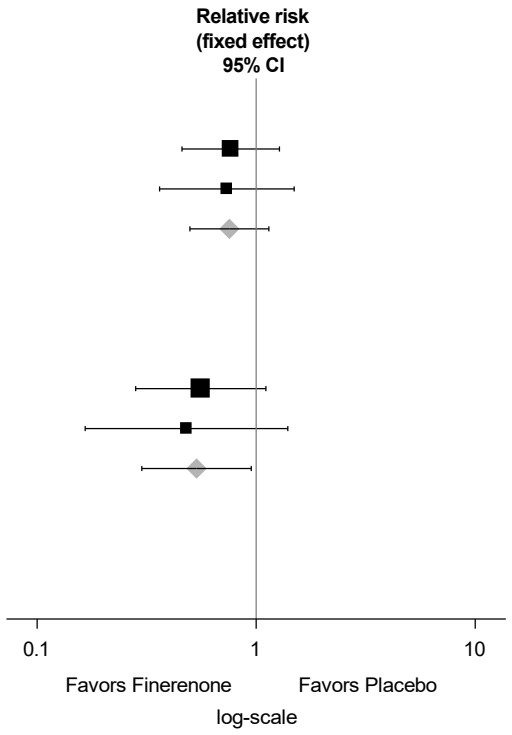
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	28 / 1634	40 / 1657	63.2	0.71 [0.44,1.14]	
FIGARO-DKD	17 / 1010	22 / 989	36.8	0.76 [0.40,1.42]	
Total	45 / 2644	62 / 2646		0.73 [0.50,1.06]	Z=-1.65, p=0.0996
Heterogeneity:	Q=0.03 (df=1)	p=0.8739	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	0 / 115	0.0	808E8 [808E8,808E8]	
FIGARO-DKD	0 / 43	4 / 71	0.0	0.00 [0.00,17E296]	
Total	2 / 172	4 / 186		0.65 [0.12,3.53]	Z=-0.50, p=0.6182
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	7 / 678	12 / 677	100.0	0.58 [0.23,1.47]	
FIGARO-DKD	0 / 252	1 / 251	0.0	0.00 [0.00,11E296]	
Total	7 / 930	13 / 928		0.54 [0.22,1.34]	Z=-1.33, p=0.1834
Heterogeneity:	Q=0.03 (df=1)	p=0.8667	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	3 / 161	59.7	0.30 [0.03,2.90]	
FIGARO-DKD	1 / 52	1 / 45	40.3	0.87 [0.06,13.44]	
Total	2 / 228	4 / 206		0.45 [0.08,2.43]	Z=-0.93, p=0.3531
Heterogeneity:	Q=0.33 (df=1)	p=0.5639	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.60 (df=3)	p=0.8958	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.39.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

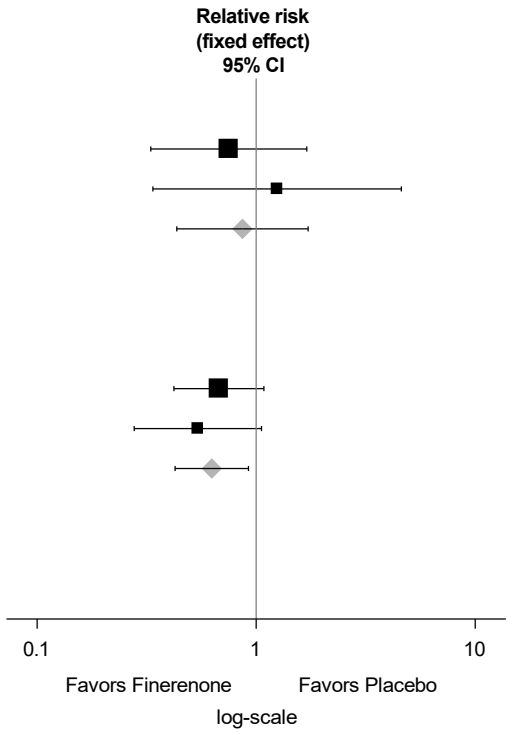
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1797	34 / 1870	65.6	0.77 [0.46,1.28]	
FIGARO-DKD	13 / 917	18 / 933	34.4	0.73 [0.36,1.49]	
Total	38 / 2714	52 / 2803		0.75 [0.50,1.14]	Z=-1.33, p=0.1835
Heterogeneity:	Q=0.01 (df=1)	p=0.9277	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 820	21 / 740	70.8	0.56 [0.28,1.11]	
FIGARO-DKD	5 / 440	10 / 423	29.2	0.48 [0.17,1.39]	
Total	18 / 1260	31 / 1163		0.53 [0.30,0.95]	Z=-2.14, p=0.0327
Heterogeneity:	Q=0.05 (df=1)	p=0.8160	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.91 (df=1)	p=0.3401	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.39.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

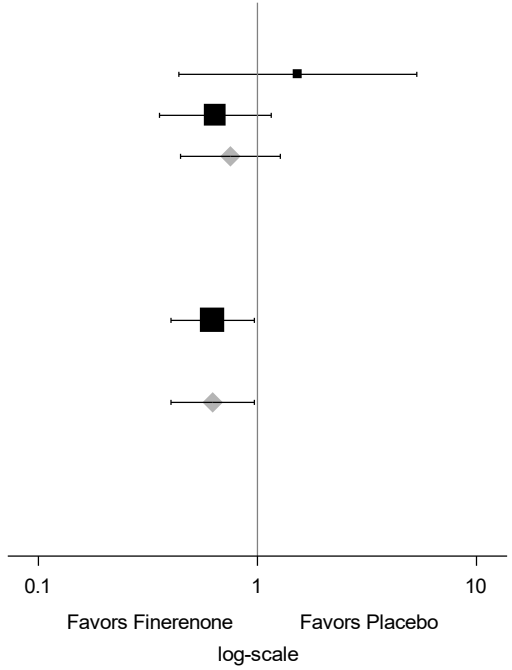
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1103	13 / 1075	71.7	0.75 [0.33,1.70]	
FIGARO-DKD	5 / 336	4 / 335	28.3	1.25 [0.34,4.60]	
Total	15 / 1439	17 / 1410		0.87 [0.43,1.73]	Z=-0.41, p=0.6823
Heterogeneity:	Q=0.42 (df=1)	p=0.5183	I^2=0.0%		
>= 65					
FIDELIO-DKD	28 / 1514	42 / 1535	66.7	0.68 [0.42,1.08]	
FIGARO-DKD	13 / 1021	24 / 1021	33.3	0.54 [0.28,1.06]	
Total	41 / 2535	66 / 2556		0.63 [0.43,0.92]	Z=-2.37, p=0.0177
Heterogeneity:	Q=0.28 (df=1)	p=0.5964	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4239	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.39.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

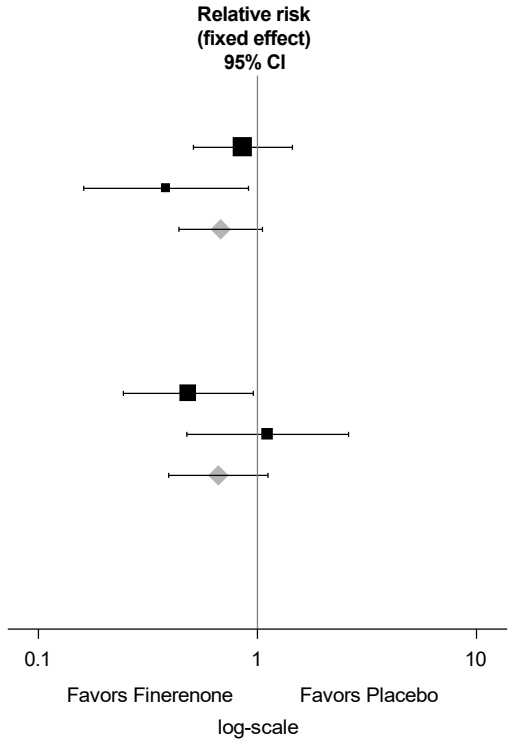
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	6 / 209	4 / 213	18.1	1.53 [0.44,5.34]	
FIGARO-DKD	18 / 1357	28 / 1356	81.9	0.64 [0.36,1.16]	
Total	24 / 1566	32 / 1569		0.75 [0.45,1.27]	Z=-1.06, p=0.2885
Heterogeneity:	Q=1.51 (df=1)	p=0.2188	I^2=33.9%		
Very High					
FIDELIO-DKD	32 / 2408	51 / 2397	100.0	0.62 [0.40,0.97]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	32 / 2408	51 / 2397		0.62 [0.40,0.97]	Z=-2.10, p=0.0353
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5926	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.39.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

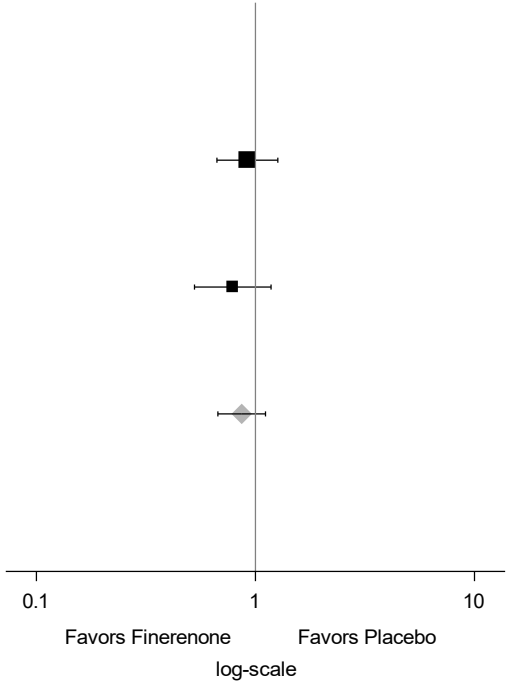
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	26 / 1556	30 / 1541	73.5	0.86 [0.51,1.44]	
FIGARO-DKD	7 / 637	18 / 627	26.5	0.38 [0.16,0.91]	
Total	33 / 2193	48 / 2168		0.68 [0.44,1.05]	Z=-1.72, p=0.0845
Heterogeneity:	Q=2.46 (df=1)	p=0.1167	I^2=59.4%		
45 - < 60					
FIDELIO-DKD	12 / 1061	25 / 1069	60.8	0.48 [0.24,0.96]	
FIGARO-DKD	11 / 720	10 / 729	39.2	1.11 [0.48,2.61]	
Total	23 / 1781	35 / 1798		0.66 [0.39,1.12]	Z=-1.54, p=0.1227
Heterogeneity:	Q=2.25 (df=1)	p=0.1337	I^2=55.5%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9438	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.40: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

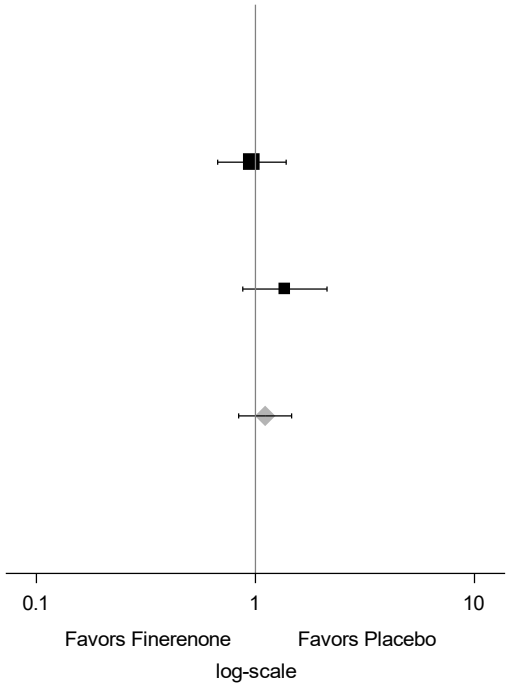
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2617	76 / 2610	61.2	0.92 [0.67,1.27]	
FIGARO-DKD	41 / 1357	52 / 1356	38.8	0.79 [0.53,1.18]	
Total	111 / 3974	128 / 3966		0.87 [0.67,1.11]	Z=-1.13, p=0.2574
Heterogeneity:	Q=0.34 (df=1)	p=0.5585	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.41: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

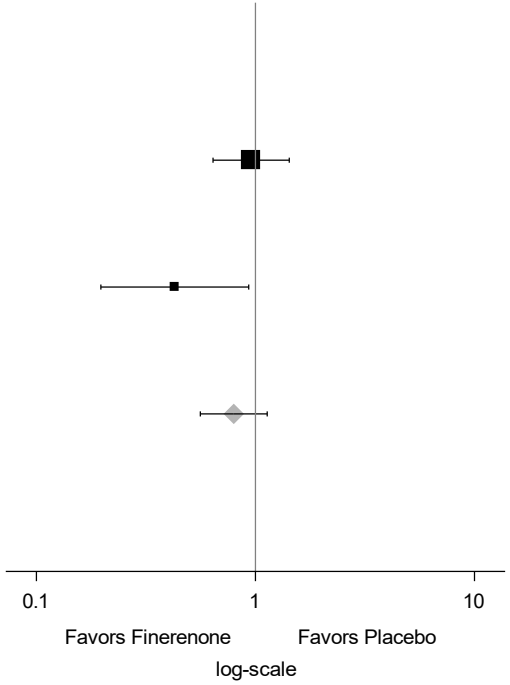
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2617	59 / 2610	60.2	0.96 [0.67,1.38]	
FIGARO-DKD	45 / 1357	33 / 1356	39.8	1.36 [0.88,2.12]	
Total	102 / 3974	92 / 3966		1.11 [0.84,1.46]	Z=0.72, p=0.4732
Heterogeneity:	Q=1.42 (df=1)	p=0.2339	I^2=29.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.42: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

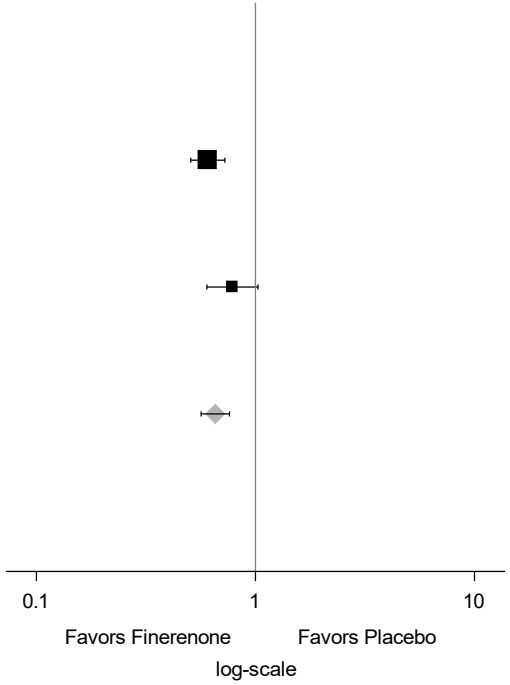
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	48 / 2610	79.0	0.96 [0.64,1.43]	
FIGARO-DKD	9 / 1357	21 / 1356	21.0	0.43 [0.20,0.93]	
Total	55 / 3974	69 / 3966		0.80 [0.56,1.13]	Z=-1.27, p=0.2035
Heterogeneity:	Q=3.24 (df=1)	p=0.0717	I^2=69.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.43: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

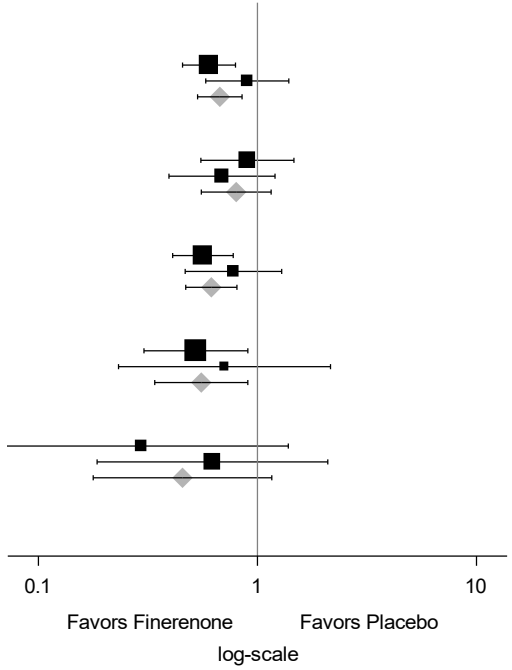
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	175 / 2617	288 / 2610	69.1	0.61 [0.51,0.73]	
FIGARO-DKD	88 / 1357	112 / 1356	30.9	0.79 [0.60,1.03]	
Total	263 / 3974	400 / 3966		0.66 [0.56,0.76]	Z=-5.55, p=<.0001
Heterogeneity:	Q=2.46 (df=1)	p=0.1166	I^2=59.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.43.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

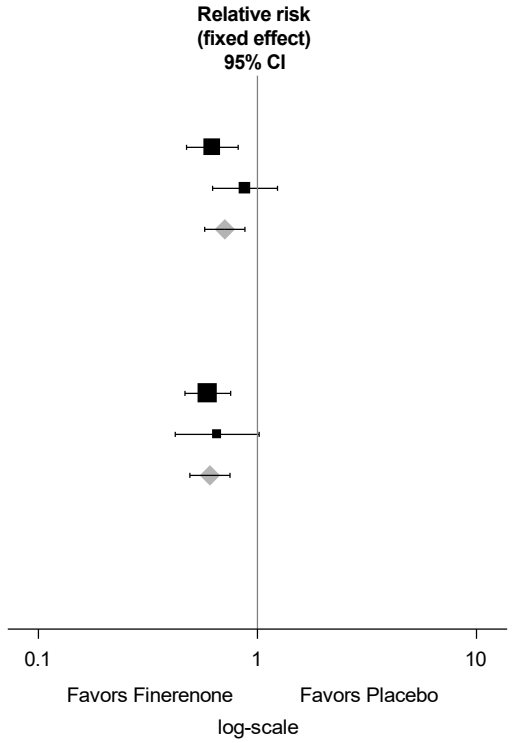
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	73 / 1075	120 / 1062	71.1	0.60 [0.45,0.79]	
FIGARO-DKD	36 / 638	40 / 637	28.9	0.90 [0.58,1.39]	
Total	109 / 1713	160 / 1699		0.67 [0.53,0.85]	Z=-3.32, p=0.0009
Heterogeneity:	Q=2.32 (df=1)	p=0.1278	I^2=56.9%		
North America					
FIDELIO-DKD	28 / 424	32 / 436	56.5	0.90 [0.55,1.47]	
FIGARO-DKD	19 / 267	28 / 271	43.5	0.69 [0.39,1.20]	
Total	47 / 691	60 / 707		0.80 [0.55,1.15]	Z=-1.19, p=0.2330
Heterogeneity:	Q=0.50 (df=1)	p=0.4800	I^2=0.0%		
Asia					
FIDELIO-DKD	54 / 751	95 / 745	71.8	0.56 [0.41,0.78]	
FIGARO-DKD	24 / 289	31 / 290	28.2	0.78 [0.47,1.29]	
Total	78 / 1040	126 / 1035		0.62 [0.47,0.81]	Z=-3.53, p=0.0004
Heterogeneity:	Q=1.10 (df=1)	p=0.2943	I^2=9.1%		
Latin America					
FIDELIO-DKD	18 / 273	34 / 270	80.6	0.52 [0.30,0.90]	
FIGARO-DKD	5 / 102	7 / 101	19.4	0.71 [0.23,2.16]	
Total	23 / 375	41 / 371		0.55 [0.34,0.90]	Z=-2.37, p=0.0180
Heterogeneity:	Q=0.23 (df=1)	p=0.6347	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	7 / 97	38.1	0.29 [0.06,1.38]	
FIGARO-DKD	4 / 61	6 / 57	61.9	0.62 [0.19,2.09]	
Total	6 / 155	13 / 154		0.45 [0.18,1.16]	Z=-1.65, p=0.0999
Heterogeneity:	Q=0.56 (df=1)	p=0.4540	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=4)	p=0.6580	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.43.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

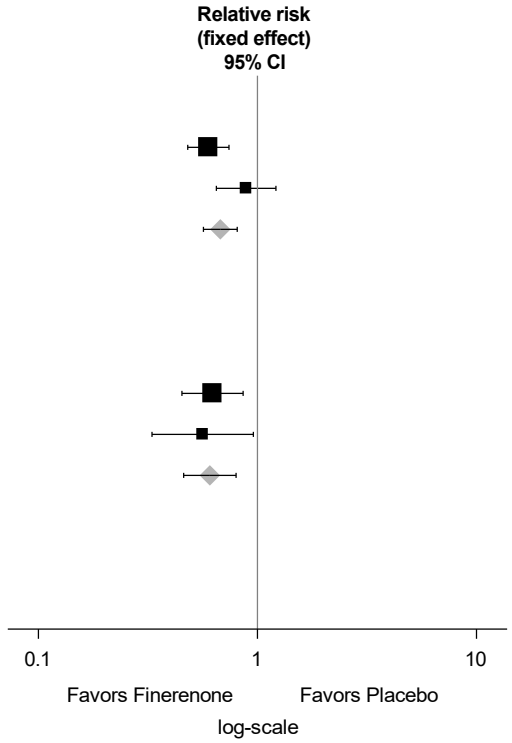
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	78 / 1213	125 / 1210	61.2	0.62 [0.47,0.82]	
FIGARO-DKD	58 / 862	65 / 848	38.8	0.88 [0.62,1.23]	
Total	136 / 2075	190 / 2058		0.71 [0.57,0.88]	Z=-3.18, p=0.0015
Heterogeneity:	Q=2.39 (df=1)	p=0.1221	I^2=58.2%		
Absent					
FIDELIO-DKD	97 / 1404	163 / 1400	77.1	0.59 [0.47,0.75]	
FIGARO-DKD	30 / 495	47 / 508	22.9	0.66 [0.42,1.02]	
Total	127 / 1899	210 / 1908		0.61 [0.49,0.75]	Z=-4.64, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.6996	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3047	I^2=5.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.43.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	120 / 1735	197 / 1700	67.6	0.60 [0.48,0.74]	
FIGARO-DKD	68 / 924	77 / 929	32.4	0.89 [0.65,1.21]	
Total	188 / 2659	274 / 2629		0.68 [0.57,0.81]	Z=-4.31, p=<.0001
Heterogeneity:	Q=4.18 (df=1)	p=0.0410	I^2=76.1%		
> 4.5					
FIDELIO-DKD	55 / 882	91 / 910	73.3	0.62 [0.45,0.86]	
FIGARO-DKD	20 / 433	35 / 426	26.7	0.56 [0.33,0.96]	
Total	75 / 1315	126 / 1336		0.61 [0.46,0.80]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.11 (df=1)	p=0.7442	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5108	I^2=0.0%		

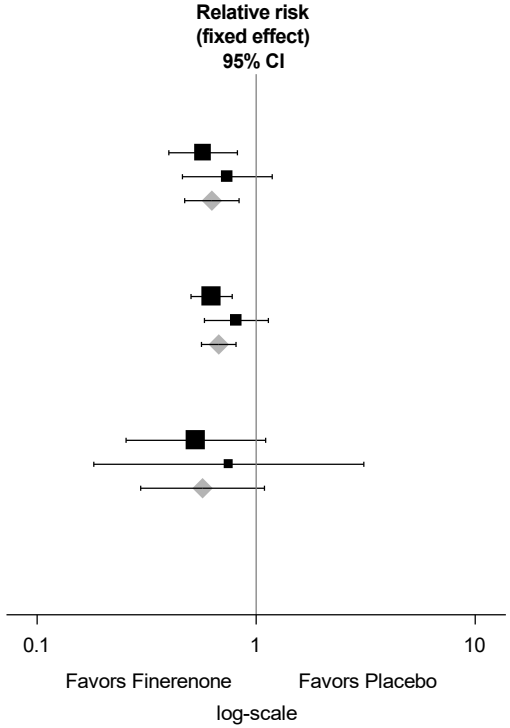


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.43.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

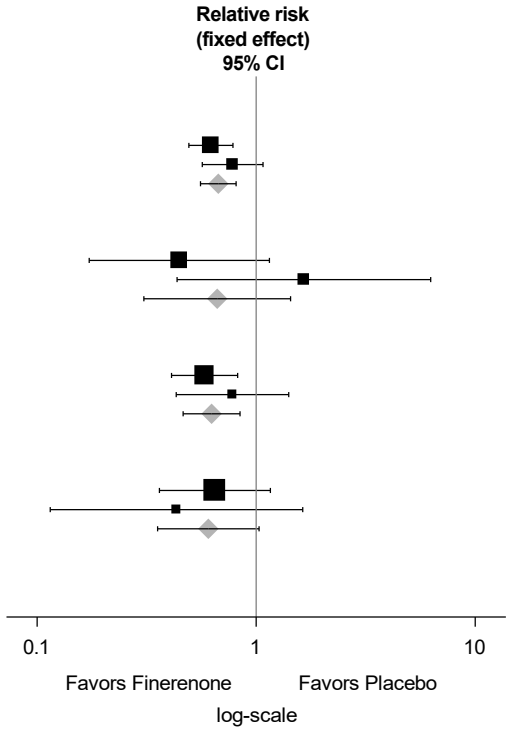
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	43 / 724	75 / 723	63.2	0.57 [0.40,0.82]	
FIGARO-DKD	28 / 494	38 / 495	36.8	0.74 [0.46,1.18]	
Total	71 / 1218	113 / 1218		0.63 [0.47,0.84]	Z=-3.19, p=0.0014
Heterogeneity:	Q=0.70 (df=1)	p=0.4012	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	122 / 1759	195 / 1760	70.7	0.63 [0.50,0.78]	
FIGARO-DKD	57 / 829	70 / 827	29.3	0.81 [0.58,1.14]	
Total	179 / 2588	265 / 2587		0.67 [0.56,0.81]	Z=-4.25, p=<.0001
Heterogeneity:	Q=1.63 (df=1)	p=0.2014	I^2=38.7%		
>= 160					
FIDELIO-DKD	10 / 133	18 / 127	78.9	0.53 [0.25,1.10]	
FIGARO-DKD	3 / 34	4 / 34	21.1	0.75 [0.18,3.10]	
Total	13 / 167	22 / 161		0.57 [0.30,1.09]	Z=-1.70, p=0.0896
Heterogeneity:	Q=0.18 (df=1)	p=0.6710	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=2)	p=0.8323	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.43.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

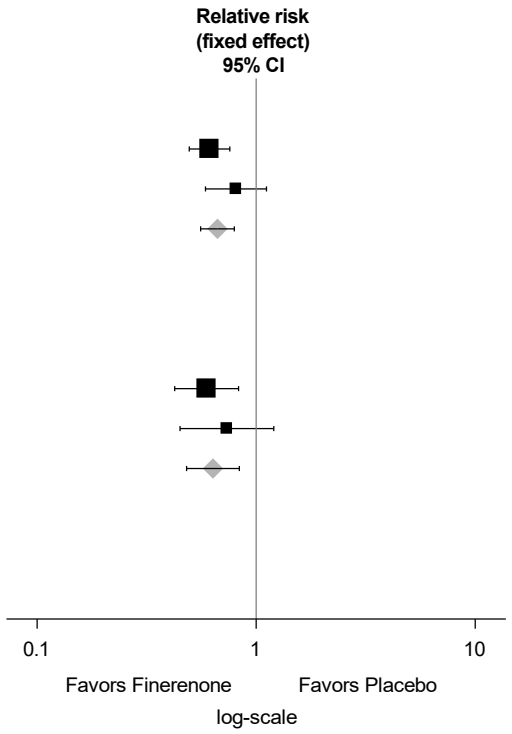
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	106 / 1634	173 / 1657	65.5	0.62 [0.49,0.78]	
FIGARO-DKD	63 / 1010	79 / 989	34.5	0.78 [0.57,1.07]	
Total	169 / 2644	252 / 2646		0.67 [0.56,0.81]	Z=-4.17, p=<.0001
Heterogeneity:	Q=1.29 (df=1)	p=0.2562	I^2=22.4%		
Black					
FIDELIO-DKD	6 / 129	12 / 115	66.5	0.45 [0.17,1.15]	
FIGARO-DKD	4 / 43	4 / 71	33.5	1.65 [0.44,6.26]	
Total	10 / 172	16 / 186		0.66 [0.31,1.44]	Z=-1.04, p=0.2980
Heterogeneity:	Q=2.47 (df=1)	p=0.1158	I^2=59.6%		
Asian					
FIDELIO-DKD	46 / 678	79 / 677	74.3	0.58 [0.41,0.82]	
FIGARO-DKD	18 / 252	23 / 251	25.7	0.78 [0.43,1.41]	
Total	64 / 930	102 / 928		0.63 [0.46,0.84]	Z=-3.07, p=0.0021
Heterogeneity:	Q=0.70 (df=1)	p=0.4022	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 176	24 / 161	83.8	0.65 [0.36,1.16]	
FIGARO-DKD	3 / 52	6 / 45	16.2	0.43 [0.11,1.63]	
Total	20 / 228	30 / 206		0.60 [0.35,1.03]	Z=-1.85, p=0.0645
Heterogeneity:	Q=0.30 (df=1)	p=0.5850	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.25 (df=3)	p=0.9700	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.43.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

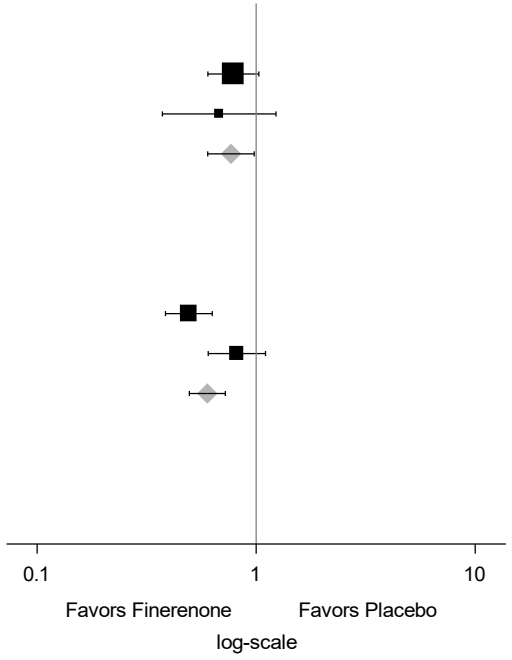
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	123 / 1797	209 / 1870	69.4	0.61 [0.49,0.76]	
FIGARO-DKD	62 / 917	78 / 933	30.6	0.81 [0.59,1.11]	
Total	185 / 2714	287 / 2803		0.67 [0.56,0.79]	Z=-4.50, p=<.0001
Heterogeneity:	Q=2.00 (df=1)	p=0.1570	I^2=50.1%		
Female					
FIDELIO-DKD	52 / 820	79 / 740	68.3	0.59 [0.42,0.83]	
FIGARO-DKD	26 / 440	34 / 423	31.7	0.74 [0.45,1.20]	
Total	78 / 1260	113 / 1163		0.63 [0.48,0.84]	Z=-3.21, p=0.0013
Heterogeneity:	Q=0.49 (df=1)	p=0.4834	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7776	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.43.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

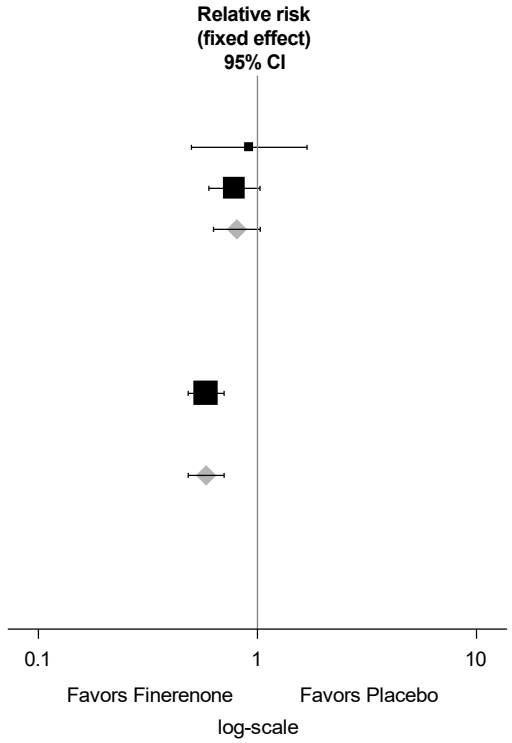
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	88 / 1103	109 / 1075	83.2	0.79 [0.60,1.03]	
FIGARO-DKD	17 / 336	25 / 335	16.8	0.68 [0.37,1.23]	
Total	105 / 1439	134 / 1410		0.77 [0.60,0.98]	Z=-2.12, p=0.0336
Heterogeneity:	Q=0.20 (df=1)	p=0.6557	I^2=0.0%		
>= 65					
FIDELIO-DKD	87 / 1514	179 / 1535	60.0	0.49 [0.39,0.63]	
FIGARO-DKD	71 / 1021	87 / 1021	40.0	0.82 [0.60,1.10]	
Total	158 / 2535	266 / 2556		0.60 [0.50,0.72]	Z=-5.32, p=<.0001
Heterogeneity:	Q=6.47 (df=1)	p=0.0110	I^2=84.5%		
Subgroup Heterogeneity:	Q=2.48 (df=1)	p=0.1150	I^2=59.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.43.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

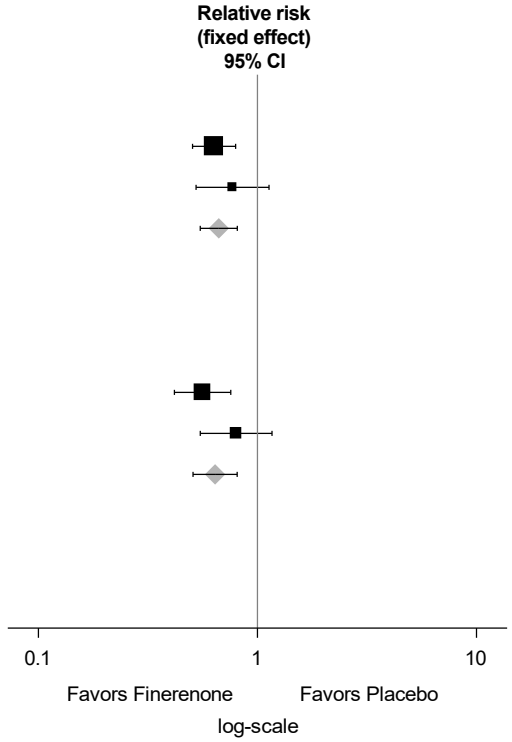
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	18 / 209	20 / 213	16.4	0.92 [0.50,1.68]	
FIGARO-DKD	88 / 1357	112 / 1356	83.6	0.79 [0.60,1.03]	
Total	106 / 1566	132 / 1569		0.81 [0.63,1.03]	Z=-1.73, p=0.0841
Heterogeneity:	Q=0.21 (df=1)	p=0.6464	I^2=0.0%		
Very High					
FIDELIO-DKD	157 / 2408	268 / 2397	100.0	0.58 [0.48,0.70]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	157 / 2408	268 / 2397		0.58 [0.48,0.70]	Z=-5.60, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.17 (df=1)	p=0.0412	I^2=76.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.43.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

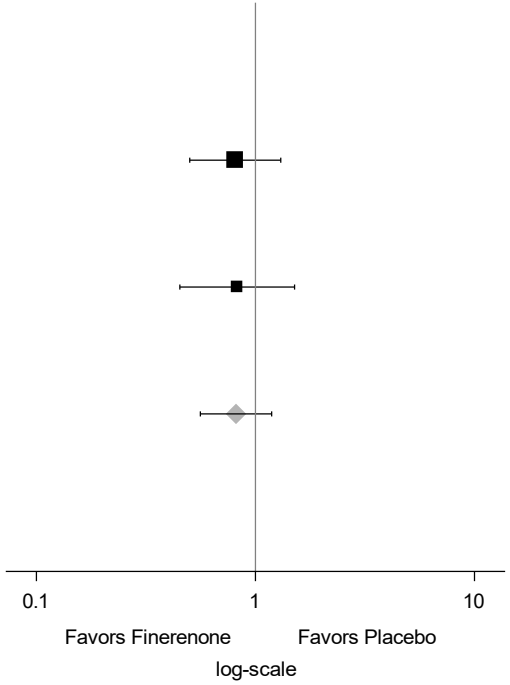
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	112 / 1556	175 / 1541	74.1	0.63 [0.51,0.79]	
FIGARO-DKD	43 / 637	55 / 627	25.9	0.77 [0.52,1.13]	
Total	155 / 2193	230 / 2168		0.67 [0.55,0.81]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.73 (df=1)	p=0.3931	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	63 / 1061	113 / 1069	61.8	0.56 [0.42,0.76]	
FIGARO-DKD	45 / 720	57 / 729	38.2	0.80 [0.55,1.17]	
Total	108 / 1781	170 / 1798		0.64 [0.51,0.81]	Z=-3.76, p=0.0002
Heterogeneity:	Q=2.08 (df=1)	p=0.1492	I^2=51.9%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8012	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.44: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

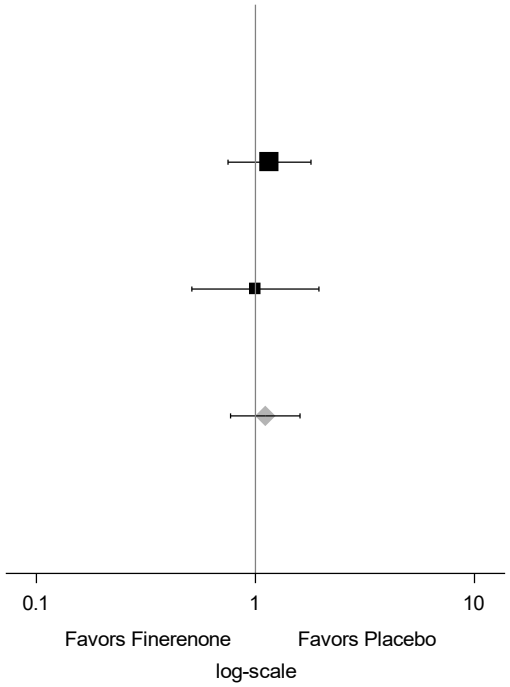
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	37 / 2610	61.4	0.81 [0.50,1.30]	
FIGARO-DKD	19 / 1357	23 / 1356	38.6	0.83 [0.45,1.51]	
Total	49 / 3974	60 / 3966		0.82 [0.56,1.19]	Z=-1.07, p=0.2850
Heterogeneity:	Q=0.00 (df=1)	p=0.9582	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.45: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

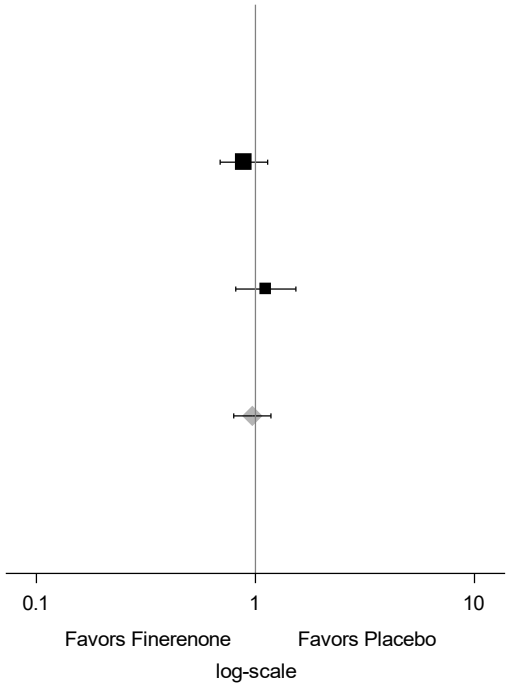
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	37 / 2610	70.1	1.16 [0.75,1.79]	
FIGARO-DKD	17 / 1357	17 / 1356	29.9	1.00 [0.51,1.95]	
Total	60 / 3974	54 / 3966		1.11 [0.77,1.60]	Z=0.55, p=0.5789
Heterogeneity:	Q=0.13 (df=1)	p=0.7155	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.46: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

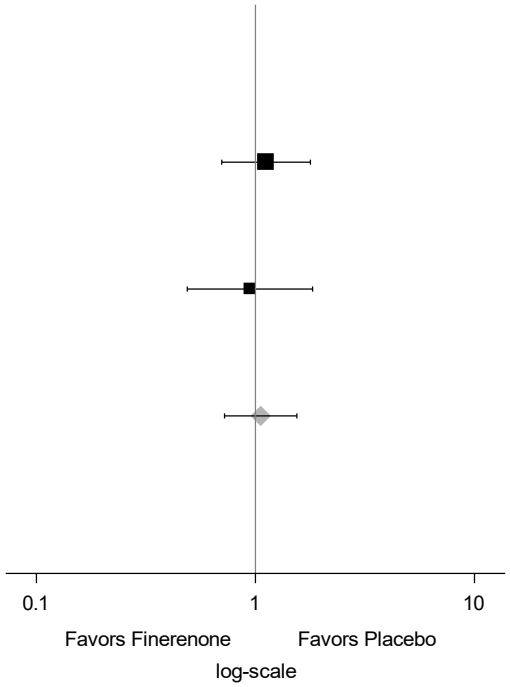
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2617	125 / 2610	61.6	0.89 [0.69,1.14]	
FIGARO-DKD	77 / 1357	69 / 1356	38.4	1.12 [0.81,1.53]	
Total	188 / 3974	194 / 3966		0.97 [0.80,1.18]	Z=-0.33, p=0.7421
Heterogeneity:	Q=1.26 (df=1)	p=0.2623	I^2=20.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.47: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

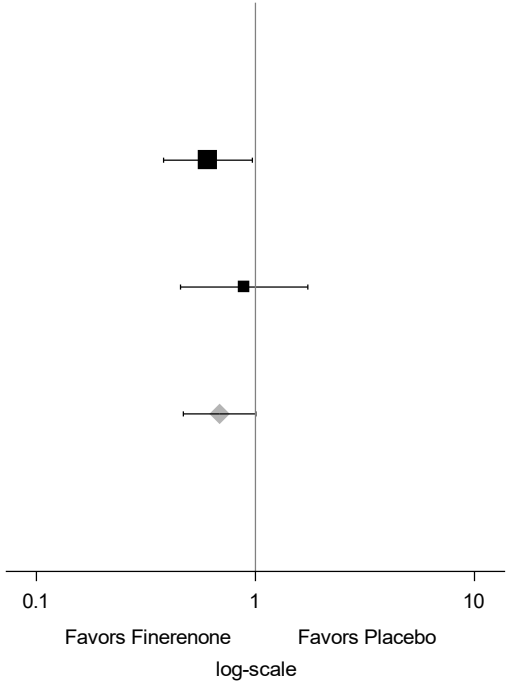
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	33 / 2610	66.6	1.12 [0.70,1.78]	
FIGARO-DKD	17 / 1357	18 / 1356	33.4	0.94 [0.49,1.82]	
Total	54 / 3974	51 / 3966		1.06 [0.72,1.55]	Z=0.28, p=0.7762
Heterogeneity:	Q=0.17 (df=1)	p=0.6803	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.48: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

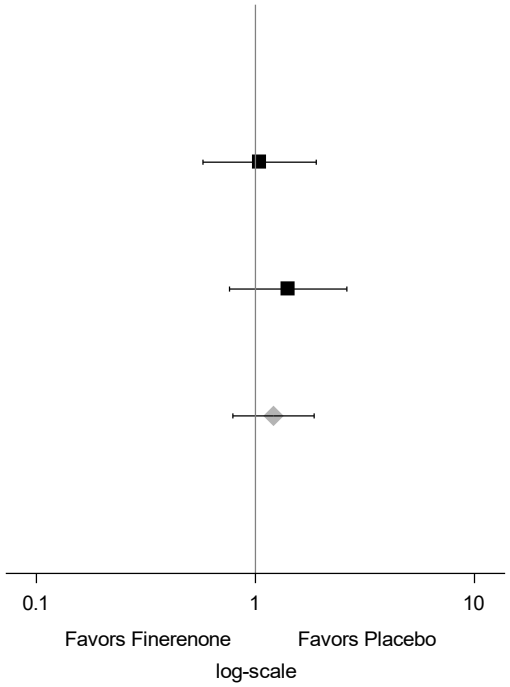
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	46 / 2610	67.3	0.61 [0.38,0.97]	
FIGARO-DKD	16 / 1357	18 / 1356	32.7	0.89 [0.45,1.73]	
Total	44 / 3974	64 / 3966		0.69 [0.47,1.00]	Z=-1.94, p=0.0527
Heterogeneity:	Q=0.84 (df=1)	p=0.3605	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.49: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

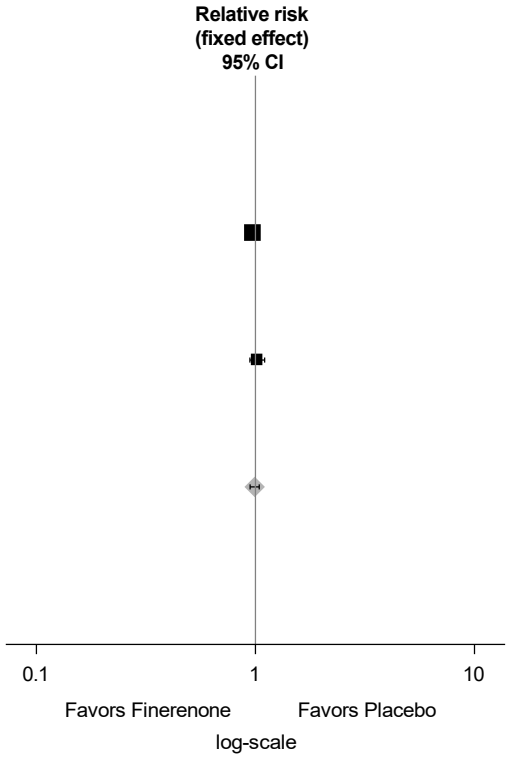
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	22 / 2617	21 / 2610	51.8	1.04 [0.58,1.90]	
FIGARO-DKD	24 / 1357	17 / 1356	48.2	1.41 [0.76,2.61]	
Total	46 / 3974	38 / 3966		1.21 [0.79,1.85]	Z=0.87, p=0.3837
Heterogeneity:	Q=0.47 (df=1)	p=0.4924	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.50: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

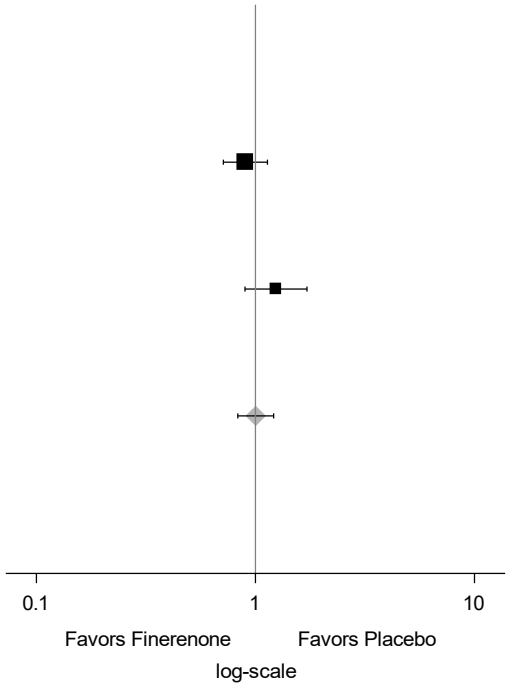
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1139 / 2617	1165 / 2610	61.8	0.98 [0.92,1.04]	
FIGARO-DKD	664 / 1357	651 / 1356	38.2	1.02 [0.94,1.10]	
Total	1803 / 3974	1816 / 3966		0.99 [0.95,1.04]	Z=-0.34, p=0.7343
Heterogeneity:	Q=0.77 (df=1)	p=0.3795	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.51: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

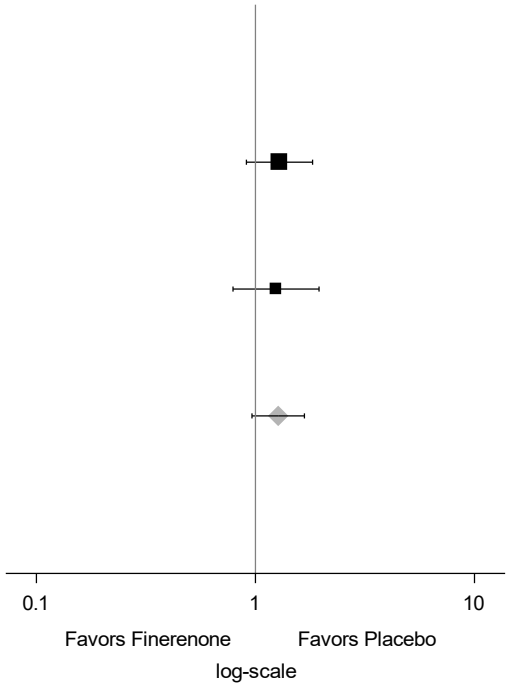
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2617	143 / 2610	66.4	0.90 [0.71,1.13]	
FIGARO-DKD	77 / 1357	62 / 1356	33.6	1.24 [0.90,1.72]	
Total	206 / 3974	205 / 3966		1.00 [0.83,1.21]	Z=0.03, p=0.9769
Heterogeneity:	Q=2.49 (df=1)	p=0.1149	I^2=59.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.52: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

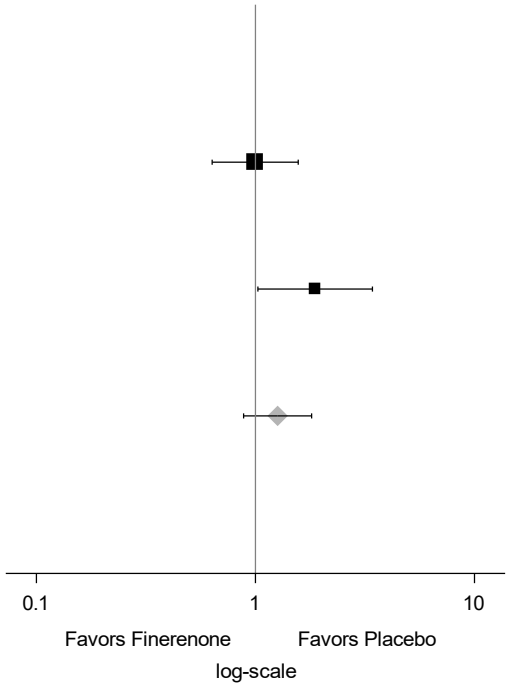
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	71 / 2617	55 / 2610	62.8	1.29 [0.91,1.82]	
FIGARO-DKD	41 / 1357	33 / 1356	37.2	1.24 [0.79,1.95]	
Total	112 / 3974	88 / 3966		1.27 [0.96,1.67]	Z=1.70, p=0.0891
Heterogeneity:	Q=0.02 (df=1)	p=0.9006	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.53: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

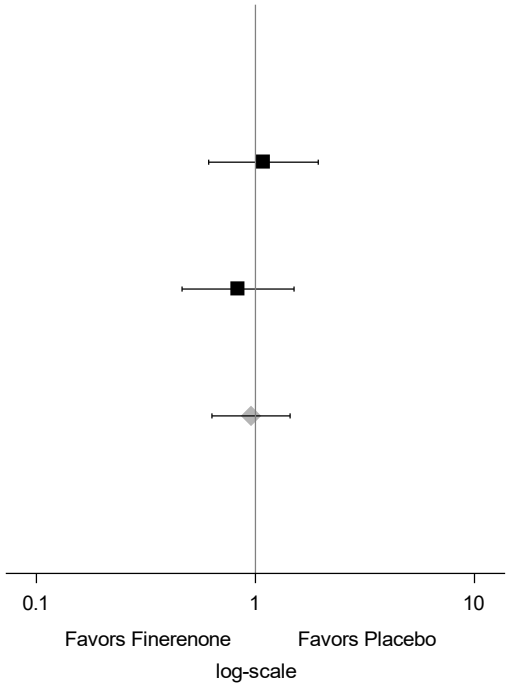
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	37 / 2610	63.9	1.00 [0.63,1.57]	
FIGARO-DKD	30 / 1357	16 / 1356	36.1	1.87 [1.03,3.42]	
Total	67 / 3974	53 / 3966		1.26 [0.88,1.80]	Z=1.28, p=0.2018
Heterogeneity:	Q=2.69 (df=1)	p=0.1007	I^2=62.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.54: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cystitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

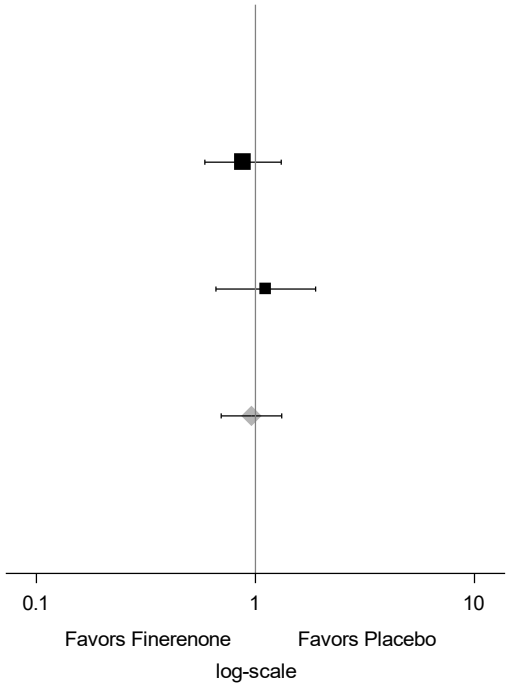
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2617	22 / 2610	51.1	1.09 [0.61,1.94]	
FIGARO-DKD	20 / 1357	24 / 1356	48.9	0.83 [0.46,1.50]	
Total	44 / 3974	46 / 3966		0.95 [0.63,1.44]	Z=-0.22, p=0.8237
Heterogeneity:	Q=0.40 (df=1)	p=0.5245	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.55: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

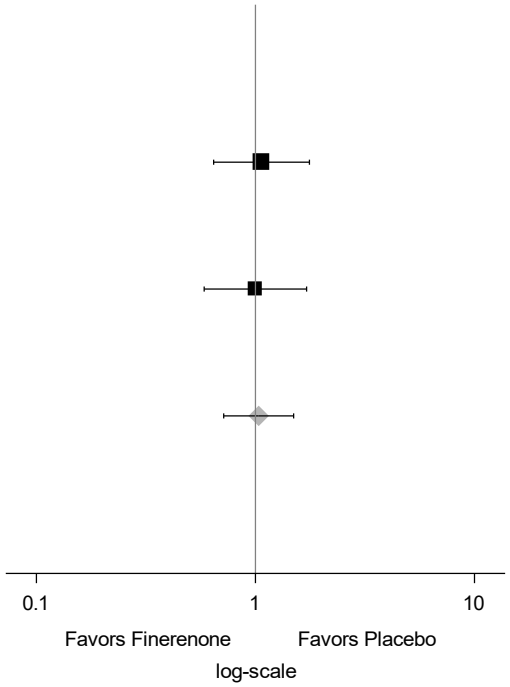
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2617	50 / 2610	63.0	0.88 [0.59,1.31]	
FIGARO-DKD	29 / 1357	26 / 1356	37.0	1.11 [0.66,1.88]	
Total	73 / 3974	76 / 3966		0.96 [0.70,1.32]	Z=-0.26, p=0.7953
Heterogeneity:	Q=0.50 (df=1)	p=0.4780	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.56: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

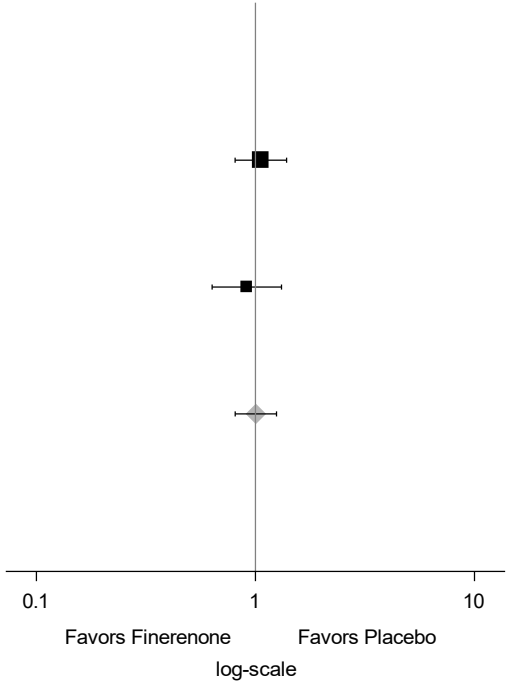
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	29 / 2610	53.3	1.07 [0.64,1.76]	
FIGARO-DKD	26 / 1357	26 / 1356	46.7	1.00 [0.58,1.71]	
Total	57 / 3974	55 / 3966		1.03 [0.72,1.49]	Z=0.18, p=0.8569
Heterogeneity:	Q=0.03 (df=1)	p=0.8633	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.57: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

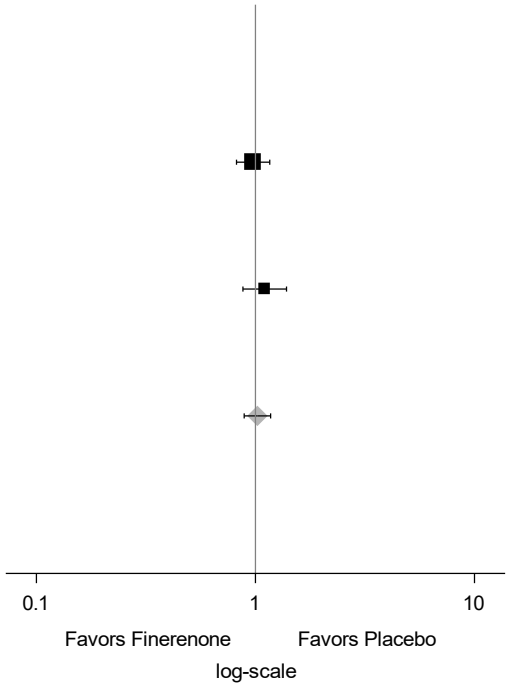
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2617	98 / 2610	64.5	1.06 [0.81,1.39]	
FIGARO-DKD	53 / 1357	58 / 1356	35.5	0.91 [0.63,1.32]	
Total	157 / 3974	156 / 3966		1.00 [0.81,1.25]	Z=0.04, p=0.9689
Heterogeneity:	Q=0.41 (df=1)	p=0.5240	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.58: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

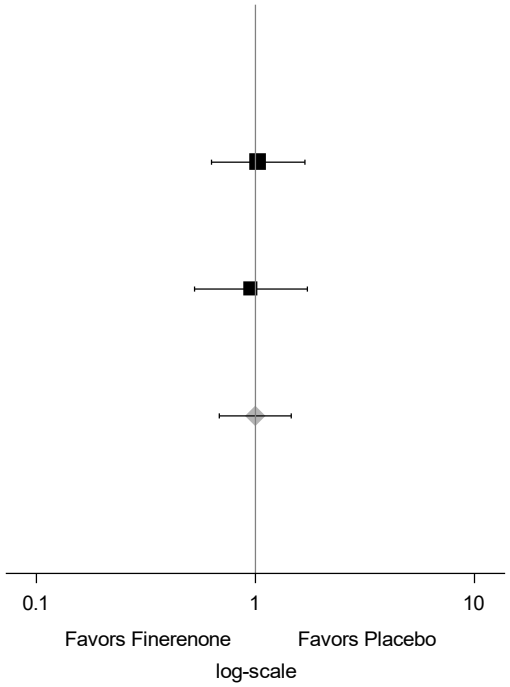
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	227 / 2617	232 / 2610	63.2	0.98 [0.82,1.16]	
FIGARO-DKD	139 / 1357	126 / 1356	36.8	1.10 [0.88,1.39]	
Total	366 / 3974	358 / 3966		1.02 [0.89,1.17]	Z=0.29, p=0.7730
Heterogeneity:	Q=0.69 (df=1)	p=0.4069	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.59: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

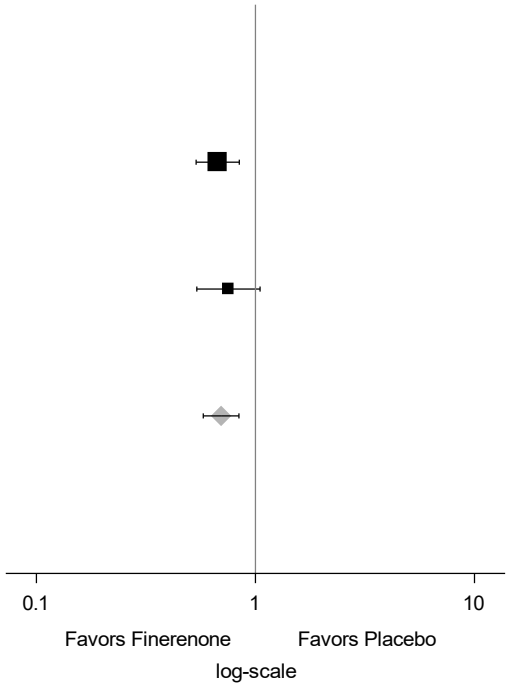
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	31 / 2610	59.3	1.03 [0.63,1.68]	
FIGARO-DKD	21 / 1357	22 / 1356	40.7	0.95 [0.53,1.73]	
Total	53 / 3974	53 / 3966		1.00 [0.68,1.46]	Z=-0.01, p=0.9919
Heterogeneity:	Q=0.04 (df=1)	p=0.8460	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.60: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

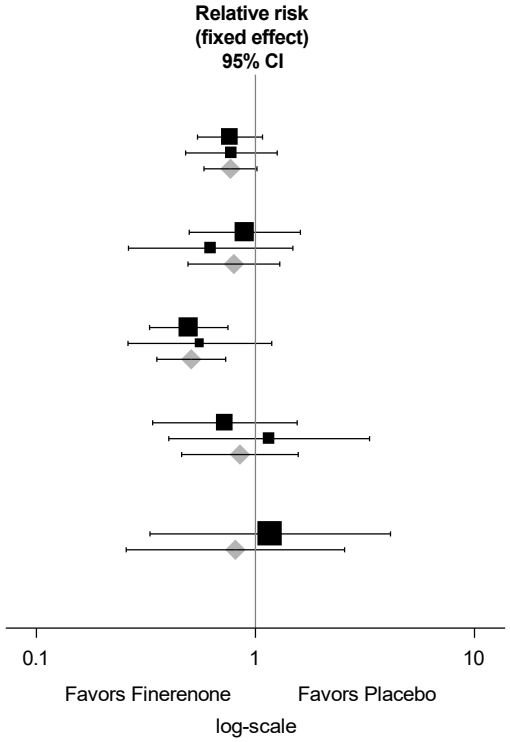
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	118 / 2617	175 / 2610	68.2	0.67 [0.54,0.84]	
FIGARO-DKD	58 / 1357	77 / 1356	31.8	0.75 [0.54,1.05]	
Total	176 / 3974	252 / 3966		0.70 [0.58,0.84]	Z=-3.78, p=0.0002
Heterogeneity:	Q=0.30 (df=1)	p=0.5832	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.60.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

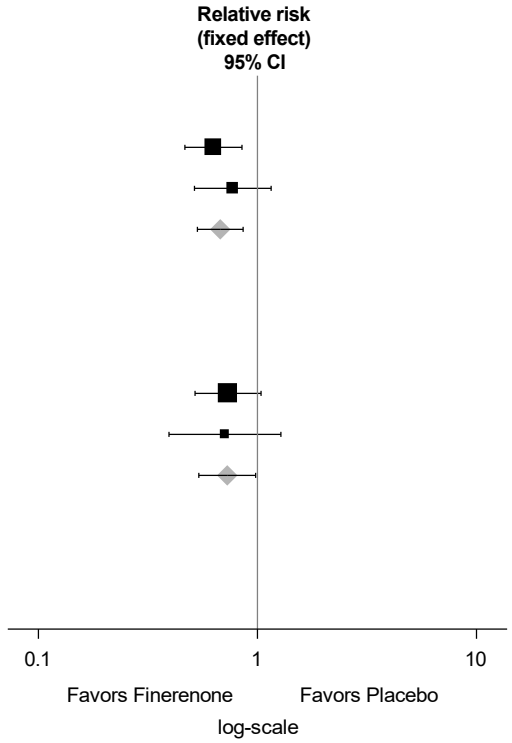
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	55 / 1075	71 / 1062	66.5	0.77 [0.54,1.08]	
FIGARO-DKD	28 / 638	36 / 637	33.5	0.78 [0.48,1.26]	
Total	83 / 1713	107 / 1699		0.77 [0.58,1.02]	Z=-1.85, p=0.0647
Heterogeneity:	Q=0.00 (df=1)	p=0.9613	I^2=0.0%		
North America					
FIDELIO-DKD	20 / 424	23 / 436	68.6	0.89 [0.50,1.60]	
FIGARO-DKD	8 / 267	13 / 271	31.4	0.62 [0.26,1.48]	
Total	28 / 691	36 / 707		0.80 [0.49,1.29]	Z=-0.92, p=0.3568
Heterogeneity:	Q=0.45 (df=1)	p=0.5002	I^2=0.0%		
Asia					
FIDELIO-DKD	32 / 751	64 / 745	77.1	0.50 [0.33,0.75]	
FIGARO-DKD	10 / 289	18 / 290	22.9	0.56 [0.26,1.19]	
Total	42 / 1040	82 / 1035		0.51 [0.35,0.73]	Z=-3.66, p=0.0003
Heterogeneity:	Q=0.07 (df=1)	p=0.7902	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 273	15 / 270	65.9	0.73 [0.34,1.55]	
FIGARO-DKD	7 / 102	6 / 101	34.1	1.16 [0.40,3.32]	
Total	18 / 375	21 / 371		0.85 [0.46,1.57]	Z=-0.52, p=0.6020
Heterogeneity:	Q=0.49 (df=1)	p=0.4828	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	5 / 61	4 / 57	100.0	1.17 [0.33,4.14]	
Total	5 / 155	6 / 154		0.81 [0.26,2.55]	Z=-0.36, p=0.7189
Heterogeneity:	Q=0.32 (df=1)	p=0.5703	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.13 (df=4)	p=0.3882	I^2=3.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.60.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

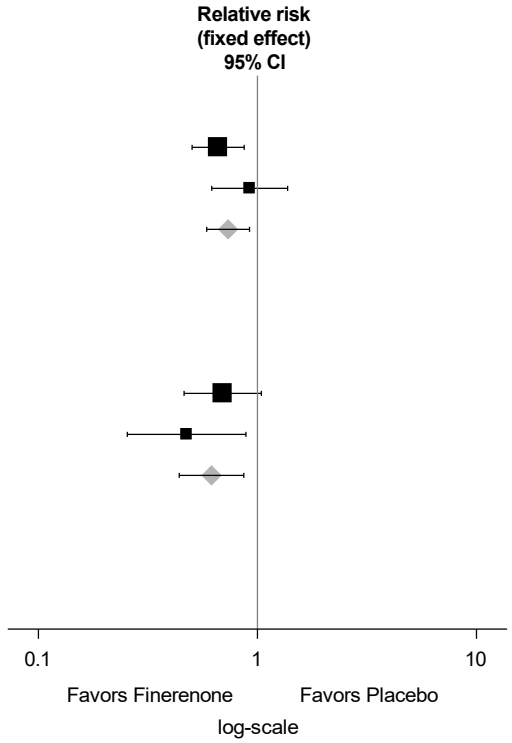
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	65 / 1213	103 / 1210	64.3	0.63 [0.47,0.85]	
FIGARO-DKD	40 / 862	51 / 848	35.7	0.77 [0.52,1.15]	
Total	105 / 2075	154 / 2058		0.68 [0.53,0.86]	Z=-3.19, p=0.0014
Heterogeneity:	Q=0.63 (df=1)	p=0.4273	I^2=0.0%		
Absent					
FIDELIO-DKD	53 / 1404	72 / 1400	74.2	0.73 [0.52,1.04]	
FIGARO-DKD	18 / 495	26 / 508	25.8	0.71 [0.39,1.28]	
Total	71 / 1899	98 / 1908		0.73 [0.54,0.98]	Z=-2.08, p=0.0372
Heterogeneity:	Q=0.01 (df=1)	p=0.9255	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7073	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.60.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

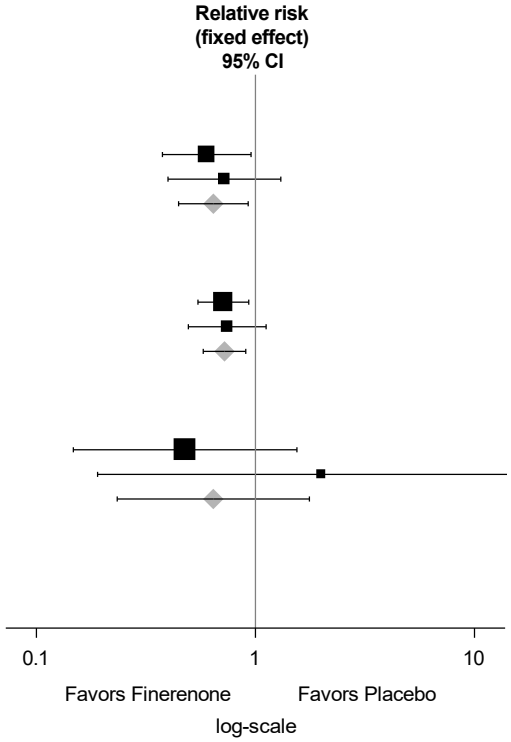
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	81 / 1735	120 / 1700	68.0	0.66 [0.50,0.87]	
FIGARO-DKD	44 / 924	48 / 929	32.0	0.92 [0.62,1.37]	
Total	125 / 2659	168 / 2629		0.73 [0.59,0.92]	Z=-2.69, p=0.0072
Heterogeneity:	Q=1.81 (df=1)	p=0.1788	I^2=44.7%		
> 4.5					
FIDELIO-DKD	37 / 882	55 / 910	70.2	0.69 [0.46,1.04]	
FIGARO-DKD	14 / 433	29 / 426	29.8	0.47 [0.25,0.89]	
Total	51 / 1315	84 / 1336		0.62 [0.44,0.87]	Z=-2.79, p=0.0053
Heterogeneity:	Q=1.00 (df=1)	p=0.3176	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.70 (df=1)	p=0.4018	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.60.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

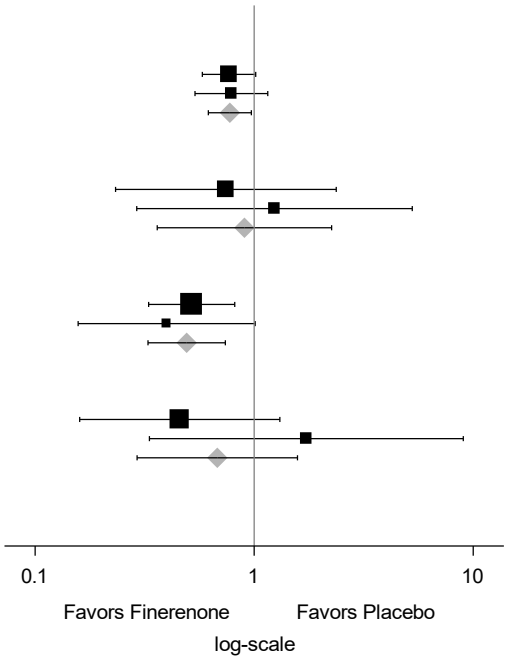
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	27 / 724	45 / 723	61.8	0.60 [0.38,0.95]	
FIGARO-DKD	18 / 494	25 / 495	38.2	0.72 [0.40,1.31]	
Total	45 / 1218	70 / 1218		0.64 [0.45,0.93]	Z=-2.37, p=0.0179
Heterogeneity:	Q=0.23 (df=1)	p=0.6292	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	87 / 1759	122 / 1760	70.1	0.71 [0.55,0.93]	
FIGARO-DKD	38 / 829	51 / 827	29.9	0.74 [0.49,1.12]	
Total	125 / 2588	173 / 2587		0.72 [0.58,0.90]	Z=-2.85, p=0.0043
Heterogeneity:	Q=0.03 (df=1)	p=0.8696	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	8 / 127	80.0	0.48 [0.15,1.55]	
FIGARO-DKD	2 / 34	1 / 34	20.0	2.00 [0.19,21.03]	
Total	6 / 167	9 / 161		0.64 [0.23,1.76]	Z=-0.86, p=0.3900
Heterogeneity:	Q=1.14 (df=1)	p=0.2857	I^2=12.3%		
Subgroup Heterogeneity:	Q=0.31 (df=2)	p=0.8555	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.60.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

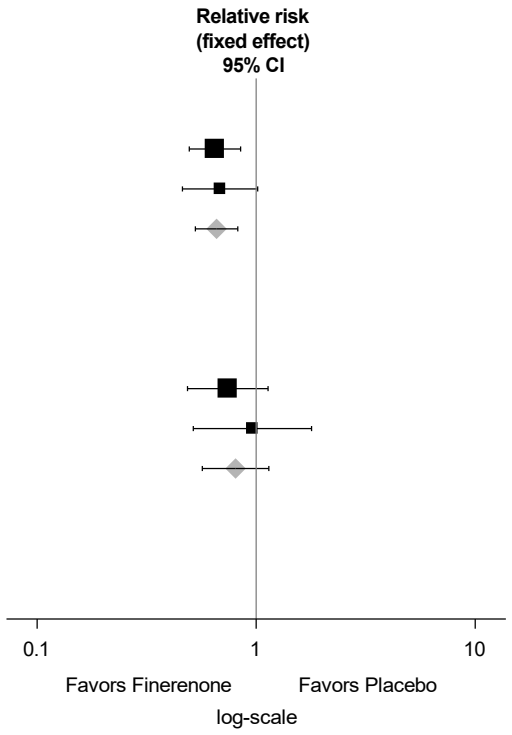
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	81 / 1634	107 / 1657	65.0	0.77 [0.58,1.02]	
FIGARO-DKD	45 / 1010	56 / 989	35.0	0.79 [0.54,1.15]	
Total	126 / 2644	163 / 2646		0.77 [0.62,0.97]	Z=-2.22, p=0.0266
Heterogeneity:	Q=0.01 (df=1)	p=0.9187	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	6 / 115	60.9	0.74 [0.23,2.37]	
FIGARO-DKD	3 / 43	4 / 71	39.1	1.24 [0.29,5.27]	
Total	8 / 172	10 / 186		0.90 [0.36,2.26]	Z=-0.22, p=0.8265
Heterogeneity:	Q=0.29 (df=1)	p=0.5893	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 678	52 / 677	80.9	0.52 [0.33,0.82]	
FIGARO-DKD	6 / 252	15 / 251	19.1	0.40 [0.16,1.01]	
Total	33 / 930	67 / 928		0.49 [0.33,0.74]	Z=-3.42, p=0.0006
Heterogeneity:	Q=0.25 (df=1)	p=0.6178	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 176	10 / 161	71.1	0.46 [0.16,1.31]	
FIGARO-DKD	4 / 52	2 / 45	28.9	1.73 [0.33,9.01]	
Total	9 / 228	12 / 206		0.68 [0.29,1.58]	Z=-0.90, p=0.3673
Heterogeneity:	Q=1.78 (df=1)	p=0.1825	I^2=43.7%		
Subgroup Heterogeneity:	Q=3.96 (df=3)	p=0.2661	I^2=24.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.60.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

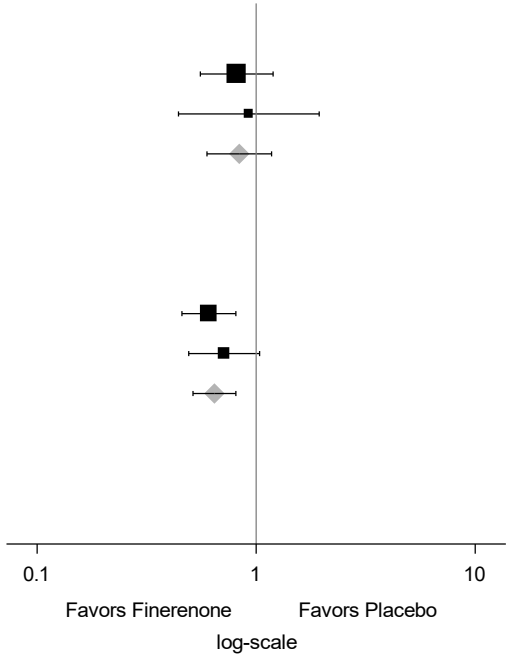
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	81 / 1797	130 / 1870	68.2	0.65 [0.50,0.85]	
FIGARO-DKD	39 / 917	58 / 933	31.8	0.68 [0.46,1.02]	
Total	120 / 2714	188 / 2803		0.66 [0.53,0.82]	Z=-3.66, p=0.0003
Heterogeneity:	Q=0.05 (df=1)	p=0.8261	I^2=0.0%		
Female					
FIDELIO-DKD	37 / 820	45 / 740	68.3	0.74 [0.49,1.13]	
FIGARO-DKD	19 / 440	19 / 423	31.7	0.96 [0.52,1.79]	
Total	56 / 1260	64 / 1163		0.81 [0.57,1.14]	Z=-1.21, p=0.2245
Heterogeneity:	Q=0.46 (df=1)	p=0.4998	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3454	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.60.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

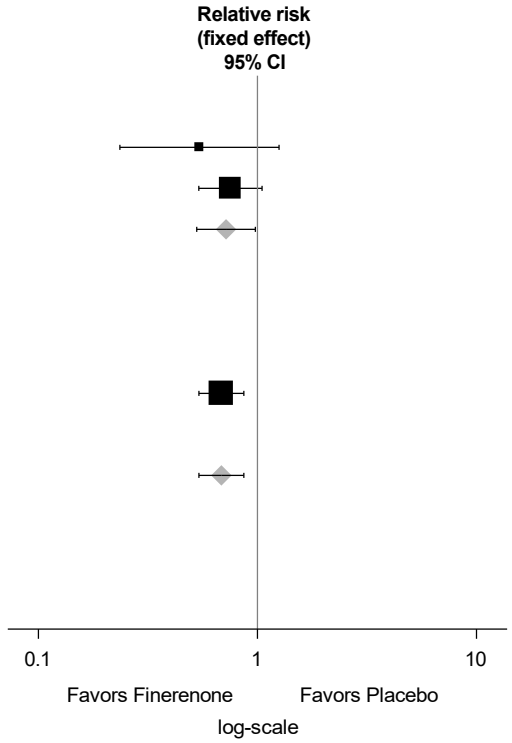
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	46 / 1103	55 / 1075	78.9	0.82 [0.56,1.19]	
FIGARO-DKD	13 / 336	14 / 335	21.1	0.93 [0.44,1.94]	
Total	59 / 1439	69 / 1410		0.84 [0.60,1.18]	Z=-1.02, p=0.3054
Heterogeneity:	Q=0.09 (df=1)	p=0.7644	I^2=0.0%		
>= 65					
FIDELIO-DKD	72 / 1514	120 / 1535	63.3	0.61 [0.46,0.81]	
FIGARO-DKD	45 / 1021	63 / 1021	36.7	0.71 [0.49,1.04]	
Total	117 / 2535	183 / 2556		0.64 [0.51,0.81]	Z=-3.82, p=0.0001
Heterogeneity:	Q=0.45 (df=1)	p=0.5014	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.58 (df=1)	p=0.2091	I^2=36.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.60.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

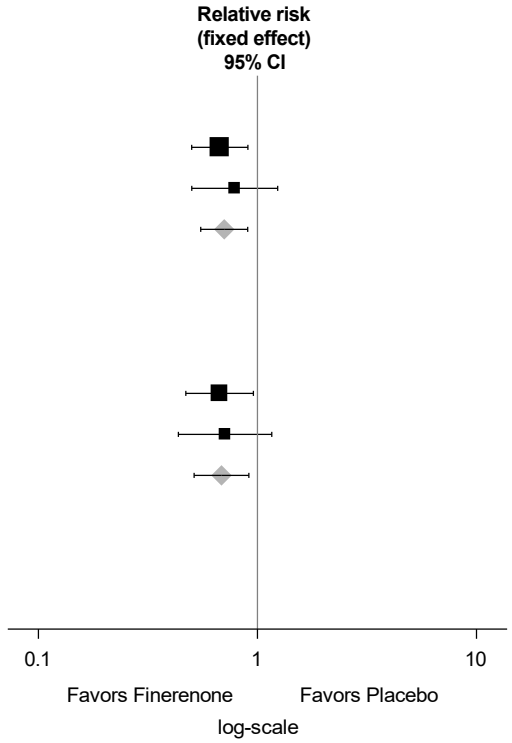
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	15 / 213	13.6	0.54 [0.24,1.25]	
FIGARO-DKD	58 / 1357	77 / 1356	86.4	0.75 [0.54,1.05]	
Total	66 / 1566	92 / 1569		0.72 [0.53,0.98]	Z=-2.10, p=0.0358
Heterogeneity:	Q=0.50 (df=1)	p=0.4784	I^2=0.0%		
Very High					
FIDELIO-DKD	110 / 2408	160 / 2397	100.0	0.68 [0.54,0.87]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	110 / 2408	160 / 2397		0.68 [0.54,0.87]	Z=-3.15, p=0.0016
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8044	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.60.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

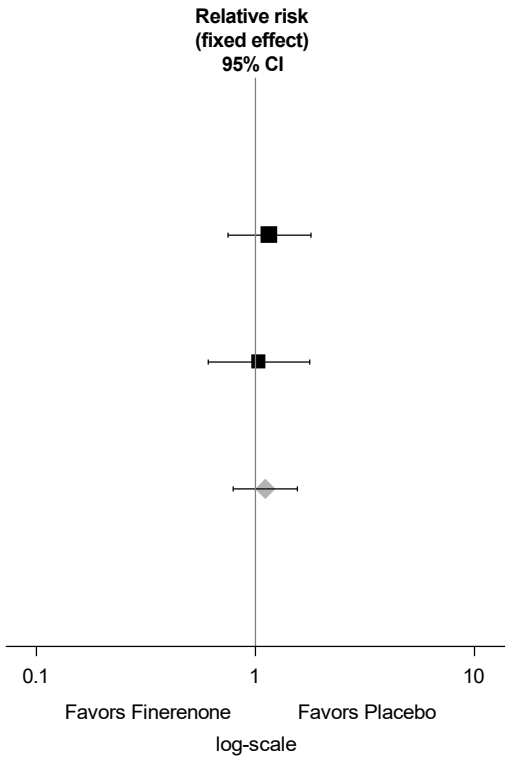
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	70 / 1556	103 / 1541	70.0	0.67 [0.50,0.90]	
FIGARO-DKD	32 / 637	40 / 627	30.0	0.79 [0.50,1.24]	
Total	102 / 2193	143 / 2168		0.71 [0.55,0.90]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.33 (df=1)	p=0.5686	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	48 / 1061	72 / 1069	65.6	0.67 [0.47,0.96]	
FIGARO-DKD	26 / 720	37 / 729	34.4	0.71 [0.44,1.16]	
Total	74 / 1781	109 / 1798		0.69 [0.51,0.91]	Z=-2.58, p=0.0100
Heterogeneity:	Q=0.03 (df=1)	p=0.8523	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8812	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.61: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

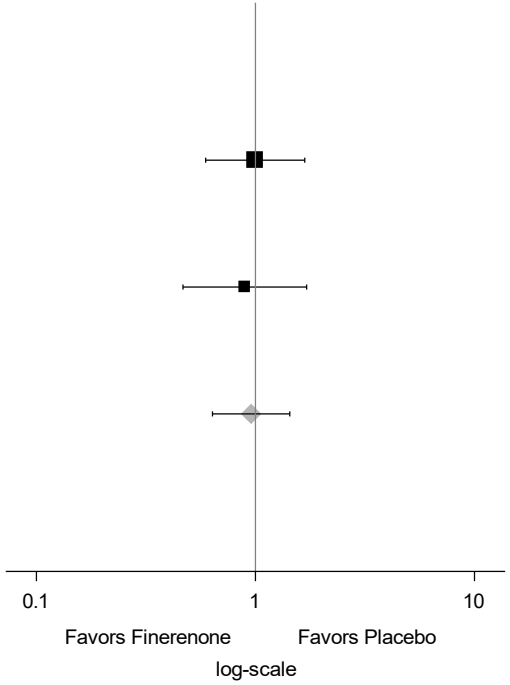
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	37 / 2610	59.9	1.16 [0.75,1.79]	
FIGARO-DKD	27 / 1357	26 / 1356	40.1	1.04 [0.61,1.77]	
Total	70 / 3974	63 / 3966		1.11 [0.79,1.55]	Z=0.60, p=0.5484
Heterogeneity:	Q=0.10 (df=1)	p=0.7530	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.62: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

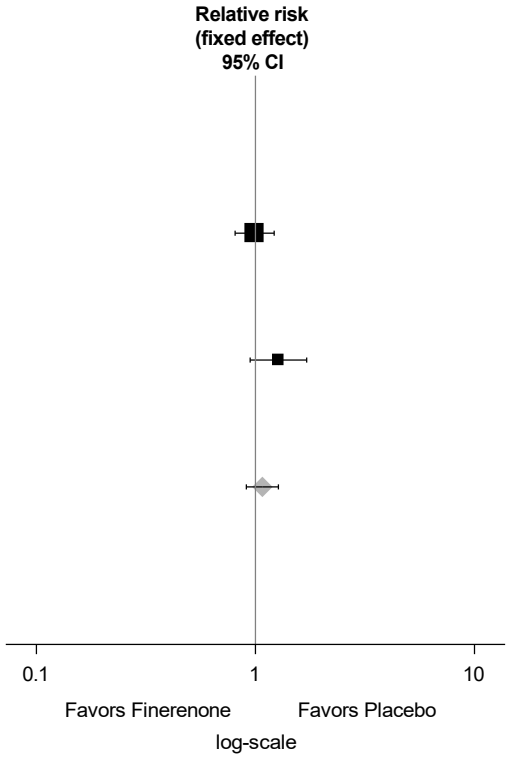
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	28 / 2610	60.9	1.00 [0.59,1.68]	
FIGARO-DKD	17 / 1357	19 / 1356	39.1	0.89 [0.47,1.71]	
Total	45 / 3974	47 / 3966		0.96 [0.64,1.43]	Z=-0.22, p=0.8264
Heterogeneity:	Q=0.07 (df=1)	p=0.7971	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.63: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

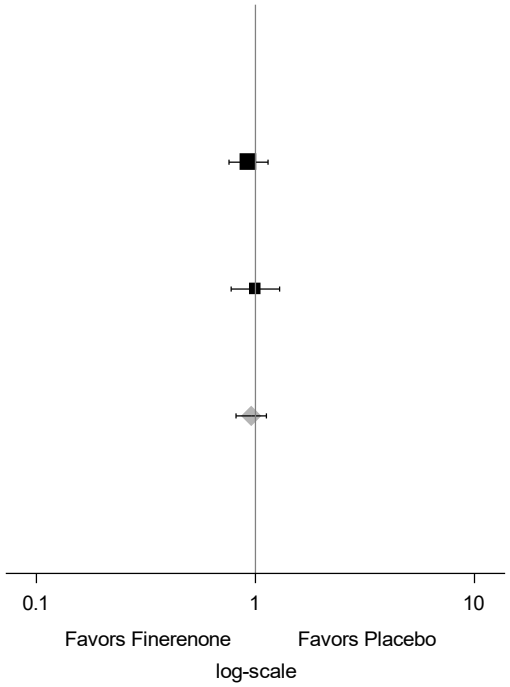
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	170 / 2617	171 / 2610	67.7	0.99 [0.81,1.22]	
FIGARO-DKD	93 / 1357	73 / 1356	32.3	1.27 [0.95,1.71]	
Total	263 / 3974	244 / 3966		1.08 [0.91,1.27]	Z=0.85, p=0.3979
Heterogeneity:	Q=1.84 (df=1)	p=0.1749	I^2=45.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.64: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

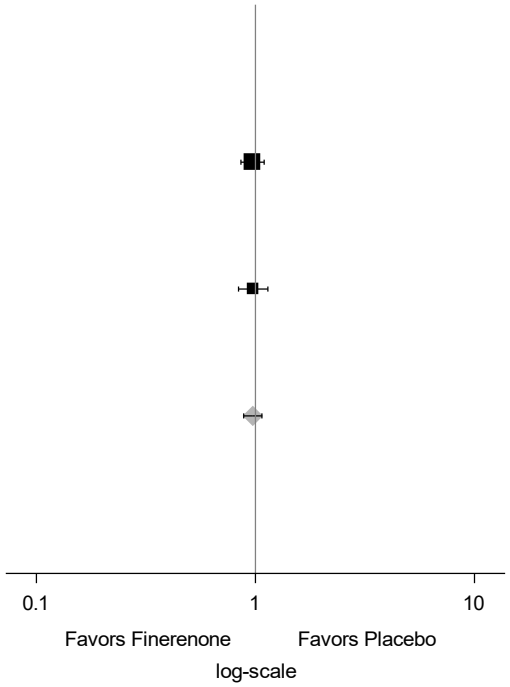
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	165 / 2617	177 / 2610	60.7	0.93 [0.76,1.14]	
FIGARO-DKD	109 / 1357	109 / 1356	39.3	1.00 [0.77,1.29]	
Total	274 / 3974	286 / 3966		0.96 [0.82,1.12]	Z=-0.55, p=0.5848
Heterogeneity:	Q=0.19 (df=1)	p=0.6653	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.65: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

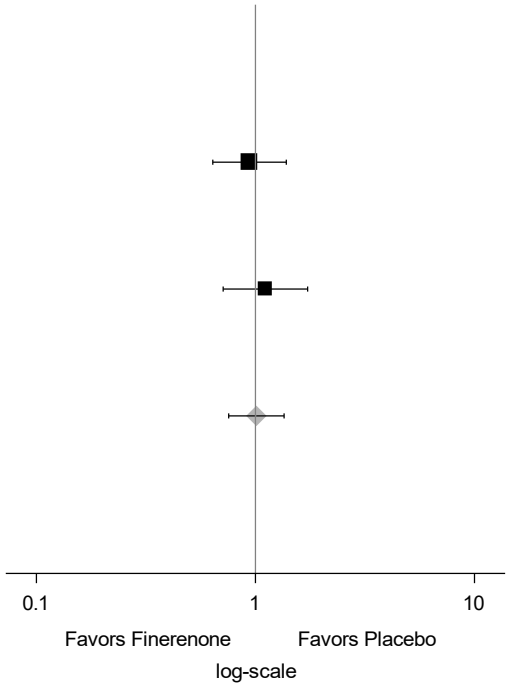
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	425 / 2617	437 / 2610	61.5	0.97 [0.86,1.10]	
FIGARO-DKD	258 / 1357	264 / 1356	38.5	0.98 [0.84,1.14]	
Total	683 / 3974	701 / 3966		0.97 [0.88,1.07]	Z=-0.57, p=0.5676
Heterogeneity:	Q=0.00 (df=1)	p=0.9460	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.66: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

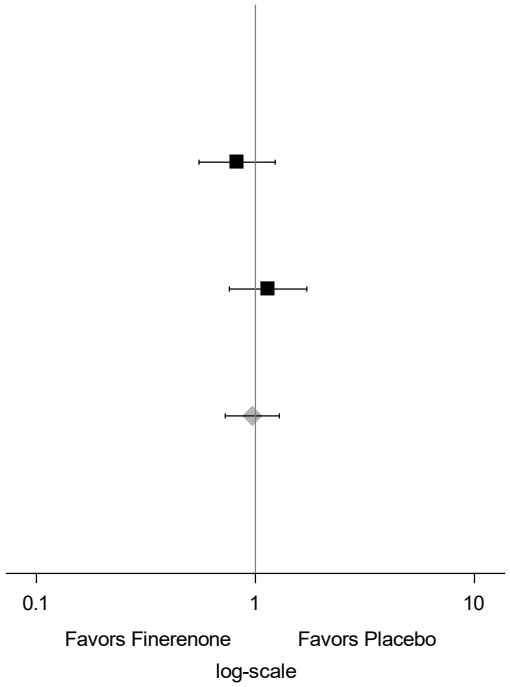
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2617	52 / 2610	56.9	0.94 [0.64,1.38]	
FIGARO-DKD	40 / 1357	36 / 1356	43.1	1.11 [0.71,1.73]	
Total	89 / 3974	88 / 3966		1.01 [0.75,1.35]	Z=0.07, p=0.9473
Heterogeneity:	Q=0.31 (df=1)	p=0.5788	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.67: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

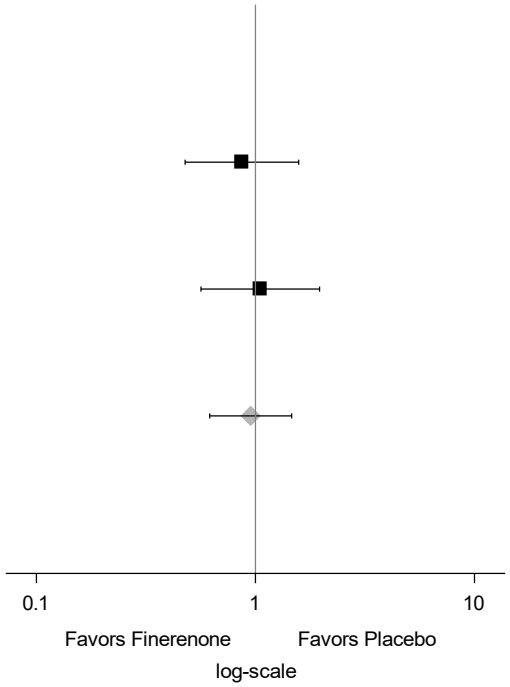
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	52 / 2610	50.9	0.82 [0.55,1.23]	
FIGARO-DKD	48 / 1357	42 / 1356	49.1	1.14 [0.76,1.72]	
Total	91 / 3974	94 / 3966		0.97 [0.73,1.29]	Z=-0.23, p=0.8206
Heterogeneity:	Q=1.25 (df=1)	p=0.2639	I^2=19.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.68: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

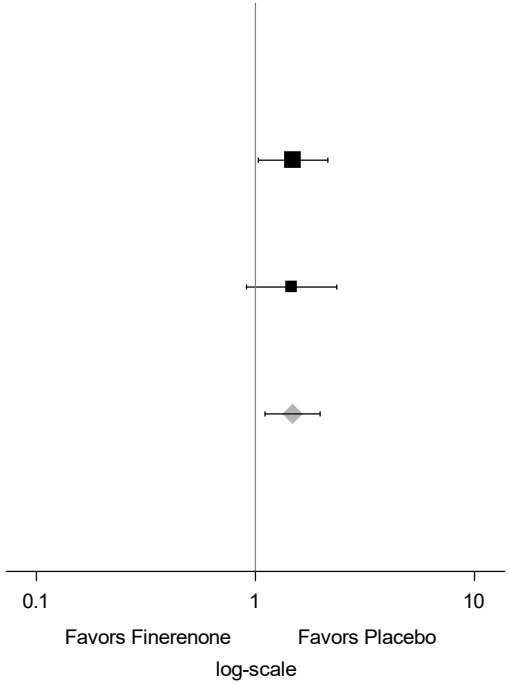
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	23 / 2610	52.2	0.87 [0.48,1.58]	
FIGARO-DKD	20 / 1357	19 / 1356	47.8	1.05 [0.56,1.96]	
Total	40 / 3974	42 / 3966		0.95 [0.62,1.46]	Z=-0.23, p=0.8191
Heterogeneity:	Q=0.19 (df=1)	p=0.6612	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.69: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

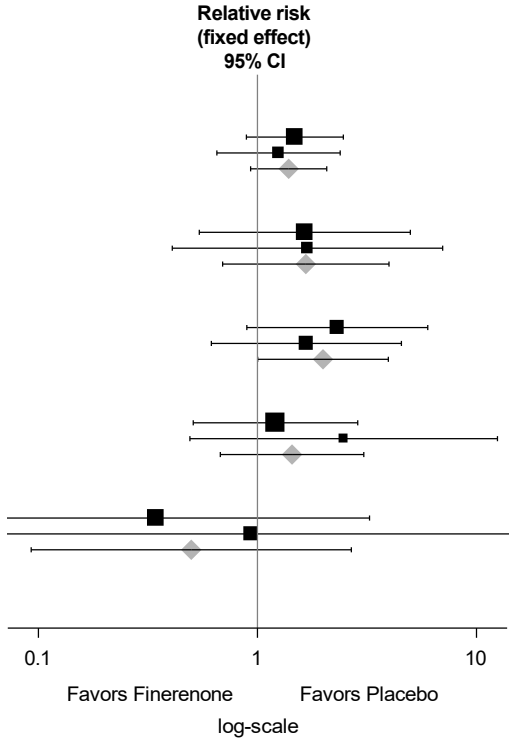
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2617	47 / 2610	62.8	1.49 [1.03,2.14]	
FIGARO-DKD	41 / 1357	28 / 1356	37.2	1.46 [0.91,2.35]	
Total	111 / 3974	75 / 3966		1.48 [1.11,1.97]	Z=2.64, p=0.0083
Heterogeneity:	Q=0.00 (df=1)	p=0.9608	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.69.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

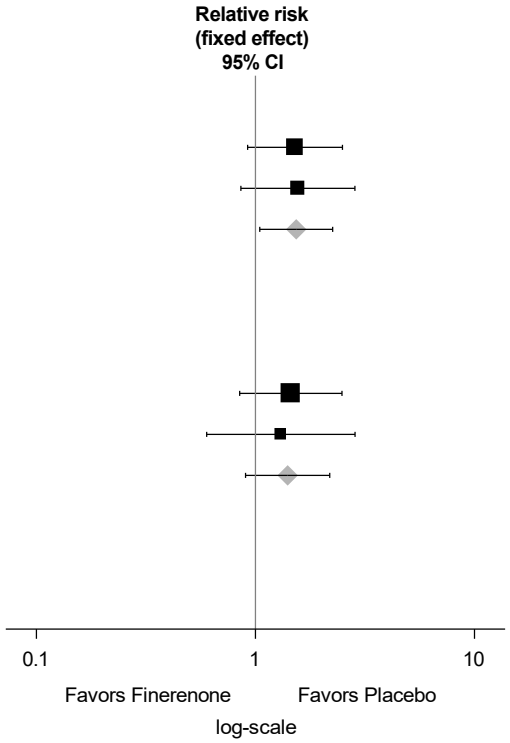
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 1075	24 / 1062	61.8	1.48 [0.89,2.47]	
FIGARO-DKD	20 / 638	16 / 637	38.2	1.25 [0.65,2.39]	
Total	56 / 1713	40 / 1699		1.39 [0.93,2.07]	Z=1.61, p=0.1079
Heterogeneity:	Q=0.17 (df=1)	p=0.6831	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	5 / 436	62.1	1.65 [0.54,4.99]	
FIGARO-DKD	5 / 267	3 / 271	37.9	1.69 [0.41,7.01]	
Total	13 / 691	8 / 707		1.66 [0.69,3.99]	Z=1.14, p=0.2545
Heterogeneity:	Q=0.00 (df=1)	p=0.9759	I^2=0.0%		
Asia					
FIDELIO-DKD	14 / 751	6 / 745	52.5	2.31 [0.89,5.99]	
FIGARO-DKD	10 / 289	6 / 290	47.5	1.67 [0.62,4.54]	
Total	24 / 1040	12 / 1035		1.99 [1.00,3.96]	Z=1.97, p=0.0492
Heterogeneity:	Q=0.21 (df=1)	p=0.6441	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 273	9 / 270	77.8	1.21 [0.51,2.87]	
FIGARO-DKD	5 / 102	2 / 101	22.2	2.48 [0.49,12.47]	
Total	16 / 375	11 / 371		1.44 [0.68,3.06]	Z=0.95, p=0.3446
Heterogeneity:	Q=0.59 (df=1)	p=0.4429	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	60.0	0.34 [0.04,3.25]	
FIGARO-DKD	1 / 61	1 / 57	40.0	0.93 [0.06,14.59]	
Total	2 / 155	4 / 154		0.50 [0.09,2.68]	Z=-0.81, p=0.4177
Heterogeneity:	Q=0.31 (df=1)	p=0.5803	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.49 (df=4)	p=0.6456	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.69.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

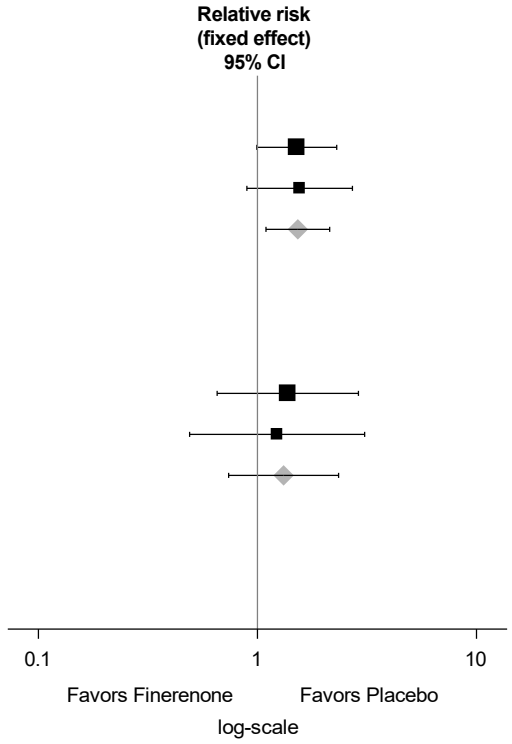
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	38 / 1213	25 / 1210	59.1	1.52 [0.92,2.50]	
FIGARO-DKD	27 / 862	17 / 848	40.9	1.56 [0.86,2.85]	
Total	65 / 2075	42 / 2058		1.53 [1.05,2.25]	Z=2.19, p=0.0284
Heterogeneity:	Q=0.01 (df=1)	p=0.9398	I^2=0.0%		
Absent					
FIDELIO-DKD	32 / 1404	22 / 1400	67.8	1.45 [0.85,2.48]	
FIGARO-DKD	14 / 495	11 / 508	32.2	1.31 [0.60,2.85]	
Total	46 / 1899	33 / 1908		1.40 [0.90,2.18]	Z=1.50, p=0.1341
Heterogeneity:	Q=0.05 (df=1)	p=0.8284	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7625	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.69.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

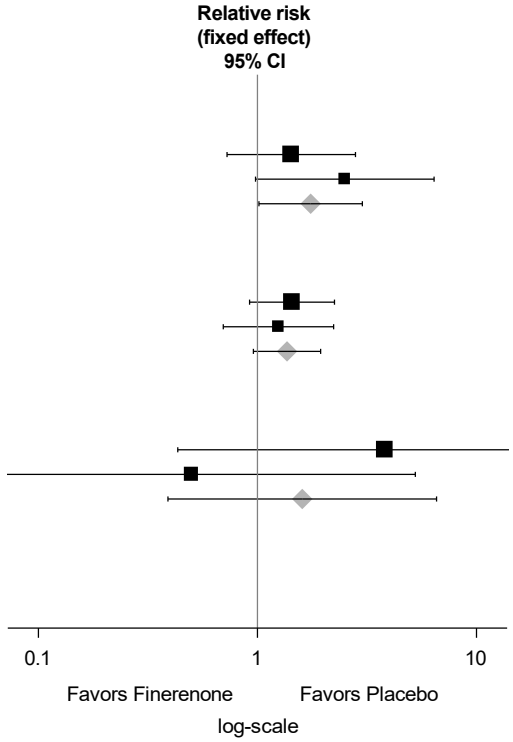
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	54 / 1735	35 / 1700	63.6	1.51 [0.99,2.30]	
FIGARO-DKD	31 / 924	20 / 929	36.4	1.56 [0.89,2.71]	
Total	85 / 2659	55 / 2629		1.53 [1.09,2.14]	Z=2.48, p=0.0130
Heterogeneity:	Q=0.01 (df=1)	p=0.9318	I^2=0.0%		
> 4.5					
FIDELIO-DKD	16 / 882	12 / 910	60.5	1.38 [0.65,2.89]	
FIGARO-DKD	10 / 433	8 / 426	39.5	1.23 [0.49,3.09]	
Total	26 / 1315	20 / 1336		1.32 [0.74,2.35]	Z=0.93, p=0.3511
Heterogeneity:	Q=0.03 (df=1)	p=0.8526	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.69.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

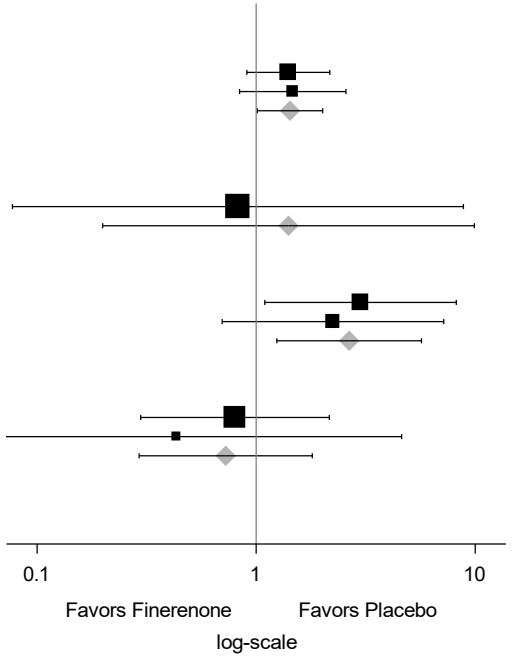
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	20 / 724	14 / 723	65.9	1.43 [0.73,2.80]	
FIGARO-DKD	15 / 494	6 / 495	34.1	2.51 [0.98,6.40]	
Total	35 / 1218	20 / 1218		1.75 [1.02,3.01]	Z=2.02, p=0.0438
Heterogeneity:	Q=0.91 (df=1)	p=0.3394	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	46 / 1759	32 / 1760	62.8	1.44 [0.92,2.25]	
FIGARO-DKD	25 / 829	20 / 827	37.2	1.25 [0.70,2.23]	
Total	71 / 2588	52 / 2587		1.36 [0.96,1.94]	Z=1.72, p=0.0849
Heterogeneity:	Q=0.15 (df=1)	p=0.7023	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	1 / 127	53.9	3.82 [0.43,33.71]	
FIGARO-DKD	1 / 34	2 / 34	46.1	0.50 [0.05,5.26]	
Total	5 / 167	3 / 161		1.60 [0.39,6.57]	Z=0.65, p=0.5133
Heterogeneity:	Q=1.55 (df=1)	p=0.2128	I^2=35.6%		
Subgroup Heterogeneity:	Q=0.58 (df=2)	p=0.7490	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.69.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

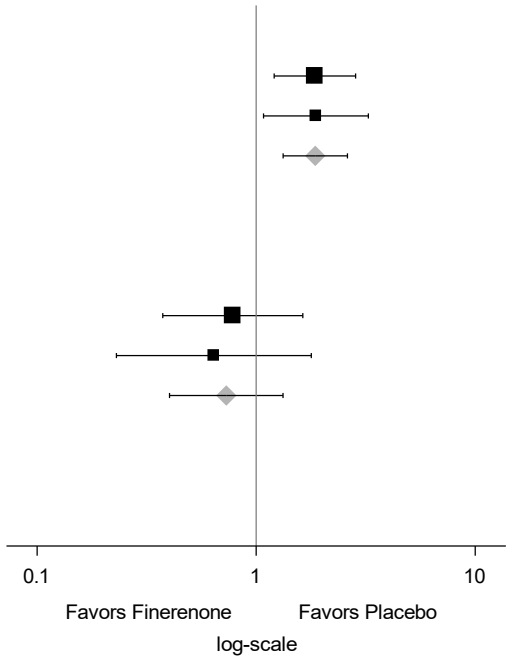
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	47 / 1634	34 / 1657	62.2	1.40 [0.91,2.17]	
FIGARO-DKD	30 / 1010	20 / 989	37.8	1.47 [0.84,2.57]	
Total	77 / 2644	54 / 2646		1.43 [1.01,2.01]	Z=2.03, p=0.0427
Heterogeneity:	Q=0.02 (df=1)	p=0.8973	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	11E10 [11E10,11E10]	
FIGARO-DKD	1 / 43	2 / 71	100.0	0.83 [0.08,8.84]	
Total	2 / 172	2 / 186		1.40 [0.20,9.91]	Z=0.34, p=0.7333
Heterogeneity:	Q=0.19 (df=1)	p=0.6604	I^2=0.0%		
Asian					
FIDELIO-DKD	15 / 678	5 / 677	57.2	3.00 [1.09,8.20]	
FIGARO-DKD	9 / 252	4 / 251	42.8	2.24 [0.70,7.18]	
Total	24 / 930	9 / 928		2.66 [1.24,5.69]	Z=2.52, p=0.0117
Heterogeneity:	Q=0.14 (df=1)	p=0.7116	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 176	8 / 161	85.1	0.80 [0.30,2.16]	
FIGARO-DKD	1 / 52	2 / 45	14.9	0.43 [0.04,4.62]	
Total	8 / 228	10 / 206		0.73 [0.29,1.80]	Z=-0.69, p=0.4902
Heterogeneity:	Q=0.22 (df=1)	p=0.6384	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.67 (df=3)	p=0.1976	I^2=35.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.69.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

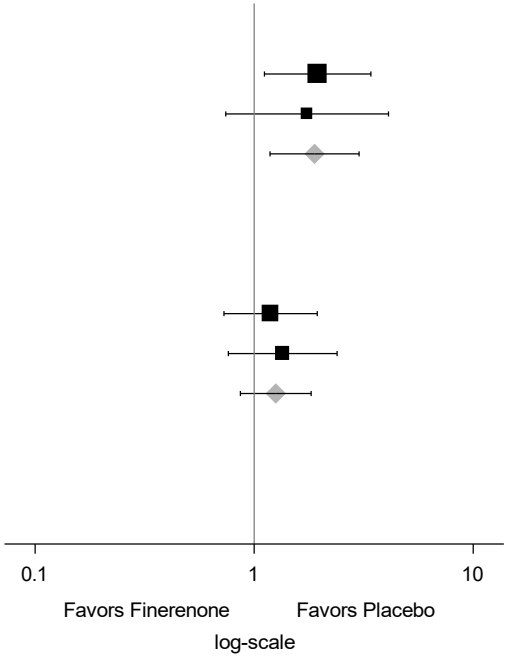
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	57 / 1797	32 / 1870	62.4	1.85 [1.21,2.84]	
FIGARO-DKD	35 / 917	19 / 933	37.6	1.87 [1.08,3.25]	
Total	92 / 2714	51 / 2803		1.86 [1.33,2.61]	Z=3.60, p=0.0003
Heterogeneity:	Q=0.00 (df=1)	p=0.9752	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 820	15 / 740	66.0	0.78 [0.37,1.63]	
FIGARO-DKD	6 / 440	9 / 423	34.0	0.64 [0.23,1.79]	
Total	19 / 1260	24 / 1163		0.73 [0.40,1.33]	Z=-1.03, p=0.3020
Heterogeneity:	Q=0.10 (df=1)	p=0.7570	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.15 (df=1)	p=0.0075	I^2=86.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.69.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

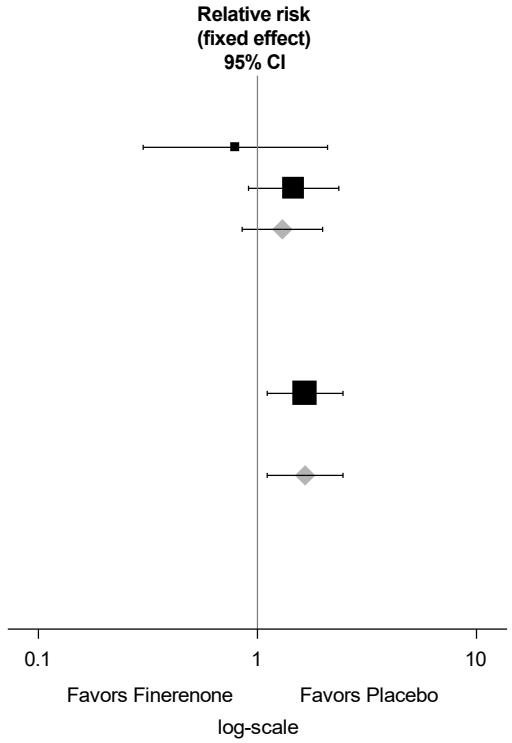
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	36 / 1103	18 / 1075	70.0	1.95 [1.11,3.41]	
FIGARO-DKD	14 / 336	8 / 335	30.0	1.74 [0.74,4.10]	
Total	50 / 1439	26 / 1410		1.89 [1.18,3.01]	Z=2.66, p=0.0079
Heterogeneity:	Q=0.05 (df=1)	p=0.8317	I^2=0.0%		
>= 65					
FIDELIO-DKD	34 / 1514	29 / 1535	57.6	1.19 [0.73,1.94]	
FIGARO-DKD	27 / 1021	20 / 1021	42.4	1.35 [0.76,2.39]	
Total	61 / 2535	49 / 2556		1.25 [0.87,1.82]	Z=1.20, p=0.2316
Heterogeneity:	Q=0.11 (df=1)	p=0.7405	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.79 (df=1)	p=0.1815	I^2=44.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.69.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

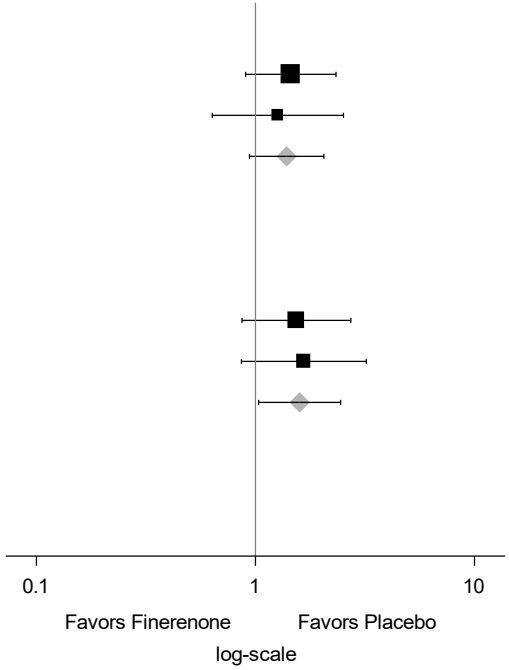
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	9 / 213	19.3	0.79 [0.30,2.09]	
FIGARO-DKD	41 / 1357	28 / 1356	80.7	1.46 [0.91,2.35]	
Total	48 / 1566	37 / 1569		1.30 [0.85,1.98]	Z=1.21, p=0.2245
Heterogeneity:	Q=1.24 (df=1)	p=0.2655	I^2=19.3%		
Very High					
FIDELIO-DKD	63 / 2408	38 / 2397	100.0	1.65 [1.11,2.46]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	63 / 2408	38 / 2397		1.65 [1.11,2.46]	Z=2.46, p=0.0138
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4204	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.69.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

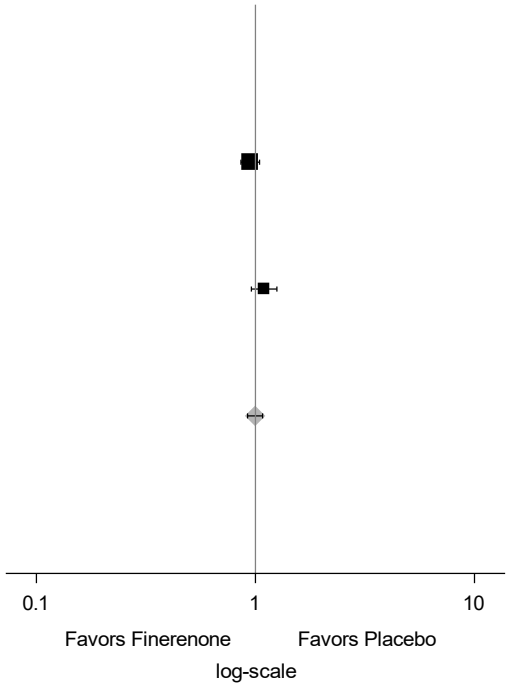
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	41 / 1556	28 / 1541	67.8	1.45 [0.90,2.33]	
FIGARO-DKD	18 / 637	14 / 627	32.2	1.27 [0.63,2.52]	
Total	59 / 2193	42 / 2168		1.39 [0.94,2.05]	Z=1.64, p=0.1002
Heterogeneity:	Q=0.10 (df=1)	p=0.7500	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	19 / 1069	56.8	1.54 [0.87,2.73]	
FIGARO-DKD	23 / 720	14 / 729	43.2	1.66 [0.86,3.21]	
Total	52 / 1781	33 / 1798		1.59 [1.03,2.45]	Z=2.11, p=0.0348
Heterogeneity:	Q=0.03 (df=1)	p=0.8598	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6464	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.70: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

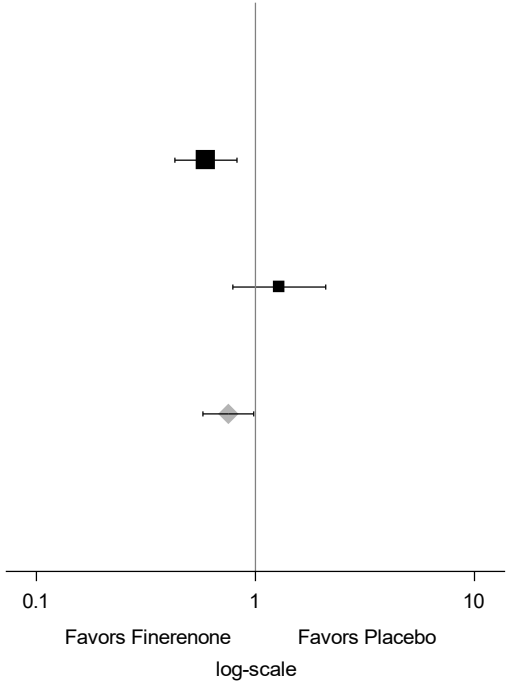
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	598 / 2617	630 / 2610	65.2	0.95 [0.86,1.04]	
FIGARO-DKD	341 / 1357	311 / 1356	34.8	1.10 [0.96,1.25]	
Total	939 / 3974	941 / 3966		1.00 [0.92,1.08]	Z=-0.10, p=0.9229
Heterogeneity:	Q=2.98 (df=1)	p=0.0843	I^2=66.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.71: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

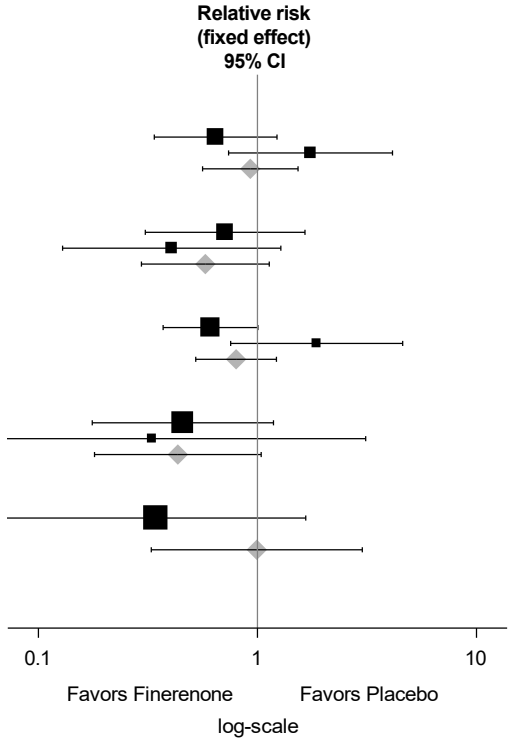
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	56 / 2617	94 / 2610	69.1	0.59 [0.43,0.82]	
FIGARO-DKD	36 / 1357	28 / 1356	30.9	1.28 [0.79,2.09]	
Total	92 / 3974	122 / 3966		0.75 [0.58,0.98]	Z=-2.09, p=0.0363
Heterogeneity:	Q=6.63 (df=1)	p=0.0100	I^2=84.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.71.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

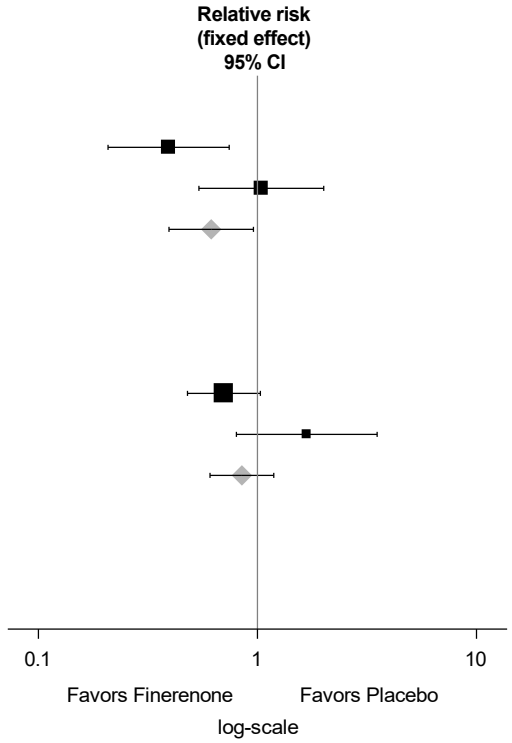
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	23 / 1062	64.1	0.64 [0.34,1.23]	
FIGARO-DKD	14 / 638	8 / 637	35.9	1.75 [0.74,4.14]	
Total	29 / 1713	31 / 1699		0.93 [0.56,1.53]	Z=-0.29, p=0.7693
Heterogeneity:	Q=3.30 (df=1)	p=0.0692	I^2=69.7%		
North America					
FIDELIO-DKD	9 / 424	13 / 436	65.1	0.71 [0.31,1.65]	
FIGARO-DKD	4 / 267	10 / 271	34.9	0.41 [0.13,1.28]	
Total	13 / 691	23 / 707		0.58 [0.30,1.13]	Z=-1.60, p=0.1101
Heterogeneity:	Q=0.60 (df=1)	p=0.4382	I^2=0.0%		
Asia					
FIDELIO-DKD	24 / 751	39 / 745	76.7	0.61 [0.37,1.00]	
FIGARO-DKD	13 / 289	7 / 290	23.3	1.86 [0.75,4.60]	
Total	37 / 1040	46 / 1035		0.80 [0.52,1.22]	Z=-1.04, p=0.2994
Heterogeneity:	Q=4.49 (df=1)	p=0.0341	I^2=77.7%		
Latin America					
FIDELIO-DKD	6 / 273	13 / 270	84.8	0.46 [0.18,1.18]	
FIGARO-DKD	1 / 102	3 / 101	15.2	0.33 [0.03,3.12]	
Total	7 / 375	16 / 371		0.43 [0.18,1.04]	Z=-1.87, p=0.0611
Heterogeneity:	Q=0.07 (df=1)	p=0.7944	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	6 / 97	100.0	0.34 [0.07,1.66]	
FIGARO-DKD	4 / 61	0 / 57	0.0	126E9 [126E9,126E9]	
Total	6 / 155	6 / 154		0.99 [0.33,3.01]	Z=-0.01, p=0.9901
Heterogeneity:	Q=1.74 (df=1)	p=0.1870	I^2=42.6%		
Subgroup Heterogeneity:	Q=3.10 (df=4)	p=0.5410	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.71.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

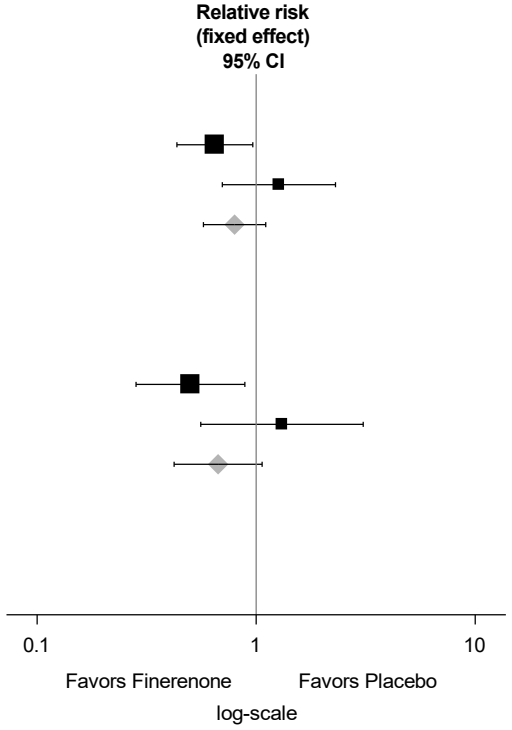
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1213	33 / 1210	51.5	0.39 [0.21,0.74]	
FIGARO-DKD	18 / 862	17 / 848	48.5	1.04 [0.54,2.01]	
Total	31 / 2075	50 / 2058		0.61 [0.39,0.96]	Z=-2.15, p=0.0318
Heterogeneity:	Q=4.38 (df=1)	p=0.0364	I^2=77.2%		
Absent					
FIDELIO-DKD	43 / 1404	61 / 1400	78.8	0.70 [0.48,1.03]	
FIGARO-DKD	18 / 495	11 / 508	21.2	1.68 [0.80,3.52]	
Total	61 / 1899	72 / 1908		0.85 [0.61,1.19]	Z=-0.96, p=0.3385
Heterogeneity:	Q=4.20 (df=1)	p=0.0405	I^2=76.2%		
Subgroup Heterogeneity:	Q=1.29 (df=1)	p=0.2556	I^2=22.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.71.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

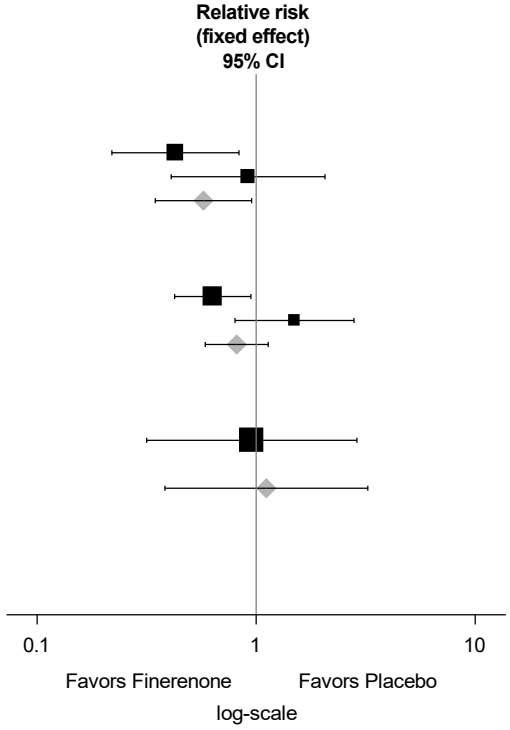
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	39 / 1735	59 / 1700	69.0	0.65 [0.43,0.97]	
FIGARO-DKD	24 / 924	19 / 929	31.0	1.27 [0.70,2.30]	
Total	63 / 2659	78 / 2629		0.80 [0.57,1.11]	Z=-1.36, p=0.1746
Heterogeneity:	Q=3.39 (df=1)	p=0.0654	I^2=70.5%		
> 4.5					
FIDELIO-DKD	17 / 882	35 / 910	69.0	0.50 [0.28,0.89]	
FIGARO-DKD	12 / 433	9 / 426	31.0	1.31 [0.56,3.08]	
Total	29 / 1315	44 / 1336		0.67 [0.42,1.06]	Z=-1.70, p=0.0899
Heterogeneity:	Q=3.37 (df=1)	p=0.0664	I^2=70.3%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5489	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.71.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

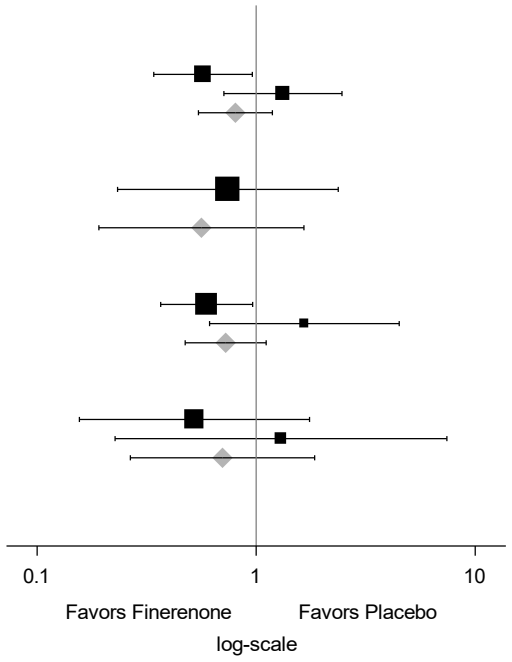
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	28 / 723	59.4	0.43 [0.22,0.83]	
FIGARO-DKD	11 / 494	12 / 495	40.6	0.92 [0.41,2.06]	
Total	23 / 1218	40 / 1218		0.57 [0.35,0.95]	Z=-2.14, p=0.0320
Heterogeneity:	Q=2.04 (df=1)	p=0.1533	I^2=51.0%		
130 - < 160					
FIDELIO-DKD	38 / 1759	60 / 1760	70.9	0.63 [0.42,0.95]	
FIGARO-DKD	24 / 829	16 / 827	29.1	1.50 [0.80,2.80]	
Total	62 / 2588	76 / 2587		0.82 [0.59,1.13]	Z=-1.21, p=0.2257
Heterogeneity:	Q=5.14 (df=1)	p=0.0234	I^2=80.6%		
>= 160					
FIDELIO-DKD	6 / 133	6 / 127	100.0	0.95 [0.32,2.88]	
FIGARO-DKD	1 / 34	0 / 34	0.0	153E9 [153E9,153E9]	
Total	7 / 167	6 / 161		1.11 [0.38,3.23]	Z=0.20, p=0.8442
Heterogeneity:	Q=0.07 (df=1)	p=0.7860	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=2)	p=0.4004	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.71.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

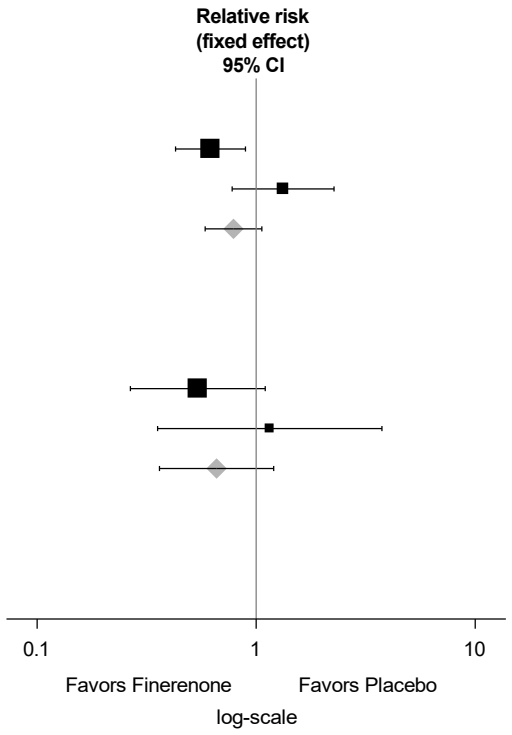
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1634	39 / 1657	58.9	0.57 [0.34,0.96]	
FIGARO-DKD	23 / 1010	17 / 989	41.1	1.32 [0.71,2.46]	
Total	45 / 2644	56 / 2646		0.80 [0.55,1.19]	Z=-1.10, p=0.2710
Heterogeneity:	Q=4.14 (df=1)	p=0.0418	I^2=75.9%		
Black					
FIDELIO-DKD	5 / 129	6 / 115	100.0	0.74 [0.23,2.37]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,22E296]	
Total	5 / 172	9 / 186		0.56 [0.19,1.65]	Z=-1.05, p=0.2951
Heterogeneity:	Q=0.22 (df=1)	p=0.6379	I^2=0.0%		
Asian					
FIDELIO-DKD	25 / 678	42 / 677	81.0	0.59 [0.37,0.96]	
FIGARO-DKD	10 / 252	6 / 251	19.0	1.66 [0.61,4.50]	
Total	35 / 930	48 / 928		0.73 [0.47,1.11]	Z=-1.48, p=0.1399
Heterogeneity:	Q=3.30 (df=1)	p=0.0692	I^2=69.7%		
Others					
FIDELIO-DKD	4 / 176	7 / 161	67.5	0.52 [0.16,1.75]	
FIGARO-DKD	3 / 52	2 / 45	32.5	1.30 [0.23,7.43]	
Total	7 / 228	9 / 206		0.70 [0.27,1.85]	Z=-0.72, p=0.4739
Heterogeneity:	Q=0.71 (df=1)	p=0.4010	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.44 (df=3)	p=0.9324	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.71.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

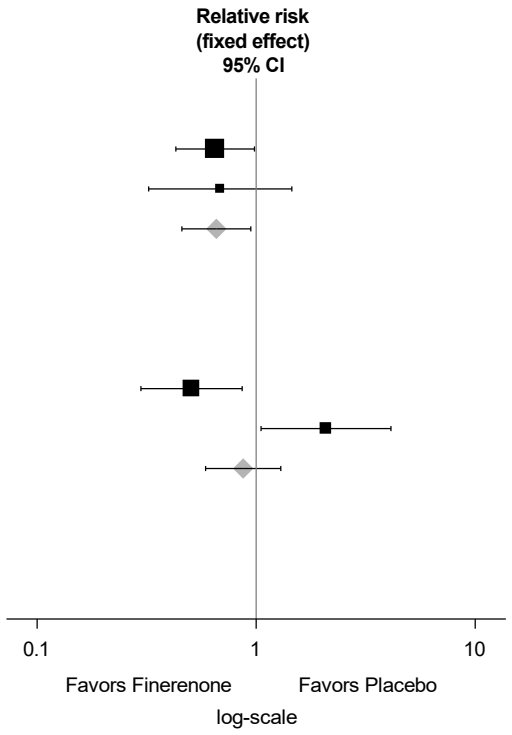
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	44 / 1797	74 / 1870	68.0	0.62 [0.43,0.89]	
FIGARO-DKD	30 / 917	23 / 933	32.0	1.33 [0.78,2.27]	
Total	74 / 2714	97 / 2803		0.79 [0.58,1.06]	Z=-1.57, p=0.1167
Heterogeneity:	Q=5.30 (df=1)	p=0.0213	I^2=81.1%		
Female					
FIDELIO-DKD	12 / 820	20 / 740	73.5	0.54 [0.27,1.10]	
FIGARO-DKD	6 / 440	5 / 423	26.5	1.15 [0.35,3.75]	
Total	18 / 1260	25 / 1163		0.66 [0.36,1.20]	Z=-1.36, p=0.1743
Heterogeneity:	Q=1.16 (df=1)	p=0.2812	I^2=13.9%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6031	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.71.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

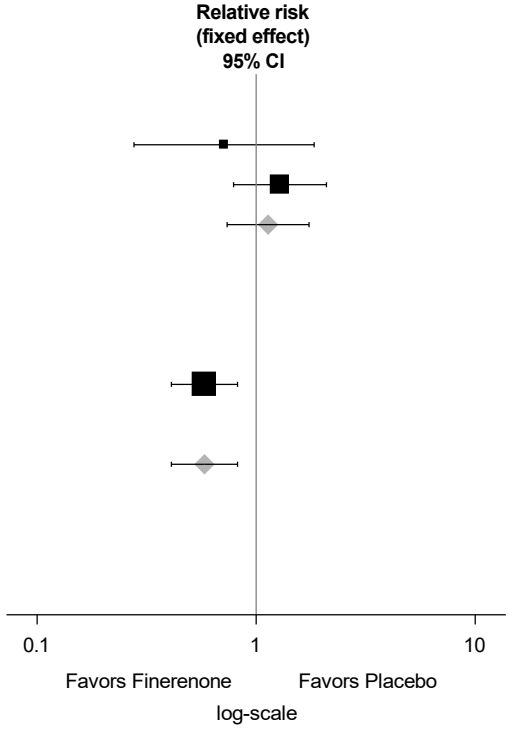
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	36 / 1103	54 / 1075	76.8	0.65 [0.43,0.98]	
FIGARO-DKD	11 / 336	16 / 335	23.2	0.69 [0.32,1.45]	
Total	47 / 1439	70 / 1410		0.66 [0.46,0.94]	Z=-2.27, p=0.0234
Heterogeneity:	Q=0.01 (df=1)	p=0.9028	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1514	40 / 1535	62.2	0.51 [0.30,0.86]	
FIGARO-DKD	25 / 1021	12 / 1021	37.8	2.08 [1.05,4.12]	
Total	45 / 2535	52 / 2556		0.87 [0.59,1.30]	Z=-0.68, p=0.4983
Heterogeneity:	Q=10.24 (df=1)	p=0.0014	I^2=90.2%		
Subgroup Heterogeneity:	Q=1.06 (df=1)	p=0.3021	I^2=6.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.71.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

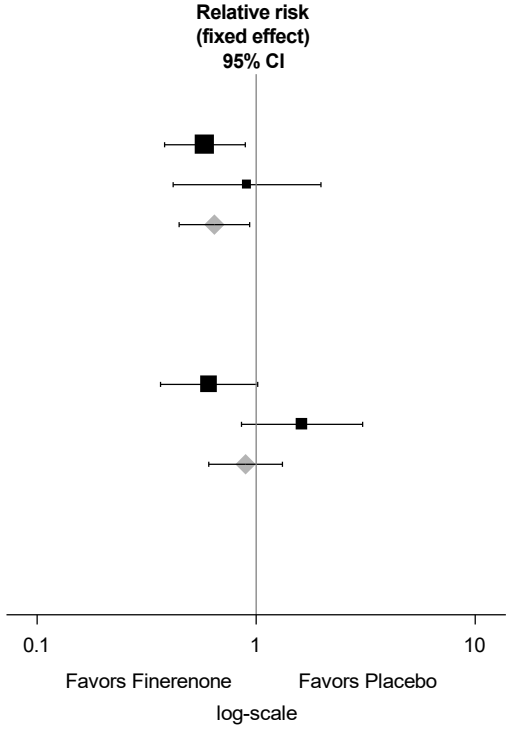
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	10 / 213	21.0	0.71 [0.28,1.84]	
FIGARO-DKD	36 / 1357	28 / 1356	79.0	1.28 [0.79,2.09]	
Total	43 / 1566	38 / 1569		1.13 [0.74,1.74]	Z=0.57, p=0.5682
Heterogeneity:	Q=1.17 (df=1)	p=0.2791	I^2=14.7%		
Very High					
FIDELIO-DKD	49 / 2408	84 / 2397	100.0	0.58 [0.41,0.82]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	49 / 2408	84 / 2397		0.58 [0.41,0.82]	Z=-3.06, p=0.0022
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.61 (df=1)	p=0.0178	I^2=82.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.71.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

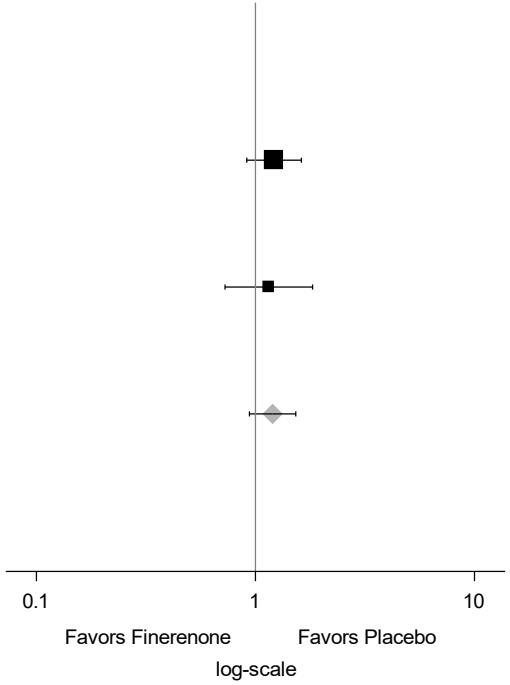
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	33 / 1556	56 / 1541	77.0	0.58 [0.38,0.89]	
FIGARO-DKD	12 / 637	13 / 627	23.0	0.91 [0.42,1.98]	
Total	45 / 2193	69 / 2168		0.64 [0.44,0.93]	Z=-2.32, p=0.0202
Heterogeneity:	Q=0.96 (df=1)	p=0.3270	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	23 / 1061	38 / 1069	60.9	0.61 [0.37,1.02]	
FIGARO-DKD	24 / 720	15 / 729	39.1	1.62 [0.86,3.06]	
Total	47 / 1781	53 / 1798		0.89 [0.61,1.32]	Z=-0.56, p=0.5738
Heterogeneity:	Q=5.50 (df=1)	p=0.0190	I^2=81.8%		
Subgroup Heterogeneity:	Q=1.44 (df=1)	p=0.2304	I^2=30.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.72: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

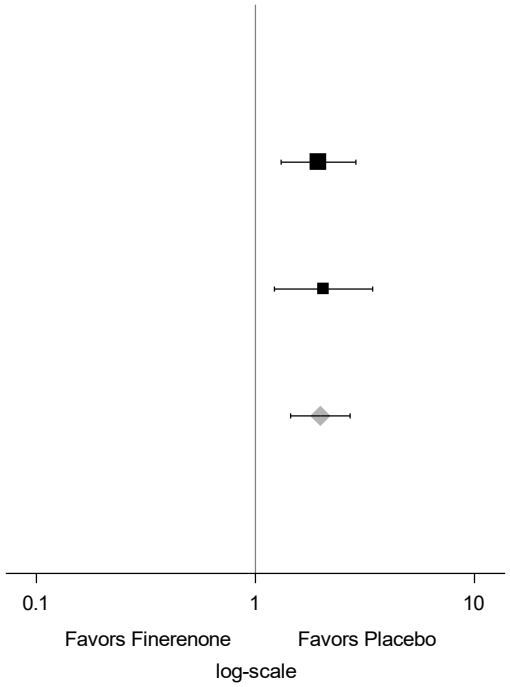
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	82 / 2610	72.0	1.22 [0.91,1.62]	
FIGARO-DKD	38 / 1357	33 / 1356	28.0	1.15 [0.73,1.82]	
Total	138 / 3974	115 / 3966		1.20 [0.94,1.53]	Z=1.45, p=0.1467
Heterogeneity:	Q=0.04 (df=1)	p=0.8412	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.73: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

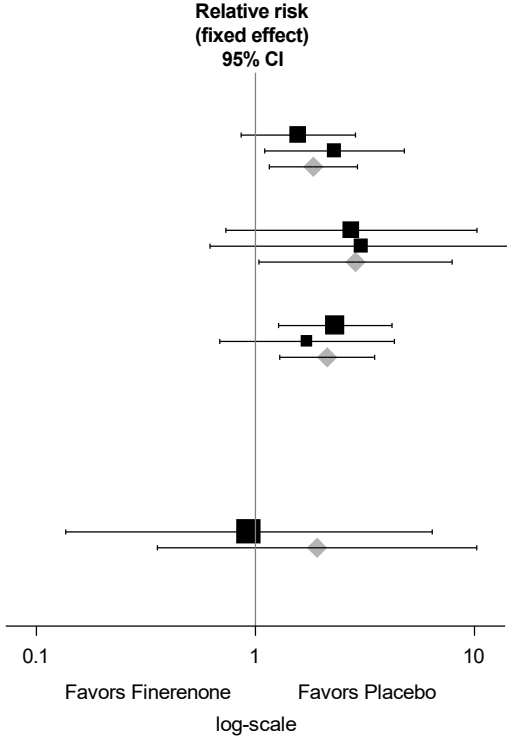
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	72 / 2617	37 / 2610	63.3	1.94 [1.31,2.87]	
FIGARO-DKD	43 / 1357	21 / 1356	36.7	2.05 [1.22,3.43]	
Total	115 / 3974	58 / 3966		1.98 [1.45,2.71]	Z=4.28, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8731	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.73.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

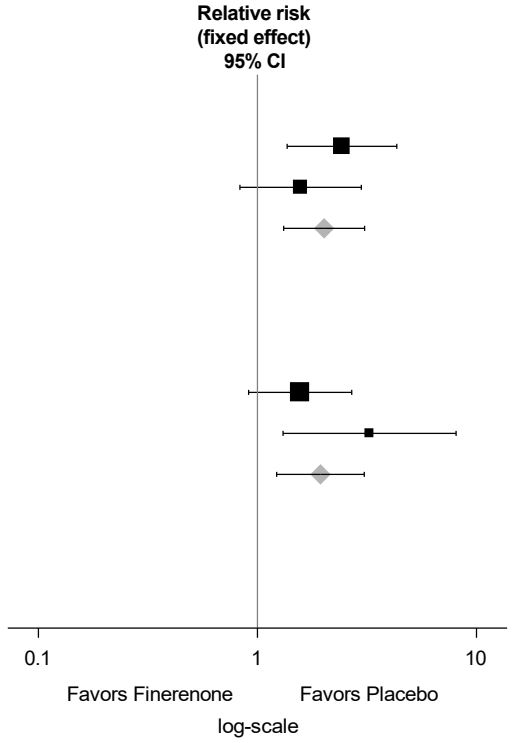
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 1075	17 / 1062	59.9	1.57 [0.86,2.86]	
FIGARO-DKD	23 / 638	10 / 637	40.1	2.30 [1.10,4.79]	
Total	50 / 1713	27 / 1699		1.84 [1.16,2.92]	Z=2.58, p=0.0100
Heterogeneity:	Q=0.62 (df=1)	p=0.4312	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	3 / 436	59.2	2.74 [0.73,10.27]	
FIGARO-DKD	6 / 267	2 / 271	40.8	3.04 [0.62,14.95]	
Total	14 / 691	5 / 707		2.86 [1.04,7.91]	Z=2.03, p=0.0423
Heterogeneity:	Q=0.01 (df=1)	p=0.9209	I^2=0.0%		
Asia					
FIDELIO-DKD	35 / 751	15 / 745	70.3	2.31 [1.28,4.20]	
FIGARO-DKD	12 / 289	7 / 290	29.7	1.72 [0.69,4.31]	
Total	47 / 1040	22 / 1035		2.13 [1.29,3.50]	Z=2.96, p=0.0030
Heterogeneity:	Q=0.28 (df=1)	p=0.5950	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	2 / 270	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	0 / 375	2 / 371		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 94	0 / 97	0.0	111E9 [111E9,111E9]	
FIGARO-DKD	2 / 61	2 / 57	100.0	0.93 [0.14,6.41]	
Total	4 / 155	2 / 154		1.91 [0.36,10.24]	Z=0.76, p=0.4493
Heterogeneity:	Q=0.53 (df=1)	p=0.4664	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=4)	p=0.9569	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.73.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

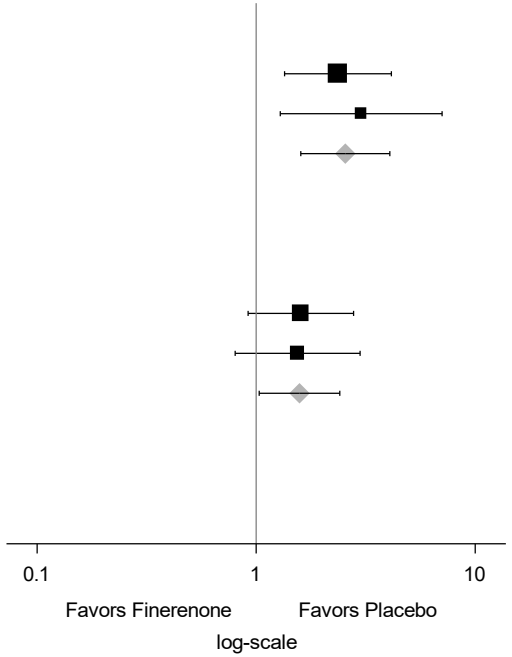
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	39 / 1213	16 / 1210	55.1	2.43 [1.37,4.33]	
FIGARO-DKD	24 / 862	15 / 848	44.9	1.57 [0.83,2.98]	
Total	63 / 2075	31 / 2058		2.02 [1.32,3.09]	Z=3.23, p=0.0012
Heterogeneity:	Q=0.98 (df=1)	p=0.3213	I^2=0.0%		
Absent					
FIDELIO-DKD	33 / 1404	21 / 1400	73.8	1.57 [0.91,2.69]	
FIGARO-DKD	19 / 495	6 / 508	26.2	3.25 [1.31,8.07]	
Total	52 / 1899	27 / 1908		1.94 [1.22,3.07]	Z=2.82, p=0.0048
Heterogeneity:	Q=1.83 (df=1)	p=0.1759	I^2=45.4%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9044	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.73.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

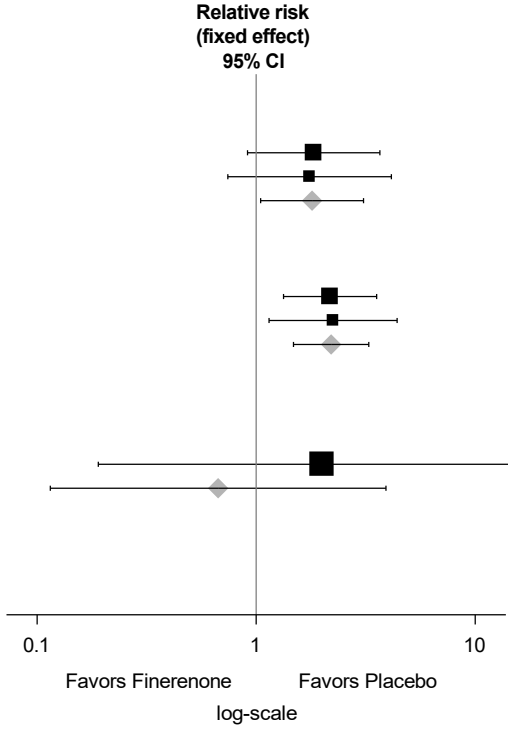
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	41 / 1735	17 / 1700	69.7	2.36 [1.35,4.14]	
FIGARO-DKD	21 / 924	7 / 929	30.3	3.02 [1.29,7.06]	
Total	62 / 2659	24 / 2629		2.55 [1.60,4.08]	Z=3.92, p=<.0001
Heterogeneity:	Q=0.22 (df=1)	p=0.6387	I^2=0.0%		
> 4.5					
FIDELIO-DKD	31 / 882	20 / 910	58.4	1.60 [0.92,2.78]	
FIGARO-DKD	22 / 433	14 / 426	41.6	1.55 [0.80,2.98]	
Total	53 / 1315	34 / 1336		1.58 [1.03,2.41]	Z=2.11, p=0.0351
Heterogeneity:	Q=0.01 (df=1)	p=0.9385	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.24 (df=1)	p=0.1349	I^2=55.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.73.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

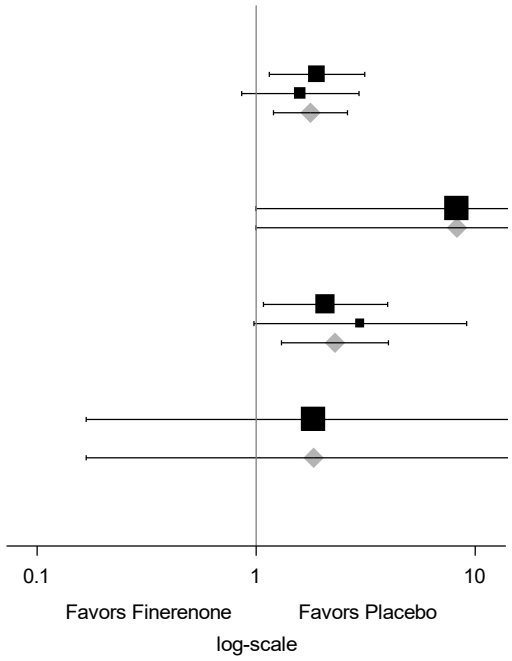
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	22 / 724	12 / 723	60.4	1.83 [0.91,3.67]	
FIGARO-DKD	14 / 494	8 / 495	39.6	1.75 [0.74,4.14]	
Total	36 / 1218	20 / 1218		1.80 [1.05,3.09]	Z=2.13, p=0.0332
Heterogeneity:	Q=0.01 (df=1)	p=0.9391	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	50 / 1759	23 / 1760	65.4	2.18 [1.33,3.55]	
FIGARO-DKD	27 / 829	12 / 827	34.6	2.24 [1.14,4.40]	
Total	77 / 2588	35 / 2587		2.20 [1.48,3.27]	Z=3.90, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9410	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	2 / 127	0.0	0.00 [0.00,81E295]	
FIGARO-DKD	2 / 34	1 / 34	100.0	2.00 [0.19,21.03]	
Total	2 / 167	3 / 161		0.67 [0.11,3.91]	Z=-0.44, p=0.6568
Heterogeneity:	Q=0.83 (df=1)	p=0.3625	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.84 (df=2)	p=0.3991	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.73.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

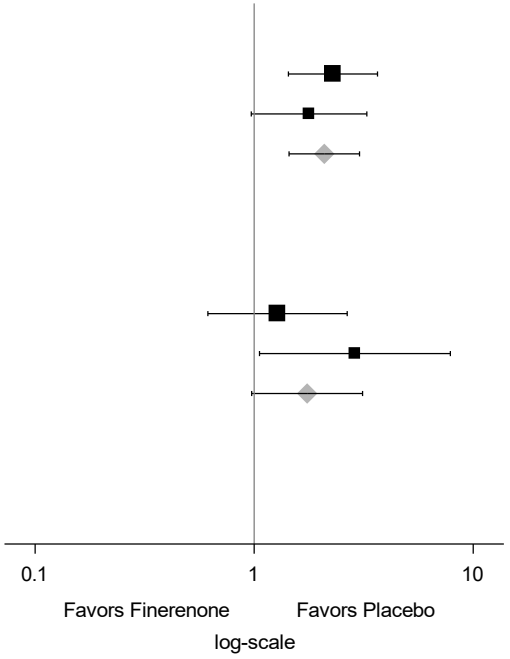
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	43 / 1634	23 / 1657	60.2	1.90 [1.15,3.13]	
FIGARO-DKD	26 / 1010	16 / 989	39.8	1.59 [0.86,2.95]	
Total	69 / 2644	39 / 2646		1.77 [1.20,2.61]	Z=2.88, p=0.0040
Heterogeneity:	Q=0.19 (df=1)	p=0.6657	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	0 / 115	0.0	-	
FIGARO-DKD	5 / 43	1 / 71	100.0	8.26 [1.00,68.33]	
Total	5 / 172	1 / 186		8.26 [1.00,68.33]	Z=1.96, p=0.0503
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 678	13 / 677	74.6	2.07 [1.08,3.98]	
FIGARO-DKD	12 / 252	4 / 251	25.4	2.99 [0.98,9.14]	
Total	39 / 930	17 / 928		2.29 [1.30,4.02]	Z=2.89, p=0.0039
Heterogeneity:	Q=0.31 (df=1)	p=0.5801	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.83 [0.17,19.99]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	2 / 228	1 / 206		1.83 [0.17,19.99]	Z=0.50, p=0.6205
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.33 (df=3)	p=0.5062	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.73.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

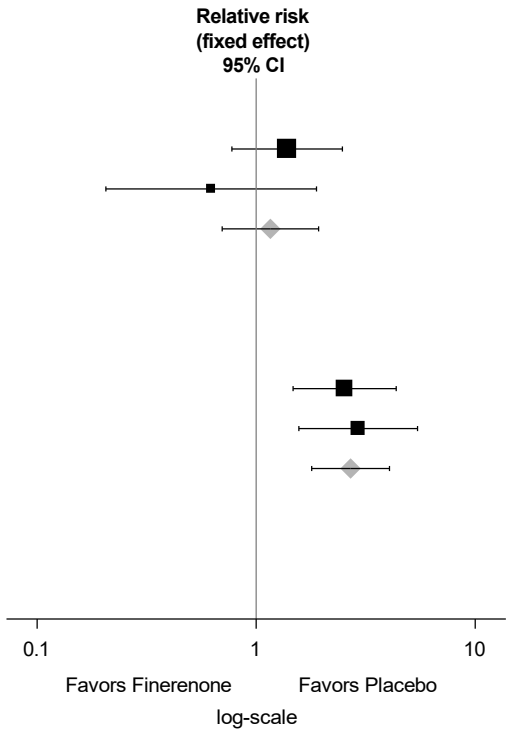
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	55 / 1797	25 / 1870	62.7	2.29 [1.43,3.66]	
FIGARO-DKD	28 / 917	16 / 933	37.3	1.78 [0.97,3.27]	
Total	83 / 2714	41 / 2803		2.09 [1.44,3.03]	Z=3.90, p=<.0001
Heterogeneity:	Q=0.41 (df=1)	p=0.5206	I^2=0.0%		
Female					
FIDELIO-DKD	17 / 820	12 / 740	65.2	1.28 [0.61,2.66]	
FIGARO-DKD	15 / 440	5 / 423	34.8	2.88 [1.06,7.87]	
Total	32 / 1260	17 / 1163		1.74 [0.97,3.13]	Z=1.87, p=0.0612
Heterogeneity:	Q=1.66 (df=1)	p=0.1980	I^2=39.6%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6088	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.73.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

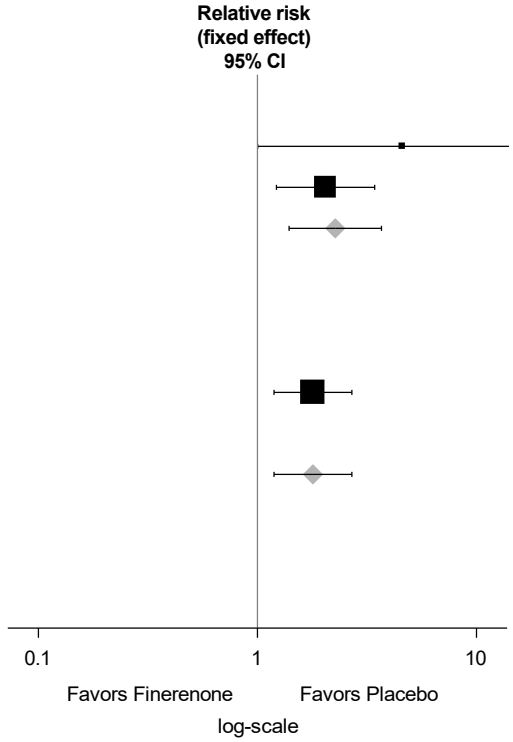
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	27 / 1103	19 / 1075	78.4	1.38 [0.77,2.48]	
FIGARO-DKD	5 / 336	8 / 335	21.6	0.62 [0.21,1.89]	
Total	32 / 1439	27 / 1410		1.16 [0.70,1.93]	Z=0.58, p=0.5634
Heterogeneity:	Q=1.57 (df=1)	p=0.2105	I^2=36.2%		
>= 65					
FIDELIO-DKD	45 / 1514	18 / 1535	57.0	2.53 [1.47,4.36]	
FIGARO-DKD	38 / 1021	13 / 1021	43.0	2.92 [1.57,5.45]	
Total	83 / 2535	31 / 2556		2.70 [1.79,4.06]	Z=4.76, p=<.0001
Heterogeneity:	Q=0.11 (df=1)	p=0.7352	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.44 (df=1)	p=0.0112	I^2=84.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.73.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	9 / 209	2 / 213	10.3	4.59 [1.00,20.97]	
FIGARO-DKD	43 / 1357	21 / 1356	89.7	2.05 [1.22,3.43]	
Total	52 / 1566	23 / 1569		2.27 [1.39,3.68]	Z=3.30, p=0.0010
Heterogeneity:	Q=0.98 (df=1)	p=0.3231	I^2=0.0%		
Very High					
FIDELIO-DKD	63 / 2408	35 / 2397	100.0	1.79 [1.19,2.70]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	63 / 2408	35 / 2397		1.79 [1.19,2.70]	Z=2.79, p=0.0052
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4686	I^2=0.0%		

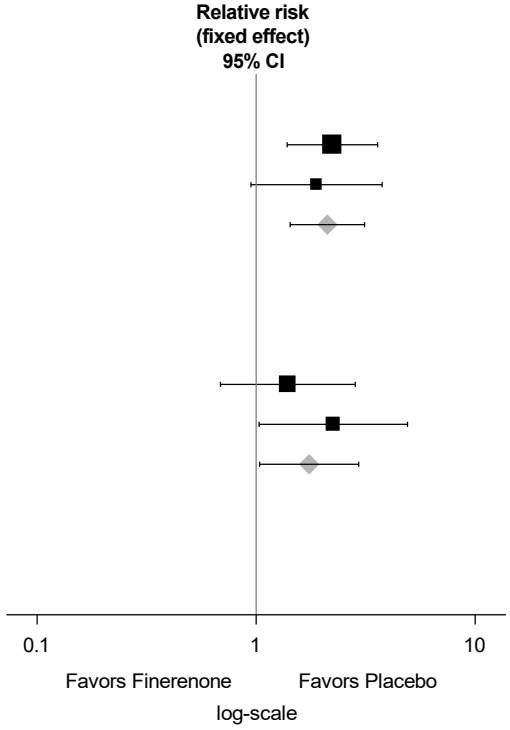


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.73.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood potassium increased (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

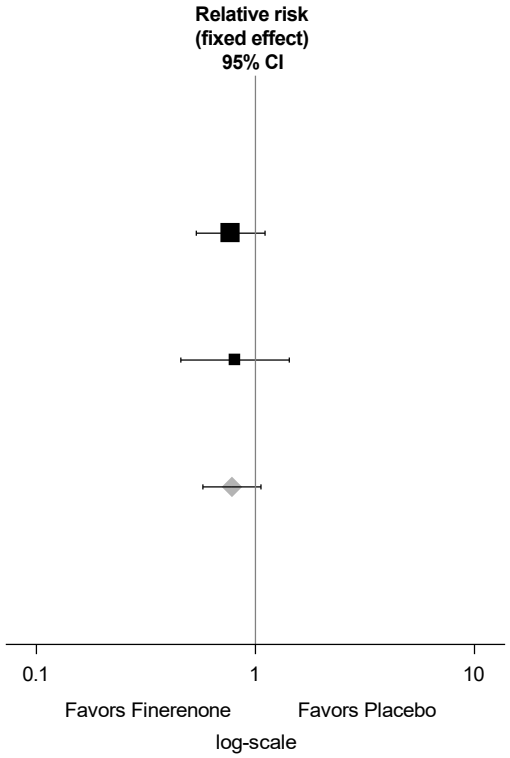
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	54 / 1556	24 / 1541	67.7	2.23 [1.38,3.59]	
FIGARO-DKD	23 / 637	12 / 627	32.3	1.89 [0.95,3.76]	
Total	77 / 2193	36 / 2168		2.11 [1.43,3.13]	Z=3.75, p=0.0002
Heterogeneity:	Q=0.15 (df=1)	p=0.6968	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	18 / 1061	13 / 1069	54.8	1.40 [0.69,2.83]	
FIGARO-DKD	20 / 720	9 / 729	45.2	2.25 [1.03,4.91]	
Total	38 / 1781	22 / 1798		1.75 [1.04,2.94]	Z=2.10, p=0.0361
Heterogeneity:	Q=0.79 (df=1)	p=0.3736	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=1)	p=0.5643	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.74: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

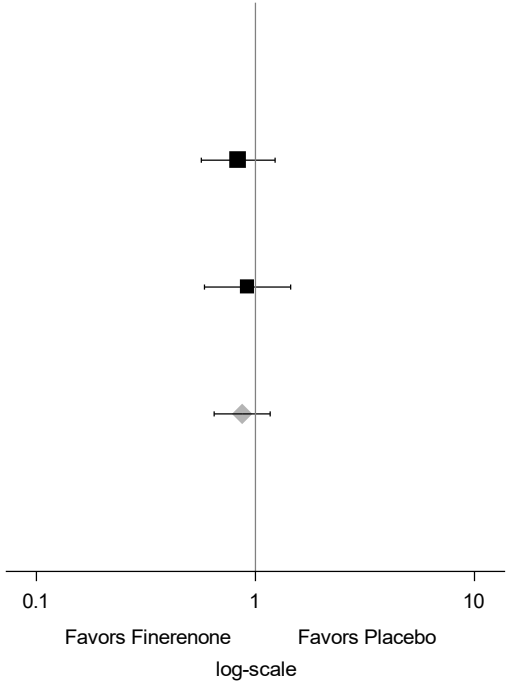
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2617	66 / 2610	71.3	0.77 [0.54,1.11]	
FIGARO-DKD	21 / 1357	26 / 1356	28.7	0.81 [0.46,1.43]	
Total	72 / 3974	92 / 3966		0.78 [0.58,1.06]	Z=-1.59, p=0.1123
Heterogeneity:	Q=0.02 (df=1)	p=0.8933	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.75: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

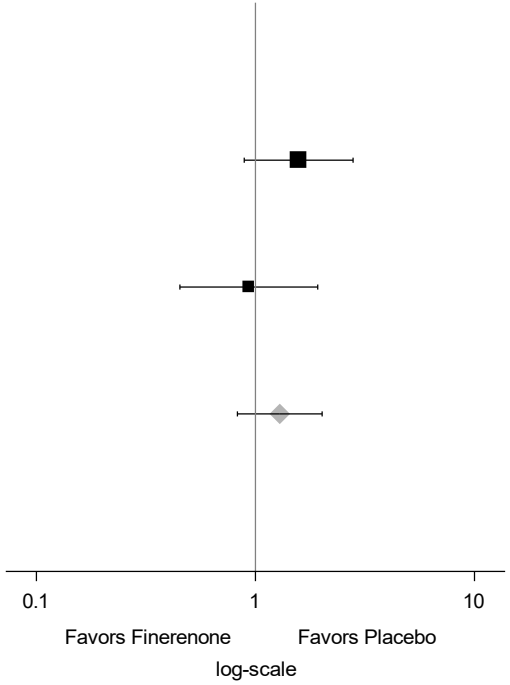
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	55 / 2610	57.7	0.83 [0.57,1.23]	
FIGARO-DKD	35 / 1357	38 / 1356	42.3	0.92 [0.59,1.45]	
Total	81 / 3974	93 / 3966		0.87 [0.65,1.17]	Z=-0.93, p=0.3521
Heterogeneity:	Q=0.10 (df=1)	p=0.7464	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.76: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

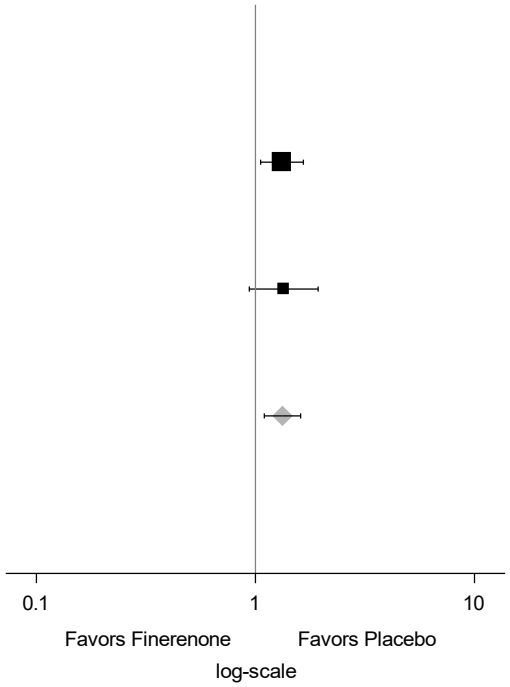
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	19 / 2610	61.6	1.57 [0.89,2.79]	
FIGARO-DKD	14 / 1357	15 / 1356	38.4	0.93 [0.45,1.92]	
Total	44 / 3974	34 / 3966		1.29 [0.83,2.02]	Z=1.13, p=0.2604
Heterogeneity:	Q=1.24 (df=1)	p=0.2660	I^2=19.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.77: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

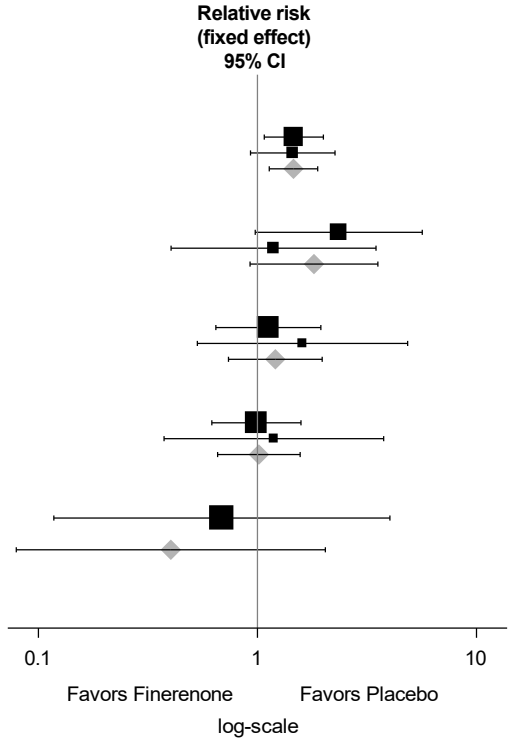
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	167 / 2617	126 / 2610	72.1	1.32 [1.06,1.66]	
FIGARO-DKD	66 / 1357	49 / 1356	27.9	1.35 [0.94,1.93]	
Total	233 / 3974	175 / 3966		1.33 [1.10,1.61]	Z=2.92, p=0.0036
Heterogeneity:	Q=0.01 (df=1)	p=0.9338	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.77.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

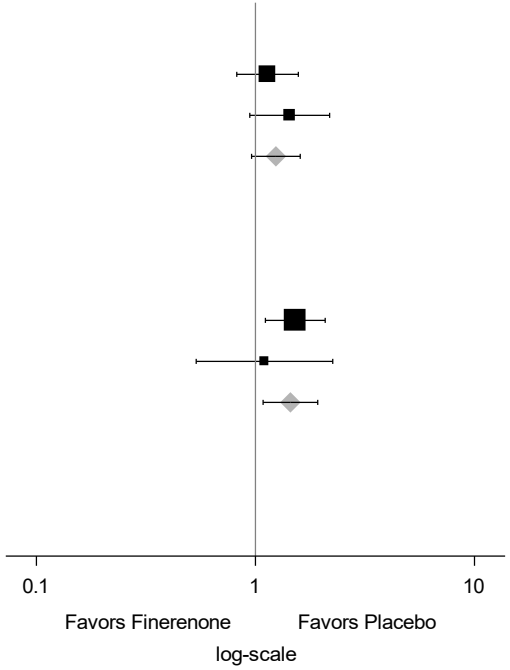
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	92 / 1075	62 / 1062	67.1	1.47 [1.07,2.00]	
FIGARO-DKD	45 / 638	31 / 637	32.9	1.45 [0.93,2.26]	
Total	137 / 1713	93 / 1699		1.46 [1.13,1.88]	Z=2.92, p=0.0035
Heterogeneity:	Q=0.00 (df=1)	p=0.9672	I^2=0.0%		
North America					
FIDELIO-DKD	16 / 424	7 / 436	60.1	2.35 [0.98,5.66]	
FIGARO-DKD	7 / 267	6 / 271	39.9	1.18 [0.40,3.48]	
Total	23 / 691	13 / 707		1.81 [0.93,3.55]	Z=1.73, p=0.0831
Heterogeneity:	Q=0.94 (df=1)	p=0.3332	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 751	23 / 745	80.1	1.12 [0.65,1.95]	
FIGARO-DKD	8 / 289	5 / 290	19.9	1.61 [0.53,4.85]	
Total	34 / 1040	28 / 1035		1.21 [0.74,1.97]	Z=0.75, p=0.4546
Heterogeneity:	Q=0.32 (df=1)	p=0.5691	I^2=0.0%		
Latin America					
FIDELIO-DKD	31 / 273	31 / 270	85.9	0.99 [0.62,1.58]	
FIGARO-DKD	6 / 102	5 / 101	14.1	1.19 [0.37,3.77]	
Total	37 / 375	36 / 371		1.02 [0.66,1.57]	Z=0.07, p=0.9459
Heterogeneity:	Q=0.08 (df=1)	p=0.7728	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	3 / 97	100.0	0.69 [0.12,4.02]	
FIGARO-DKD	0 / 61	2 / 57	0.0	0.00 [0.00,98E295]	
Total	2 / 155	5 / 154		0.40 [0.08,2.04]	Z=-1.10, p=0.2719
Heterogeneity:	Q=0.35 (df=1)	p=0.5515	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.05 (df=4)	p=0.2824	I^2=20.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.77.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

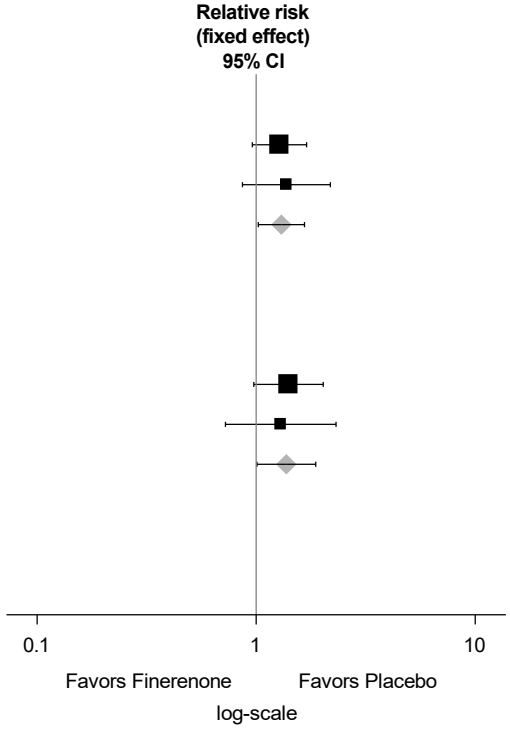
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	74 / 1213	65 / 1210	62.7	1.14 [0.82,1.57]	
FIGARO-DKD	51 / 862	35 / 848	37.3	1.43 [0.94,2.18]	
Total	125 / 2075	100 / 2058		1.24 [0.96,1.60]	Z=1.65, p=0.0995
Heterogeneity:	Q=0.74 (df=1)	p=0.3890	I^2=0.0%		
Absent					
FIDELIO-DKD	93 / 1404	61 / 1400	83.9	1.52 [1.11,2.08]	
FIGARO-DKD	15 / 495	14 / 508	16.1	1.10 [0.54,2.25]	
Total	108 / 1899	75 / 1908		1.44 [1.08,1.92]	Z=2.51, p=0.0122
Heterogeneity:	Q=0.66 (df=1)	p=0.4177	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.60 (df=1)	p=0.4370	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.77.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

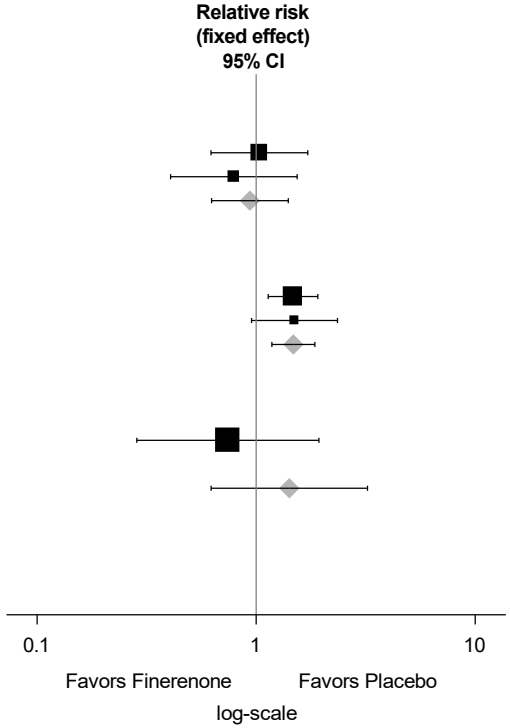
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	103 / 1735	79 / 1700	72.4	1.28 [0.96,1.70]	
FIGARO-DKD	41 / 924	30 / 929	27.6	1.37 [0.87,2.18]	
Total	144 / 2659	109 / 2629		1.30 [1.02,1.66]	Z=2.14, p=0.0324
Heterogeneity:	Q=0.07 (df=1)	p=0.7926	I^2=0.0%		
> 4.5					
FIDELIO-DKD	64 / 882	47 / 910	71.7	1.40 [0.98,2.02]	
FIGARO-DKD	25 / 433	19 / 426	28.3	1.29 [0.72,2.32]	
Total	89 / 1315	66 / 1336		1.37 [1.01,1.87]	Z=2.01, p=0.0444
Heterogeneity:	Q=0.05 (df=1)	p=0.8152	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7960	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.77.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

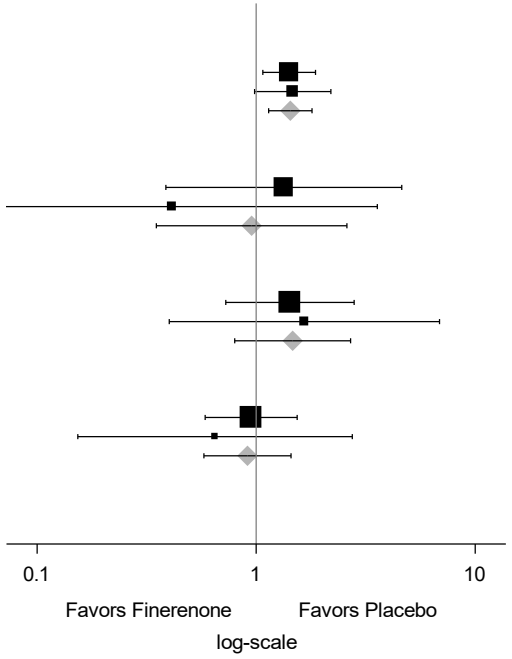
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	29 / 724	28 / 723	63.1	1.03 [0.62,1.72]	
FIGARO-DKD	15 / 494	19 / 495	36.9	0.79 [0.41,1.54]	
Total	44 / 1218	47 / 1218		0.94 [0.63,1.40]	Z=-0.32, p=0.7494
Heterogeneity:	Q=0.39 (df=1)	p=0.5305	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	131 / 1759	89 / 1760	75.0	1.47 [1.13,1.91]	
FIGARO-DKD	45 / 829	30 / 827	25.0	1.50 [0.95,2.35]	
Total	176 / 2588	119 / 2587		1.48 [1.18,1.85]	Z=3.39, p=0.0007
Heterogeneity:	Q=0.00 (df=1)	p=0.9523	I^2=0.0%		
>= 160					
FIDELIO-DKD	7 / 133	9 / 127	100.0	0.74 [0.29,1.93]	
FIGARO-DKD	6 / 34	0 / 34	0.0	338E9 [338E9,338E9]	
Total	13 / 167	9 / 161		1.42 [0.62,3.22]	Z=0.83, p=0.4062
Heterogeneity:	Q=1.75 (df=1)	p=0.1861	I^2=42.8%		
Subgroup Heterogeneity:	Q=3.77 (df=2)	p=0.1515	I^2=47.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.77.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

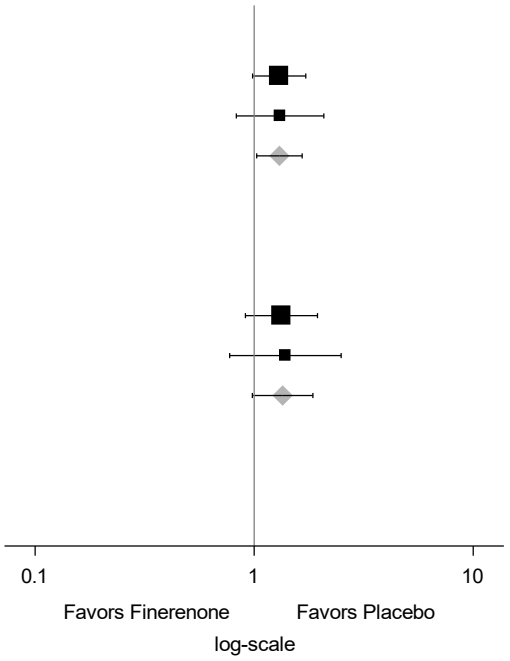
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	113 / 1634	81 / 1657	67.7	1.41 [1.07,1.87]	
FIGARO-DKD	57 / 1010	38 / 989	32.3	1.47 [0.98,2.19]	
Total	170 / 2644	119 / 2646		1.43 [1.14,1.80]	Z=3.09, p=0.0020
Heterogeneity:	Q=0.02 (df=1)	p=0.8800	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 129	4 / 115	75.2	1.34 [0.39,4.62]	
FIGARO-DKD	1 / 43	4 / 71	24.8	0.41 [0.05,3.57]	
Total	7 / 172	8 / 186		0.95 [0.35,2.60]	Z=-0.09, p=0.9256
Heterogeneity:	Q=0.86 (df=1)	p=0.3527	I^2=0.0%		
Asian					
FIDELIO-DKD	20 / 678	14 / 677	81.6	1.43 [0.73,2.80]	
FIGARO-DKD	5 / 252	3 / 251	18.4	1.66 [0.40,6.87]	
Total	25 / 930	17 / 928		1.47 [0.80,2.70]	Z=1.23, p=0.2172
Heterogeneity:	Q=0.04 (df=1)	p=0.8501	I^2=0.0%		
Others					
FIDELIO-DKD	28 / 176	27 / 161	89.9	0.95 [0.58,1.54]	
FIGARO-DKD	3 / 52	4 / 45	10.1	0.65 [0.15,2.75]	
Total	31 / 228	31 / 206		0.91 [0.58,1.44]	Z=-0.39, p=0.6950
Heterogeneity:	Q=0.24 (df=1)	p=0.6249	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.50 (df=3)	p=0.3205	I^2=14.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.77.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

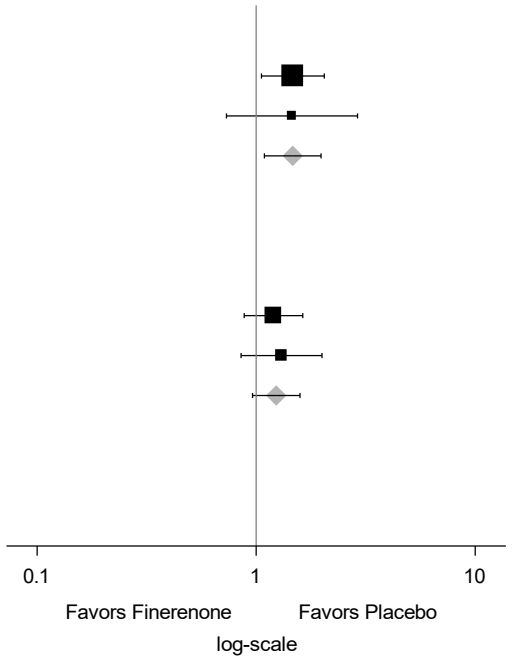
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	105 / 1797	84 / 1870	73.0	1.30 [0.98,1.72]	
FIGARO-DKD	40 / 917	31 / 933	27.0	1.31 [0.83,2.08]	
Total	145 / 2714	115 / 2803		1.30 [1.03,1.66]	Z=2.18, p=0.0294
Heterogeneity:	Q=0.00 (df=1)	p=0.9732	I^2=0.0%		
Female					
FIDELIO-DKD	62 / 820	42 / 740	70.5	1.33 [0.91,1.95]	
FIGARO-DKD	26 / 440	18 / 423	29.5	1.39 [0.77,2.49]	
Total	88 / 1260	60 / 1163		1.35 [0.98,1.85]	Z=1.84, p=0.0654
Heterogeneity:	Q=0.01 (df=1)	p=0.9072	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8684	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.77.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

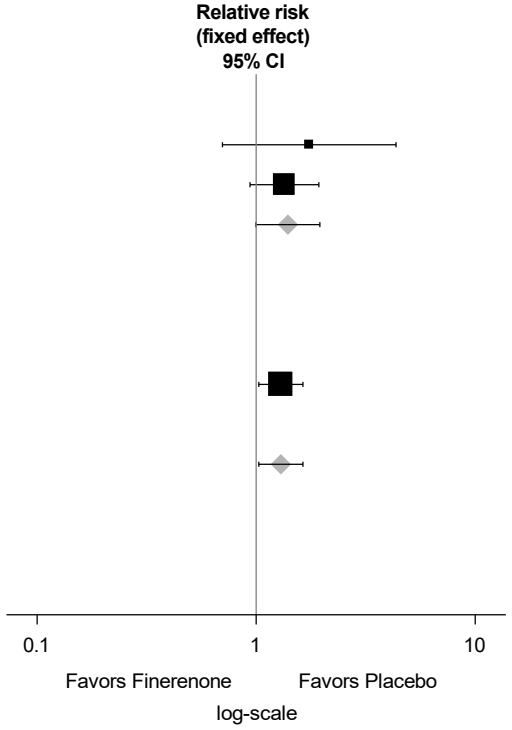
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	83 / 1103	55 / 1075	81.3	1.47 [1.06,2.05]	
FIGARO-DKD	19 / 336	13 / 335	18.7	1.46 [0.73,2.90]	
Total	102 / 1439	68 / 1410		1.47 [1.09,1.98]	Z=2.53, p=0.0115
Heterogeneity:	Q=0.00 (df=1)	p=0.9810	I^2=0.0%		
>= 65					
FIDELIO-DKD	84 / 1514	71 / 1535	65.6	1.20 [0.88,1.63]	
FIGARO-DKD	47 / 1021	36 / 1021	34.4	1.31 [0.85,2.00]	
Total	131 / 2535	107 / 2556		1.24 [0.96,1.58]	Z=1.66, p=0.0970
Heterogeneity:	Q=0.10 (df=1)	p=0.7518	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.76 (df=1)	p=0.3829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.77.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

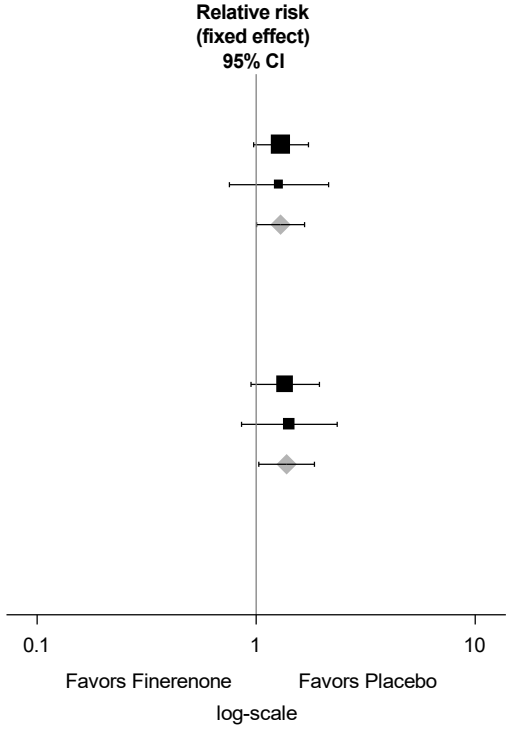
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	12 / 209	7 / 213	13.6	1.75 [0.70,4.35]	
FIGARO-DKD	66 / 1357	49 / 1356	86.4	1.35 [0.94,1.93]	
Total	78 / 1566	56 / 1569		1.40 [1.00,1.95]	Z=1.94, p=0.0518
Heterogeneity:	Q=0.27 (df=1)	p=0.6024	I^2=0.0%		
Very High					
FIDELIO-DKD	155 / 2408	119 / 2397	100.0	1.30 [1.03,1.64]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	155 / 2408	119 / 2397		1.30 [1.03,1.64]	Z=2.19, p=0.0283
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7233	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.77.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

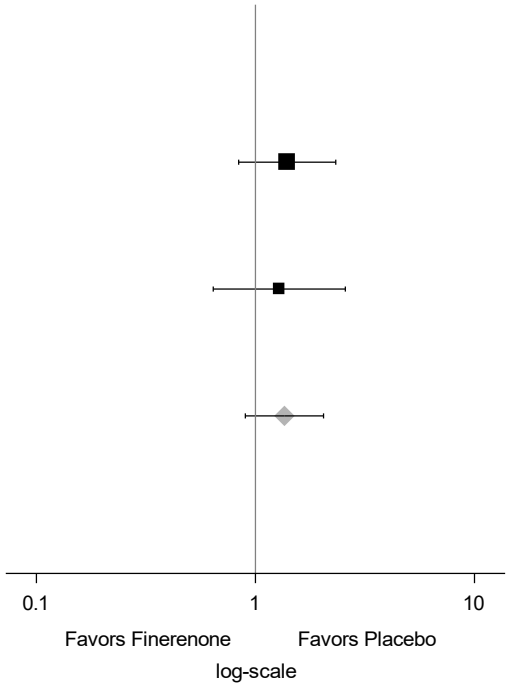
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	101 / 1556	77 / 1541	76.6	1.30 [0.97,1.73]	
FIGARO-DKD	31 / 637	24 / 627	23.4	1.27 [0.75,2.14]	
Total	132 / 2193	101 / 2168		1.29 [1.00,1.66]	Z=1.99, p=0.0461
Heterogeneity:	Q=0.01 (df=1)	p=0.9436	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	66 / 1061	49 / 1069	66.1	1.36 [0.95,1.94]	
FIGARO-DKD	35 / 720	25 / 729	33.9	1.42 [0.86,2.34]	
Total	101 / 1781	74 / 1798		1.38 [1.03,1.85]	Z=2.14, p=0.0320
Heterogeneity:	Q=0.02 (df=1)	p=0.8902	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7472	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.78: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

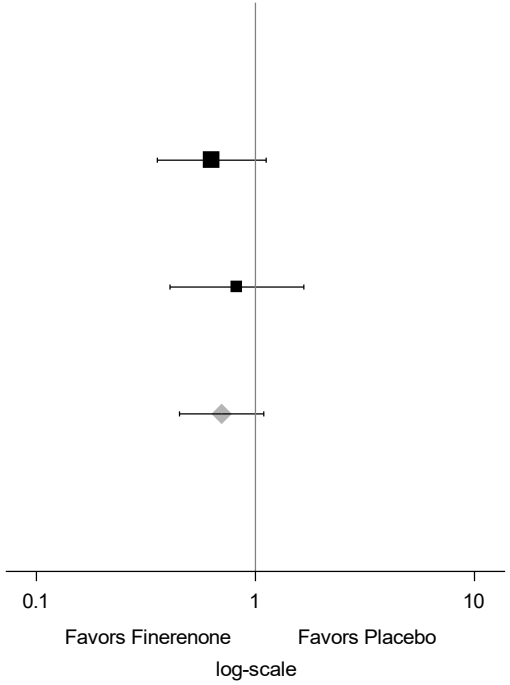
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	25 / 2610	64.9	1.40 [0.84,2.33]	
FIGARO-DKD	18 / 1357	14 / 1356	35.1	1.28 [0.64,2.57]	
Total	53 / 3974	39 / 3966		1.36 [0.90,2.05]	Z=1.45, p=0.1463
Heterogeneity:	Q=0.04 (df=1)	p=0.8499	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.79: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

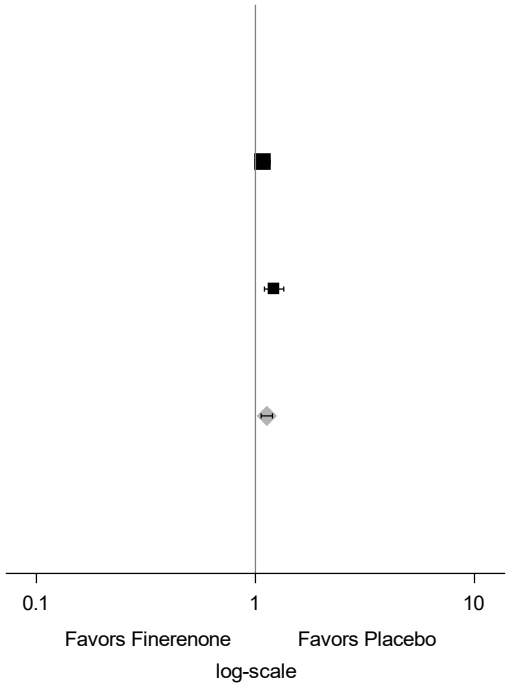
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	19 / 2617	30 / 2610	60.2	0.63 [0.36,1.12]	
FIGARO-DKD	14 / 1357	17 / 1356	39.8	0.82 [0.41,1.66]	
Total	33 / 3974	47 / 3966		0.70 [0.45,1.09]	Z=-1.57, p=0.1158
Heterogeneity:	Q=0.33 (df=1)	p=0.5674	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.80: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

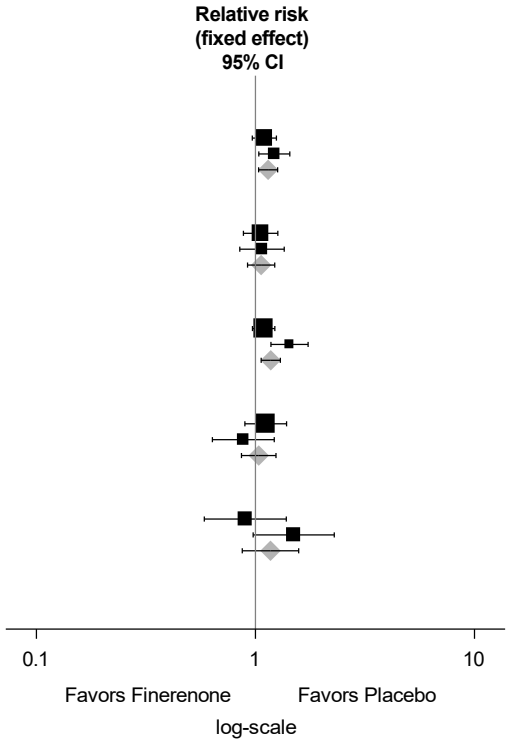
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	971 / 2617	894 / 2610	66.1	1.08 [1.01,1.17]	
FIGARO-DKD	532 / 1357	437 / 1356	33.9	1.22 [1.10,1.35]	
Total	1503 / 3974	1331 / 3966		1.13 [1.06,1.20]	Z=3.96, p=<.0001
Heterogeneity:	Q=3.30 (df=1)	p=0.0692	I^2=69.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.80.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

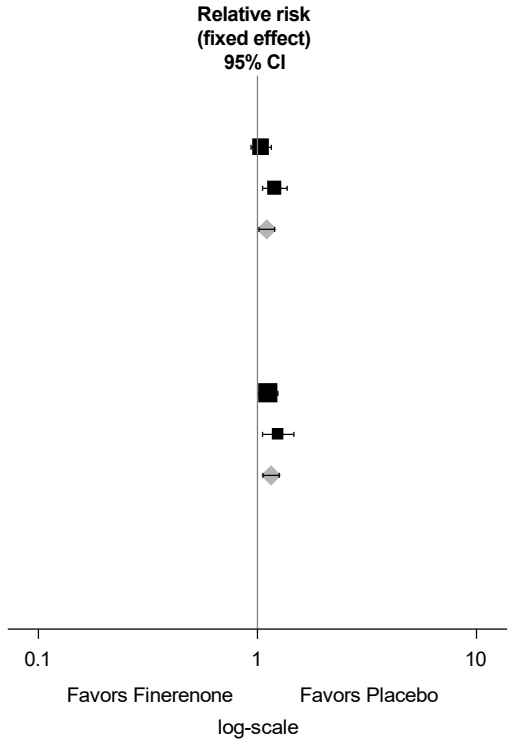
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	349 / 1075	314 / 1062	62.3	1.10 [0.97,1.25]	
FIGARO-DKD	221 / 638	181 / 637	37.7	1.22 [1.04,1.43]	
Total	570 / 1713	495 / 1699		1.14 [1.03,1.26]	Z=2.61, p=0.0091
Heterogeneity:	Q=0.99 (df=1)	p=0.3207	I^2=0.0%		
North America					
FIDELIO-DKD	154 / 424	150 / 436	62.5	1.06 [0.88,1.26]	
FIGARO-DKD	95 / 267	90 / 271	37.5	1.07 [0.85,1.35]	
Total	249 / 691	240 / 707		1.06 [0.92,1.22]	Z=0.82, p=0.4128
Heterogeneity:	Q=0.01 (df=1)	p=0.9222	I^2=0.0%		
Asia					
FIDELIO-DKD	334 / 751	304 / 745	73.4	1.09 [0.97,1.23]	
FIGARO-DKD	144 / 289	101 / 290	26.6	1.43 [1.18,1.74]	
Total	478 / 1040	405 / 1035		1.17 [1.06,1.30]	Z=3.13, p=0.0017
Heterogeneity:	Q=5.47 (df=1)	p=0.0194	I^2=81.7%		
Latin America					
FIDELIO-DKD	107 / 273	95 / 270	68.8	1.11 [0.89,1.39]	
FIGARO-DKD	40 / 102	45 / 101	31.2	0.88 [0.64,1.22]	
Total	147 / 375	140 / 371		1.03 [0.86,1.24]	Z=0.37, p=0.7111
Heterogeneity:	Q=1.39 (df=1)	p=0.2391	I^2=27.9%		
Others					
FIDELIO-DKD	27 / 94	31 / 97	49.5	0.90 [0.58,1.38]	
FIGARO-DKD	32 / 61	20 / 57	50.5	1.50 [0.98,2.29]	
Total	59 / 155	51 / 154		1.17 [0.87,1.58]	Z=1.04, p=0.2964
Heterogeneity:	Q=2.71 (df=1)	p=0.0997	I^2=63.1%		
Subgroup Heterogeneity:	Q=2.30 (df=4)	p=0.6803	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.80.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

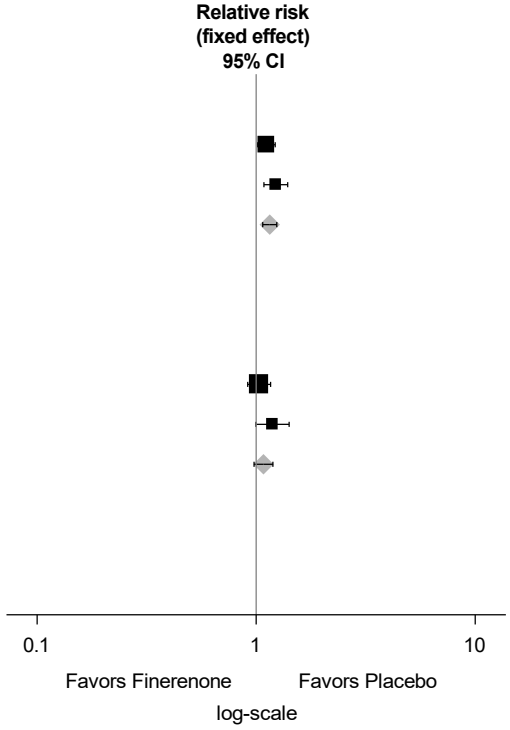
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	443 / 1213	425 / 1210	59.5	1.04 [0.93,1.16]	
FIGARO-DKD	332 / 862	272 / 848	40.5	1.20 [1.06,1.37]	
Total	775 / 2075	697 / 2058		1.10 [1.02,1.20]	Z=2.33, p=0.0198
Heterogeneity:	Q=2.84 (df=1)	p=0.0922	I^2=64.7%		
Absent					
FIDELIO-DKD	528 / 1404	469 / 1400	73.1	1.12 [1.02,1.24]	
FIGARO-DKD	200 / 495	165 / 508	26.9	1.24 [1.05,1.47]	
Total	728 / 1899	634 / 1908		1.15 [1.06,1.26]	Z=3.29, p=0.0010
Heterogeneity:	Q=1.09 (df=1)	p=0.2966	I^2=8.2%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4492	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.80.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

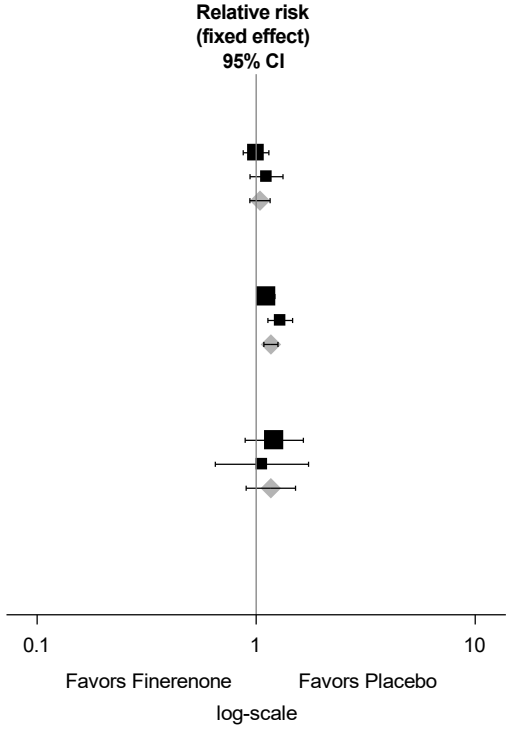
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	638 / 1735	561 / 1700	65.0	1.11 [1.02,1.22]	
FIGARO-DKD	357 / 924	292 / 929	35.0	1.23 [1.08,1.39]	
Total	995 / 2659	853 / 2629		1.15 [1.07,1.24]	Z=3.79, p=0.0002
Heterogeneity:	Q=1.54 (df=1)	p=0.2145	I^2=35.1%		
> 4.5					
FIDELIO-DKD	333 / 882	333 / 910	67.8	1.03 [0.91,1.16]	
FIGARO-DKD	175 / 433	145 / 426	32.2	1.19 [1.00,1.41]	
Total	508 / 1315	478 / 1336		1.08 [0.98,1.19]	Z=1.52, p=0.1287
Heterogeneity:	Q=1.68 (df=1)	p=0.1945	I^2=40.6%		
Subgroup Heterogeneity:	Q=1.10 (df=1)	p=0.2950	I^2=8.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.80.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

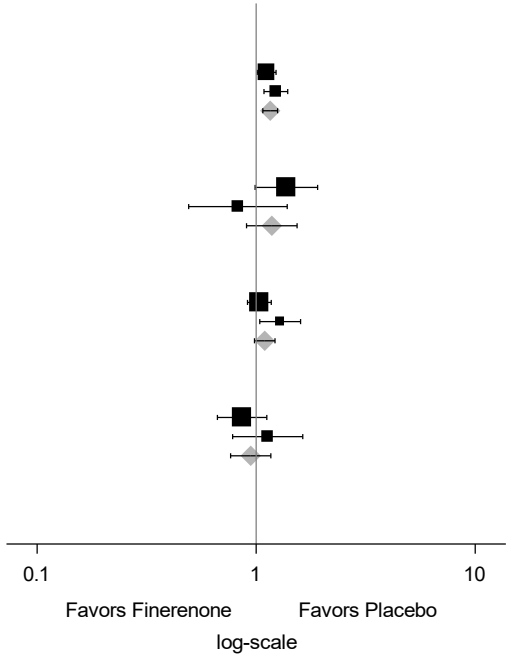
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	267 / 724	267 / 723	62.3	1.00 [0.87,1.14]	
FIGARO-DKD	178 / 494	160 / 495	37.7	1.11 [0.94,1.33]	
Total	445 / 1218	427 / 1218		1.04 [0.94,1.16]	Z=0.74, p=0.4595
Heterogeneity:	Q=0.96 (df=1)	p=0.3261	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	647 / 1759	582 / 1760	67.3	1.11 [1.02,1.22]	
FIGARO-DKD	337 / 829	261 / 827	32.7	1.29 [1.13,1.47]	
Total	984 / 2588	843 / 2587		1.17 [1.08,1.26]	Z=4.10, p=<.0001
Heterogeneity:	Q=3.31 (df=1)	p=0.0690	I^2=69.8%		
>= 160					
FIDELIO-DKD	57 / 133	45 / 127	71.9	1.21 [0.89,1.64]	
FIGARO-DKD	17 / 34	16 / 34	28.1	1.06 [0.65,1.73]	
Total	74 / 167	61 / 161		1.17 [0.90,1.51]	Z=1.17, p=0.2440
Heterogeneity:	Q=0.19 (df=1)	p=0.6601	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.08 (df=2)	p=0.2139	I^2=35.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.80.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

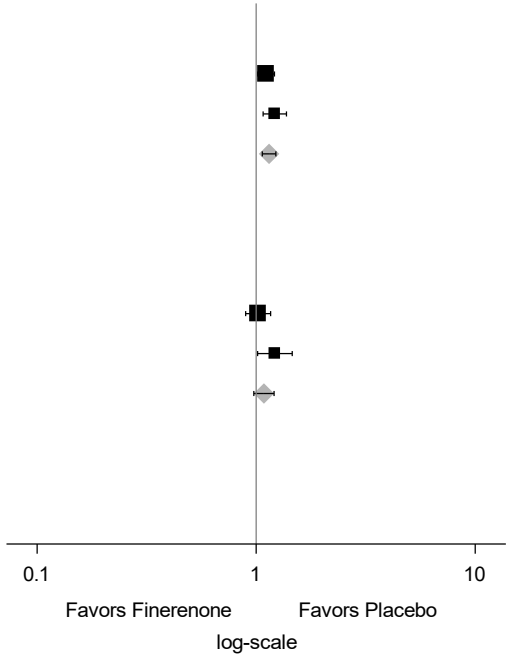
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	558 / 1634	507 / 1657	61.4	1.12 [1.01,1.23]	
FIGARO-DKD	373 / 1010	297 / 989	38.6	1.23 [1.09,1.39]	
Total	931 / 2644	804 / 2646		1.16 [1.07,1.25]	Z=3.73, p=0.0002
Heterogeneity:	Q=1.43 (df=1)	p=0.2323	I^2=29.9%		
Black					
FIDELIO-DKD	57 / 129	37 / 115	71.3	1.37 [0.99,1.91]	
FIGARO-DKD	14 / 43	28 / 71	28.7	0.83 [0.49,1.39]	
Total	71 / 172	65 / 186		1.18 [0.90,1.54]	Z=1.21, p=0.2253
Heterogeneity:	Q=2.65 (df=1)	p=0.1037	I^2=62.2%		
Asian					
FIDELIO-DKD	290 / 678	280 / 677	74.7	1.03 [0.91,1.17]	
FIGARO-DKD	115 / 252	89 / 251	25.3	1.29 [1.04,1.59]	
Total	405 / 930	369 / 928		1.09 [0.98,1.22]	Z=1.63, p=0.1021
Heterogeneity:	Q=2.98 (df=1)	p=0.0842	I^2=66.5%		
Others					
FIDELIO-DKD	66 / 176	70 / 161	66.8	0.86 [0.67,1.12]	
FIGARO-DKD	30 / 52	23 / 45	33.2	1.13 [0.78,1.63]	
Total	96 / 228	93 / 206		0.94 [0.76,1.17]	Z=-0.53, p=0.5948
Heterogeneity:	Q=1.37 (df=1)	p=0.2421	I^2=26.9%		
Subgroup Heterogeneity:	Q=3.57 (df=3)	p=0.3116	I^2=16.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.80.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

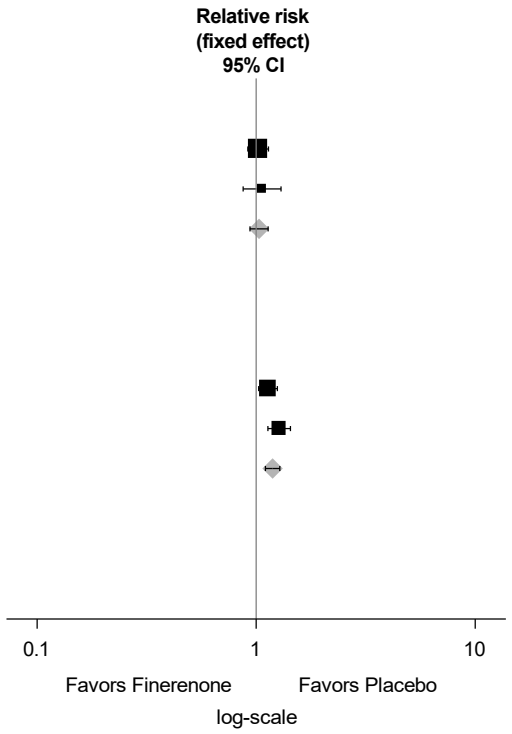
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	669 / 1797	627 / 1870	66.2	1.11 [1.02,1.21]	
FIGARO-DKD	361 / 917	302 / 933	33.8	1.22 [1.08,1.37]	
Total	1030 / 2714	929 / 2803		1.15 [1.07,1.23]	Z=3.73, p=0.0002
Heterogeneity:	Q=1.40 (df=1)	p=0.2363	I^2=28.7%		
Female					
FIDELIO-DKD	302 / 820	267 / 740	65.8	1.02 [0.90,1.16]	
FIGARO-DKD	171 / 440	135 / 423	34.2	1.22 [1.02,1.46]	
Total	473 / 1260	402 / 1163		1.09 [0.98,1.21]	Z=1.50, p=0.1331
Heterogeneity:	Q=2.38 (df=1)	p=0.1232	I^2=57.9%		
Subgroup Heterogeneity:	Q=0.68 (df=1)	p=0.4093	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.80.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	418 / 1103	399 / 1075	77.1	1.02 [0.92,1.14]	
FIGARO-DKD	127 / 336	119 / 335	22.9	1.06 [0.87,1.30]	
Total	545 / 1439	518 / 1410		1.03 [0.94,1.13]	Z=0.62, p=0.5334
Heterogeneity:	Q=0.13 (df=1)	p=0.7212	I^2=0.0%		
>= 65					
FIDELIO-DKD	553 / 1514	495 / 1535	59.2	1.13 [1.03,1.25]	
FIGARO-DKD	405 / 1021	318 / 1021	40.8	1.27 [1.13,1.43]	
Total	958 / 2535	813 / 2556		1.19 [1.10,1.28]	Z=4.48, p=<.0001
Heterogeneity:	Q=2.23 (df=1)	p=0.1355	I^2=55.1%		
Subgroup Heterogeneity:	Q=5.27 (df=1)	p=0.0217	I^2=81.0%		

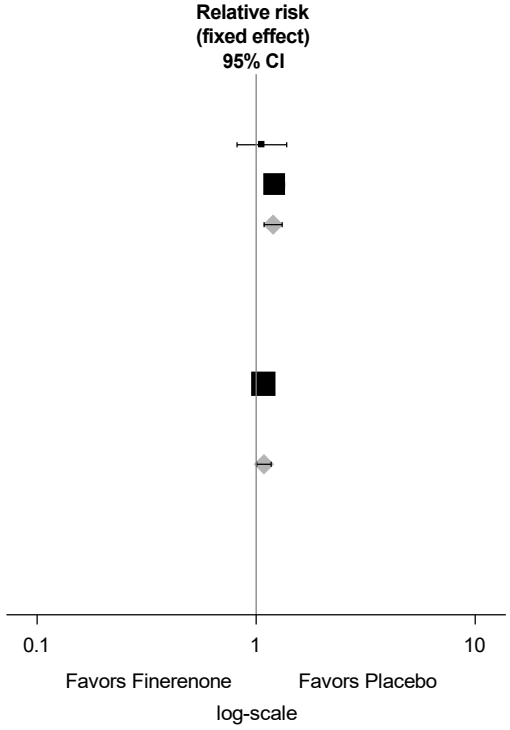


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.80.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

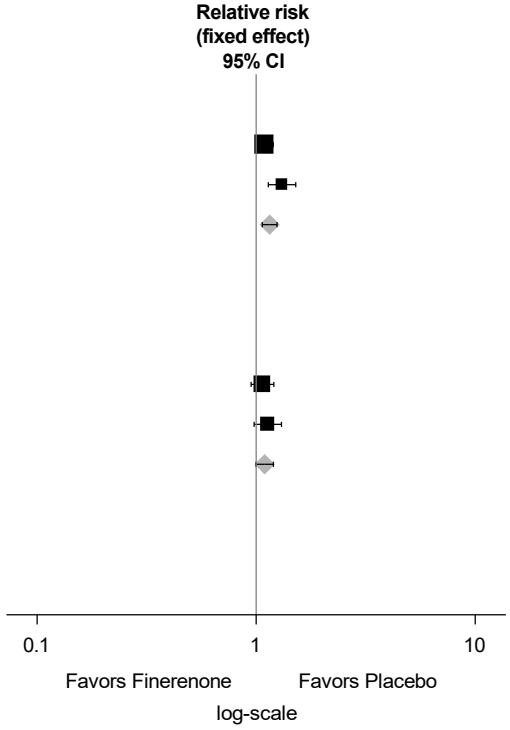
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	75 / 209	72 / 213	13.2	1.06 [0.82,1.38]	
FIGARO-DKD	532 / 1357	437 / 1356	86.8	1.22 [1.10,1.35]	
Total	607 / 1566	509 / 1569		1.20 [1.09,1.31]	Z=3.69, p=0.0002
Heterogeneity:	Q=0.91 (df=1)	p=0.3407	I^2=0.0%		
Very High					
FIDELIO-DKD	896 / 2408	822 / 2397	100.0	1.09 [1.01,1.17]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	896 / 2408	822 / 2397		1.09 [1.01,1.17]	Z=2.11, p=0.0351
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1191	I^2=58.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.80.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

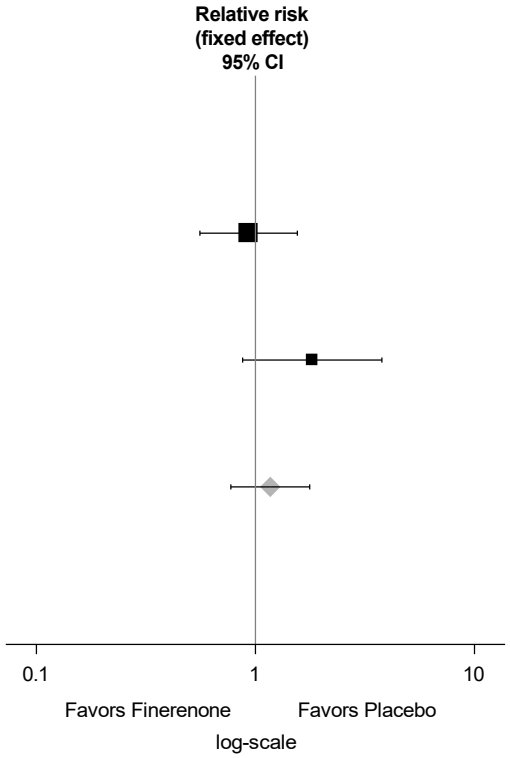
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	603 / 1556	547 / 1541	71.2	1.09 [1.00,1.20]	
FIGARO-DKD	272 / 637	204 / 627	28.8	1.31 [1.14,1.52]	
Total	875 / 2193	751 / 2168		1.15 [1.07,1.24]	Z=3.59, p=0.0003
Heterogeneity:	Q=4.45 (df=1)	p=0.0348	I^2=77.5%		
45 - < 60					
FIDELIO-DKD	368 / 1061	347 / 1069	59.1	1.07 [0.95,1.20]	
FIGARO-DKD	260 / 720	233 / 729	40.9	1.13 [0.98,1.30]	
Total	628 / 1781	580 / 1798		1.09 [1.00,1.20]	Z=1.90, p=0.0573
Heterogeneity:	Q=0.34 (df=1)	p=0.5586	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.74 (df=1)	p=0.3908	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.81: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

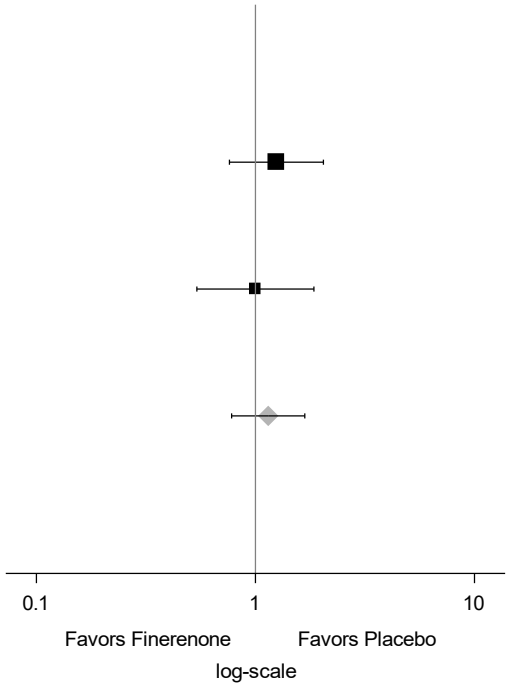
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	30 / 2610	67.1	0.93 [0.56,1.55]	
FIGARO-DKD	20 / 1357	11 / 1356	32.9	1.82 [0.87,3.78]	
Total	48 / 3974	41 / 3966		1.17 [0.77,1.77]	Z=0.74, p=0.4616
Heterogeneity:	Q=2.15 (df=1)	p=0.1422	I^2=53.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.82: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

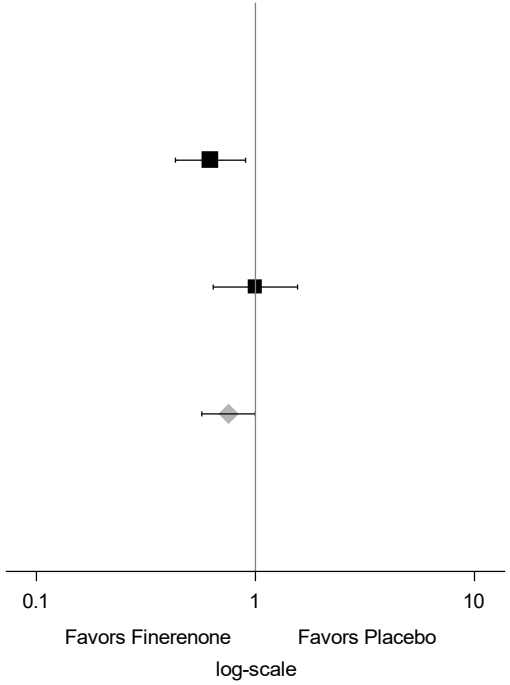
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	28 / 2610	60.8	1.25 [0.76,2.04]	
FIGARO-DKD	20 / 1357	20 / 1356	39.2	1.00 [0.54,1.85]	
Total	55 / 3974	48 / 3966		1.14 [0.78,1.68]	Z=0.68, p=0.4945
Heterogeneity:	Q=0.30 (df=1)	p=0.5827	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.83: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

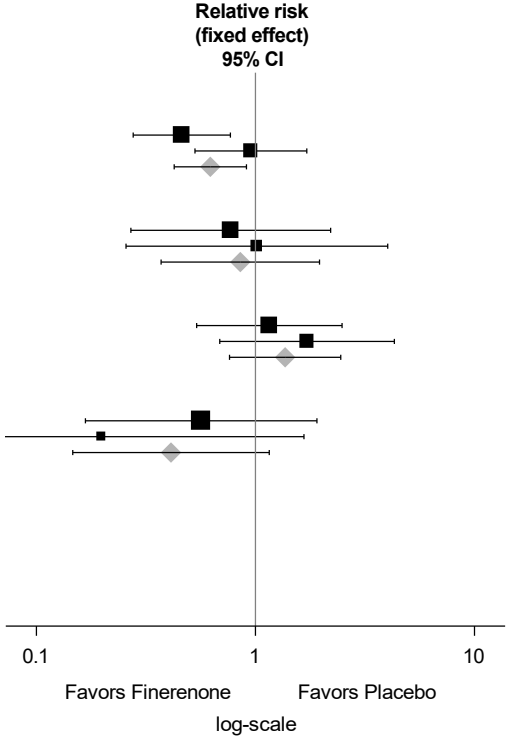
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	72 / 2610	59.1	0.62 [0.43,0.90]	
FIGARO-DKD	38 / 1357	38 / 1356	40.9	1.00 [0.64,1.56]	
Total	83 / 3974	110 / 3966		0.75 [0.57,1.00]	Z=-1.97, p=0.0489
Heterogeneity:	Q=2.58 (df=1)	p=0.1085	I^2=61.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.83.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

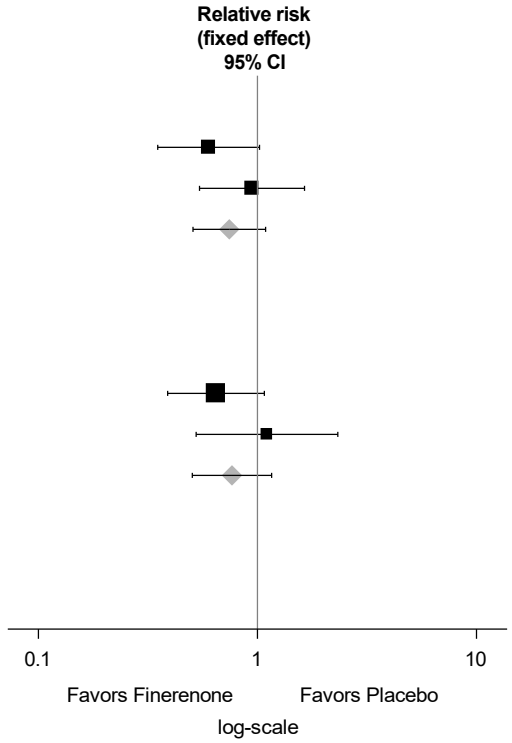
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 1075	45 / 1062	57.0	0.46 [0.28,0.77]	
FIGARO-DKD	21 / 638	22 / 637	43.0	0.95 [0.53,1.72]	
Total	42 / 1713	67 / 1699		0.62 [0.43,0.91]	Z=-2.45, p=0.0143
Heterogeneity:	Q=3.34 (df=1)	p=0.0674	I^2=70.1%		
North America					
FIDELIO-DKD	6 / 424	8 / 436	63.2	0.77 [0.27,2.20]	
FIGARO-DKD	4 / 267	4 / 271	36.8	1.01 [0.26,4.02]	
Total	10 / 691	12 / 707		0.85 [0.37,1.96]	Z=-0.37, p=0.7078
Heterogeneity:	Q=0.10 (df=1)	p=0.7558	I^2=0.0%		
Asia					
FIDELIO-DKD	14 / 751	12 / 745	59.0	1.16 [0.54,2.49]	
FIGARO-DKD	12 / 289	7 / 290	41.0	1.72 [0.69,4.31]	
Total	26 / 1040	19 / 1035		1.37 [0.76,2.45]	Z=1.05, p=0.2956
Heterogeneity:	Q=0.42 (df=1)	p=0.5154	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 273	7 / 270	75.4	0.57 [0.17,1.91]	
FIGARO-DKD	1 / 102	5 / 101	24.6	0.20 [0.02,1.67]	
Total	5 / 375	12 / 371		0.41 [0.15,1.16]	Z=-1.68, p=0.0921
Heterogeneity:	Q=0.71 (df=1)	p=0.3980	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	0 / 97	0.0	-	
FIGARO-DKD	0 / 61	0 / 57	0.0	-	
Total	0 / 155	0 / 154		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=6.36 (df=4)	p=0.1740	I^2=37.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.83.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

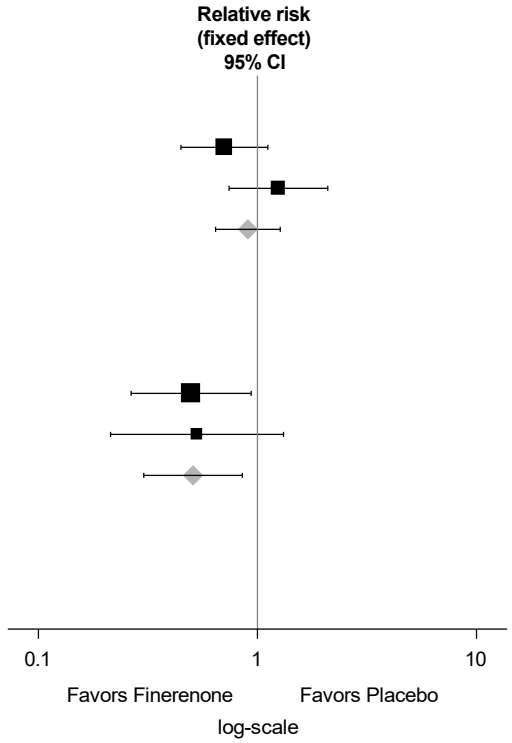
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	21 / 1213	35 / 1210	51.6	0.60 [0.35,1.02]	
FIGARO-DKD	24 / 862	25 / 848	48.4	0.94 [0.54,1.64]	
Total	45 / 2075	60 / 2058		0.74 [0.51,1.09]	Z=-1.52, p=0.1284
Heterogeneity:	Q=1.35 (df=1)	p=0.2449	I^2=26.1%		
Absent					
FIDELIO-DKD	24 / 1404	37 / 1400	68.2	0.65 [0.39,1.08]	
FIGARO-DKD	14 / 495	13 / 508	31.8	1.11 [0.52,2.33]	
Total	38 / 1899	50 / 1908		0.76 [0.50,1.16]	Z=-1.26, p=0.2079
Heterogeneity:	Q=1.36 (df=1)	p=0.2442	I^2=26.3%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9223	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.83.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	31 / 1735	43 / 1700	56.3	0.71 [0.45,1.12]	
FIGARO-DKD	31 / 924	25 / 929	43.7	1.25 [0.74,2.09]	
Total	62 / 2659	68 / 2629		0.90 [0.64,1.27]	Z=-0.58, p=0.5624
Heterogeneity:	Q=2.59 (df=1)	p=0.1073	I^2=61.4%		
> 4.5					
FIDELIO-DKD	14 / 882	29 / 910	67.5	0.50 [0.26,0.94]	
FIGARO-DKD	7 / 433	13 / 426	32.5	0.53 [0.21,1.31]	
Total	21 / 1315	42 / 1336		0.51 [0.30,0.85]	Z=-2.56, p=0.0105
Heterogeneity:	Q=0.01 (df=1)	p=0.9131	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.33 (df=1)	p=0.0682	I^2=69.9%		

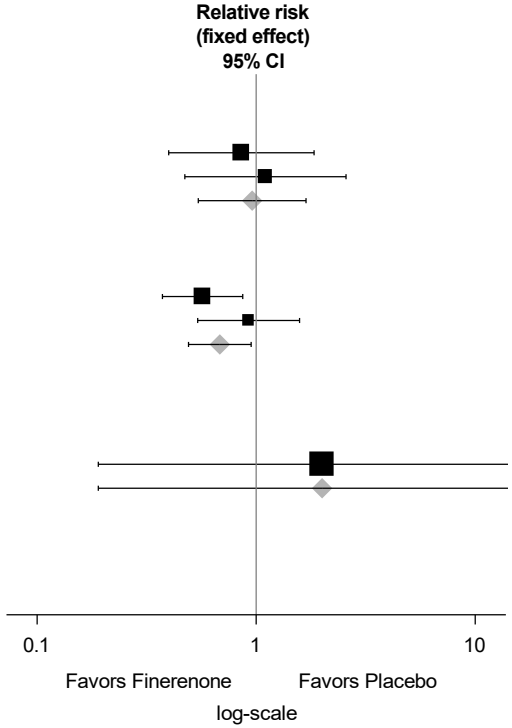


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.83.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

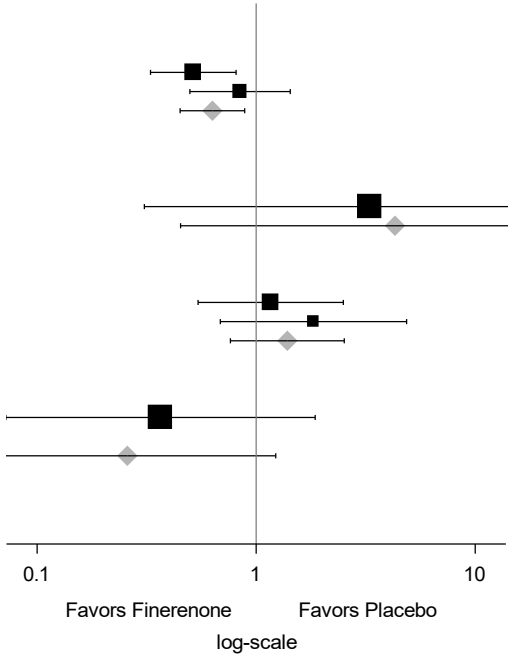
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	14 / 723	55.1	0.86 [0.40,1.84]	
FIGARO-DKD	11 / 494	10 / 495	44.9	1.10 [0.47,2.57]	
Total	23 / 1218	24 / 1218		0.96 [0.54,1.69]	Z=-0.15, p=0.8838
Heterogeneity:	Q=0.19 (df=1)	p=0.6640	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	33 / 1759	58 / 1760	61.7	0.57 [0.37,0.87]	
FIGARO-DKD	25 / 829	27 / 827	38.3	0.92 [0.54,1.58]	
Total	58 / 2588	85 / 2587		0.68 [0.49,0.95]	Z=-2.27, p=0.0229
Heterogeneity:	Q=1.94 (df=1)	p=0.1641	I^2=48.4%		
>= 160					
FIDELIO-DKD	0 / 133	0 / 127	0.0	-	
FIGARO-DKD	2 / 34	1 / 34	100.0	2.00 [0.19,21.03]	
Total	2 / 167	1 / 161		2.00 [0.19,21.03]	Z=0.58, p=0.5637
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.70 (df=2)	p=0.4267	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.83.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

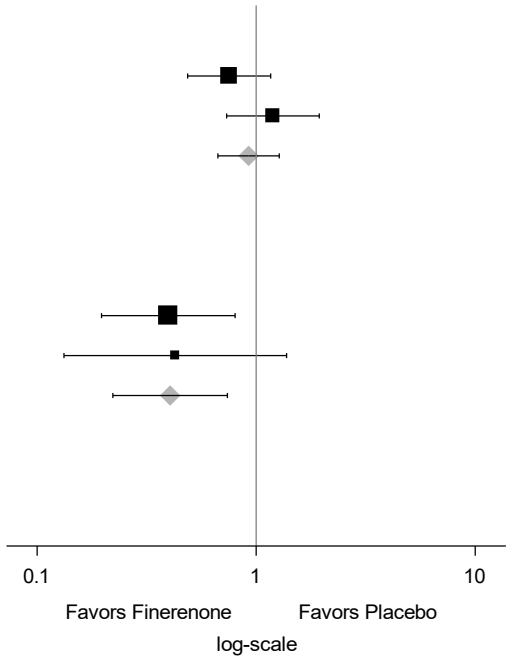
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	28 / 1634	55 / 1657	57.9	0.52 [0.33,0.81]	
FIGARO-DKD	25 / 1010	29 / 989	42.1	0.84 [0.50,1.43]	
Total	53 / 2644	84 / 2646		0.63 [0.45,0.89]	Z=-2.66, p=0.0079
Heterogeneity:	Q=1.93 (df=1)	p=0.1644	I^2=48.3%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	11E10 [11E10,11E10]	
FIGARO-DKD	2 / 43	1 / 71	100.0	3.30 [0.31,35.34]	
Total	3 / 172	1 / 186		4.30 [0.45,41.01]	Z=1.27, p=0.2045
Heterogeneity:	Q=0.05 (df=1)	p=0.8267	I^2=0.0%		
Asian					
FIDELIO-DKD	14 / 678	12 / 677	62.2	1.16 [0.54,2.50]	
FIGARO-DKD	11 / 252	6 / 251	37.8	1.83 [0.69,4.86]	
Total	25 / 930	18 / 928		1.39 [0.76,2.52]	Z=1.07, p=0.2833
Heterogeneity:	Q=0.50 (df=1)	p=0.4779	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	5 / 161	100.0	0.37 [0.07,1.86]	
FIGARO-DKD	0 / 52	2 / 45	0.0	0.00 [0.00,78E295]	
Total	2 / 228	7 / 206		0.26 [0.05,1.23]	Z=-1.70, p=0.0889
Heterogeneity:	Q=0.18 (df=1)	p=0.6739	I^2=0.0%		
Subgroup Heterogeneity:	Q=9.15 (df=3)	p=0.0274	I^2=67.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.83.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

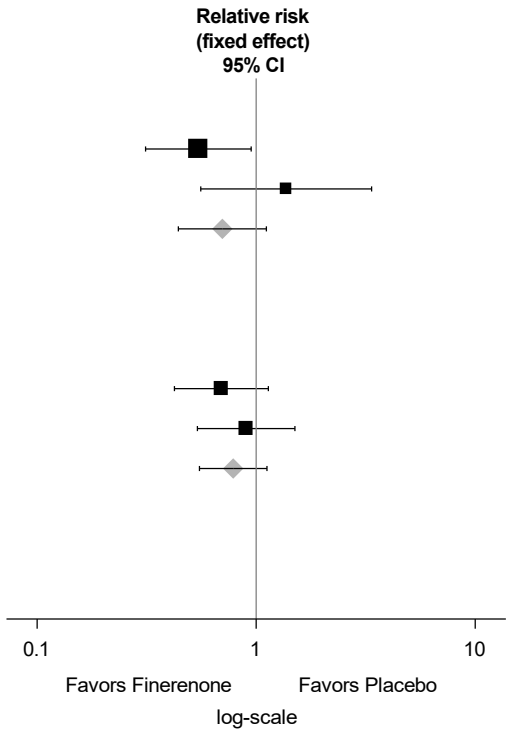
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	34 / 1797	47 / 1870	55.5	0.75 [0.49,1.16]	
FIGARO-DKD	34 / 917	29 / 933	44.5	1.19 [0.73,1.94]	
Total	68 / 2714	76 / 2803		0.92 [0.67,1.27]	Z=-0.49, p=0.6276
Heterogeneity:	Q=1.90 (df=1)	p=0.1677	I^2=47.5%		
Female					
FIDELIO-DKD	11 / 820	25 / 740	73.5	0.40 [0.20,0.80]	
FIGARO-DKD	4 / 440	9 / 423	26.5	0.43 [0.13,1.38]	
Total	15 / 1260	34 / 1163		0.40 [0.22,0.74]	Z=-2.94, p=0.0032
Heterogeneity:	Q=0.01 (df=1)	p=0.9162	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.60 (df=1)	p=0.0180	I^2=82.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.83.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

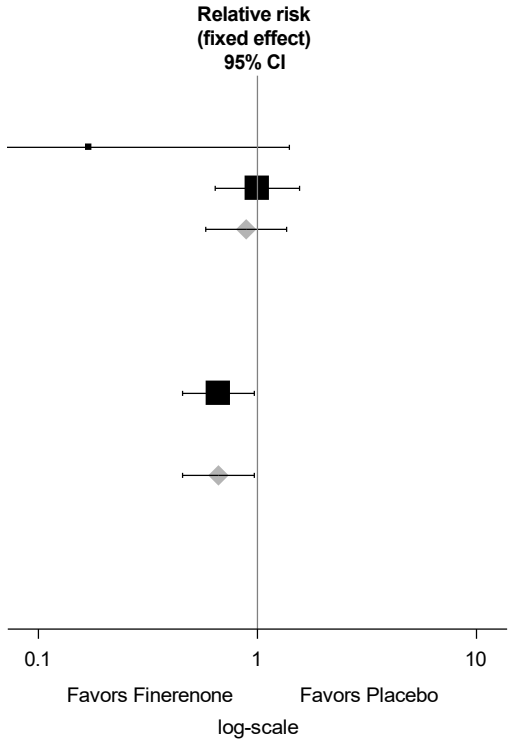
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	19 / 1103	34 / 1075	72.4	0.54 [0.31,0.95]	
FIGARO-DKD	11 / 336	8 / 335	27.6	1.37 [0.56,3.37]	
Total	30 / 1439	42 / 1410		0.70 [0.44,1.11]	Z=-1.51, p=0.1321
Heterogeneity:	Q=2.94 (df=1)	p=0.0866	I^2=66.0%		
>= 65					
FIDELIO-DKD	26 / 1514	38 / 1535	51.9	0.69 [0.42,1.14]	
FIGARO-DKD	27 / 1021	30 / 1021	48.1	0.90 [0.54,1.50]	
Total	53 / 2535	68 / 2556		0.79 [0.55,1.12]	Z=-1.33, p=0.1822
Heterogeneity:	Q=0.51 (df=1)	p=0.4734	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7015	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.83.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

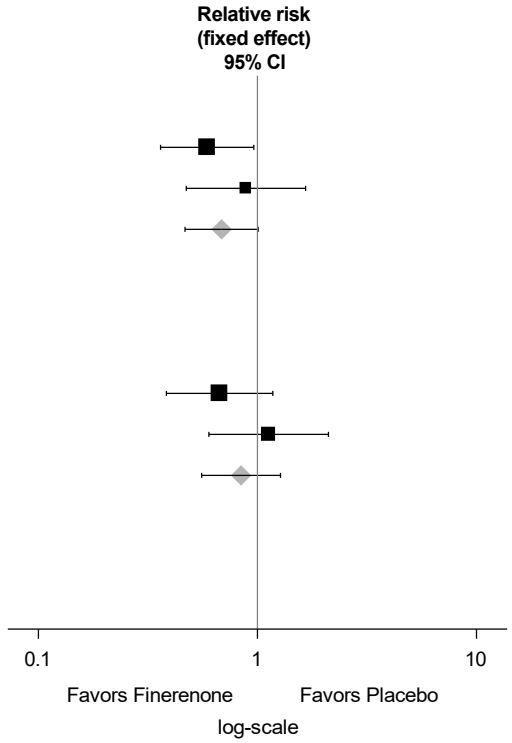
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	6 / 213	4.2	0.17 [0.02,1.40]	
FIGARO-DKD	38 / 1357	38 / 1356	95.8	1.00 [0.64,1.56]	
Total	39 / 1566	44 / 1569		0.89 [0.58,1.36]	Z=-0.55, p=0.5851
Heterogeneity:	Q=2.64 (df=1)	p=0.1045	I^2=62.1%		
Very High					
FIDELIO-DKD	44 / 2408	66 / 2397	100.0	0.66 [0.46,0.97]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	44 / 2408	66 / 2397		0.66 [0.46,0.97]	Z=-2.13, p=0.0331
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.01 (df=1)	p=0.3147	I^2=1.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.83.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

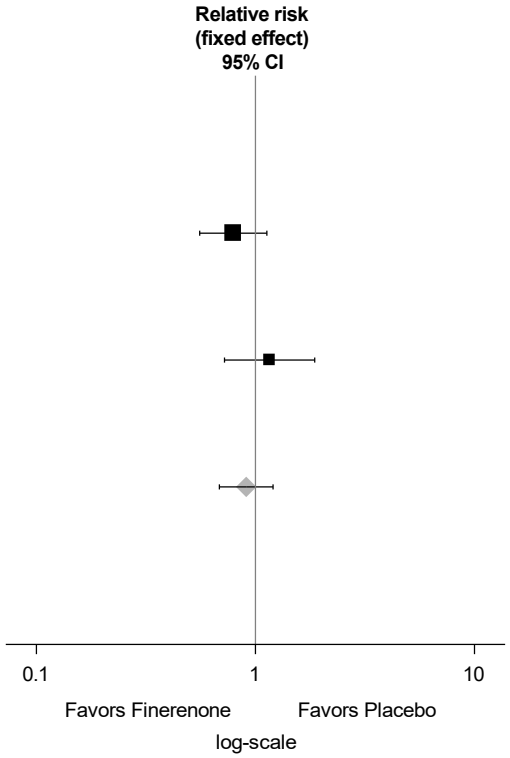
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	25 / 1556	42 / 1541	62.1	0.59 [0.36,0.96]	
FIGARO-DKD	18 / 637	20 / 627	37.9	0.89 [0.47,1.66]	
Total	43 / 2193	62 / 2168		0.69 [0.47,1.01]	Z=-1.92, p=0.0545
Heterogeneity:	Q=1.01 (df=1)	p=0.3158	I^2=0.6%		
45 - < 60					
FIDELIO-DKD	20 / 1061	30 / 1069	55.8	0.67 [0.38,1.18]	
FIGARO-DKD	20 / 720	18 / 729	44.2	1.12 [0.60,2.11]	
Total	40 / 1781	48 / 1798		0.84 [0.56,1.27]	Z=-0.82, p=0.4151
Heterogeneity:	Q=1.44 (df=1)	p=0.2295	I^2=30.7%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4778	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.84: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

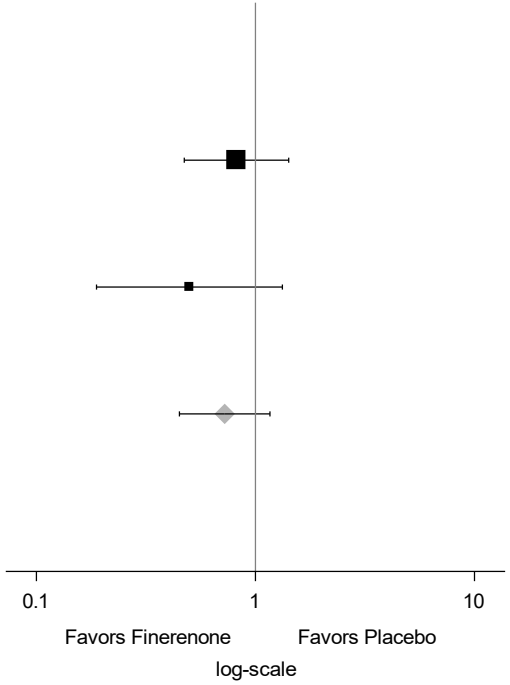
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 2617	68 / 2610	64.3	0.79 [0.56,1.13]	
FIGARO-DKD	36 / 1357	31 / 1356	35.7	1.16 [0.72,1.86]	
Total	90 / 3974	99 / 3966		0.91 [0.68,1.20]	Z=-0.68, p=0.4995
Heterogeneity:	Q=1.60 (df=1)	p=0.2055	I^2=37.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.85: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

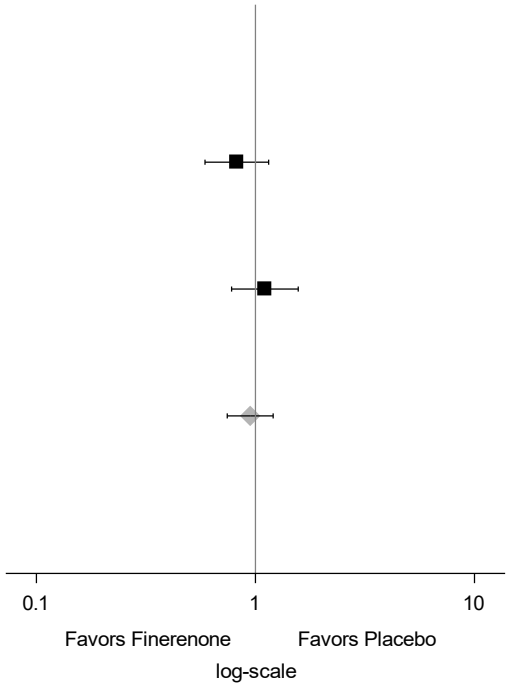
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	28 / 2610	76.0	0.82 [0.47,1.42]	
FIGARO-DKD	6 / 1357	12 / 1356	24.0	0.50 [0.19,1.33]	
Total	29 / 3974	40 / 3966		0.72 [0.45,1.16]	Z=-1.33, p=0.1828
Heterogeneity:	Q=0.75 (df=1)	p=0.3870	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.86: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

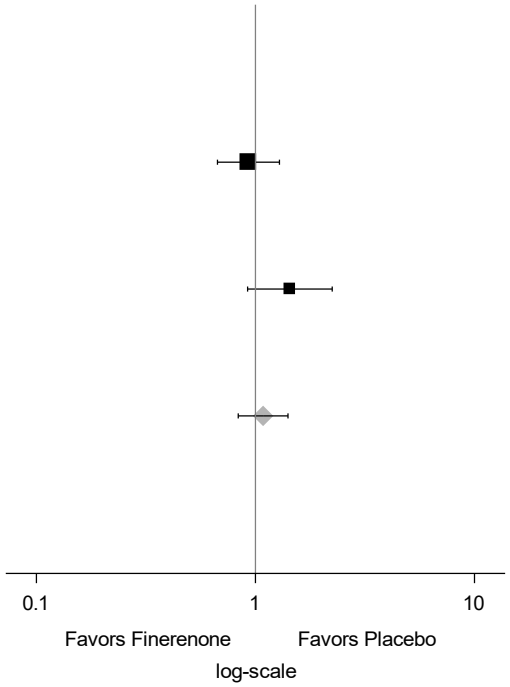
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	74 / 2610	52.3	0.82 [0.59,1.15]	
FIGARO-DKD	63 / 1357	57 / 1356	47.7	1.10 [0.78,1.57]	
Total	124 / 3974	131 / 3966		0.95 [0.74,1.20]	Z=-0.45, p=0.6534
Heterogeneity:	Q=1.43 (df=1)	p=0.2323	I^2=29.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.87: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

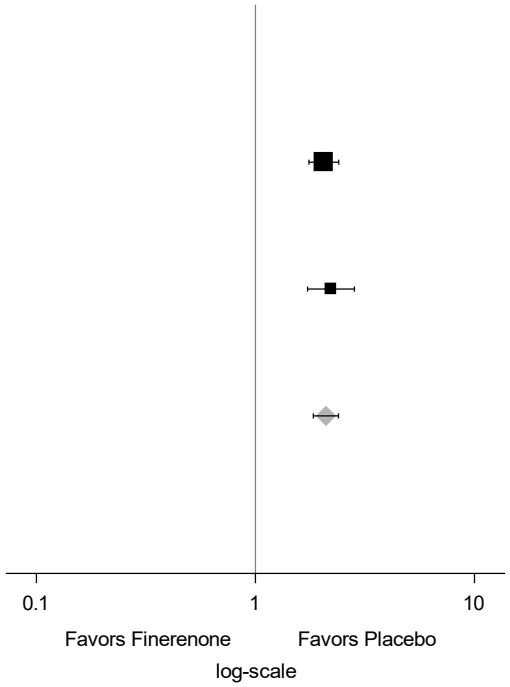
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 2617	73 / 2610	65.1	0.93 [0.67,1.29]	
FIGARO-DKD	46 / 1357	32 / 1356	34.9	1.44 [0.92,2.24]	
Total	114 / 3974	105 / 3966		1.08 [0.83,1.41]	Z=0.60, p=0.5465
Heterogeneity:	Q=2.40 (df=1)	p=0.1214	I^2=58.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.88: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

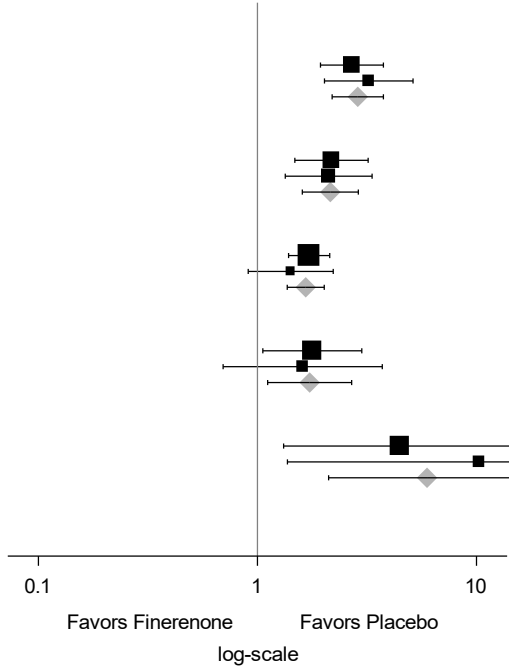
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	428 / 2617	208 / 2610	71.2	2.05 [1.75,2.40]	
FIGARO-DKD	186 / 1357	84 / 1356	28.8	2.21 [1.73,2.83]	
Total	614 / 3974	292 / 3966		2.10 [1.84,2.39]	Z=10.99, p=<.0001
Heterogeneity:	Q=0.26 (df=1)	p=0.6132	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.88.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

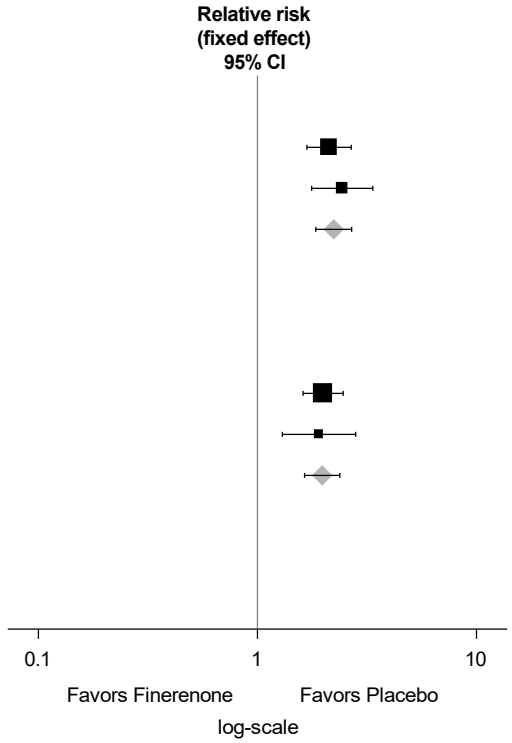
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	123 / 1075	45 / 1062	66.4	2.70 [1.94,3.76]	
FIGARO-DKD	71 / 638	22 / 637	33.6	3.22 [2.02,5.13]	
Total	194 / 1713	67 / 1699		2.87 [2.19,3.76]	Z=7.67, p=<.0001
Heterogeneity:	Q=0.37 (df=1)	p=0.5440	I^2=0.0%		
North America					
FIDELIO-DKD	72 / 424	34 / 436	58.4	2.18 [1.48,3.20]	
FIGARO-DKD	50 / 267	24 / 271	41.6	2.11 [1.34,3.34]	
Total	122 / 691	58 / 707		2.15 [1.60,2.89]	Z=5.10, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9232	I^2=0.0%		
Asia					
FIDELIO-DKD	184 / 751	106 / 745	81.0	1.72 [1.39,2.14]	
FIGARO-DKD	41 / 289	29 / 290	19.0	1.42 [0.91,2.22]	
Total	225 / 1040	135 / 1035		1.66 [1.37,2.02]	Z=5.11, p=<.0001
Heterogeneity:	Q=0.59 (df=1)	p=0.4443	I^2=0.0%		
Latin America					
FIDELIO-DKD	36 / 273	20 / 270	72.1	1.78 [1.06,2.99]	
FIGARO-DKD	13 / 102	8 / 101	27.9	1.61 [0.70,3.71]	
Total	49 / 375	28 / 371		1.73 [1.11,2.69]	Z=2.44, p=0.0148
Heterogeneity:	Q=0.04 (df=1)	p=0.8406	I^2=0.0%		
Others					
FIDELIO-DKD	13 / 94	3 / 97	73.1	4.47 [1.32,15.19]	
FIGARO-DKD	11 / 61	1 / 57	26.9	10.28 [1.37,77.10]	
Total	24 / 155	4 / 154		5.95 [2.11,16.73]	Z=3.38, p=0.0007
Heterogeneity:	Q=0.49 (df=1)	p=0.4830	I^2=0.0%		
Subgroup Heterogeneity:	Q=15.23 (df=4)	p=0.0043	I^2=73.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.88.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

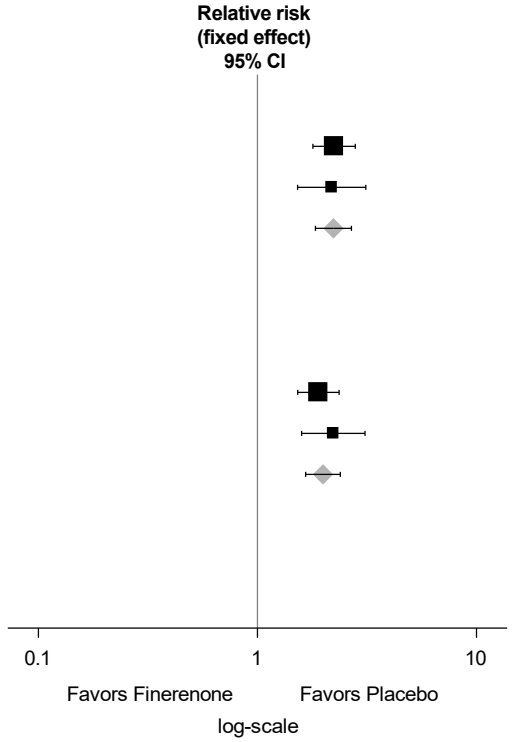
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	198 / 1213	93 / 1210	65.5	2.12 [1.68,2.68]	
FIGARO-DKD	119 / 862	48 / 848	34.5	2.44 [1.77,3.36]	
Total	317 / 2075	141 / 2058		2.23 [1.85,2.69]	Z=8.33, p=<.0001
Heterogeneity:	Q=0.47 (df=1)	p=0.4946	I^2=0.0%		
Absent					
FIDELIO-DKD	230 / 1404	115 / 1400	76.9	1.99 [1.61,2.46]	
FIGARO-DKD	67 / 495	36 / 508	23.1	1.91 [1.30,2.81]	
Total	297 / 1899	151 / 1908		1.97 [1.64,2.38]	Z=7.20, p=<.0001
Heterogeneity:	Q=0.04 (df=1)	p=0.8473	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=1)	p=0.3676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.88.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	233 / 1735	102 / 1700	72.1	2.24 [1.79,2.80]	
FIGARO-DKD	89 / 924	41 / 929	27.9	2.18 [1.52,3.12]	
Total	322 / 2659	143 / 2629		2.22 [1.84,2.69]	Z=8.27, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9068	I^2=0.0%		
> 4.5					
FIDELIO-DKD	195 / 882	106 / 910	70.1	1.90 [1.53,2.36]	
FIGARO-DKD	97 / 433	43 / 426	29.9	2.22 [1.59,3.10]	
Total	292 / 1315	149 / 1336		1.99 [1.66,2.39]	Z=7.42, p=<.0001
Heterogeneity:	Q=0.59 (df=1)	p=0.4411	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=1)	p=0.4122	I^2=0.0%		

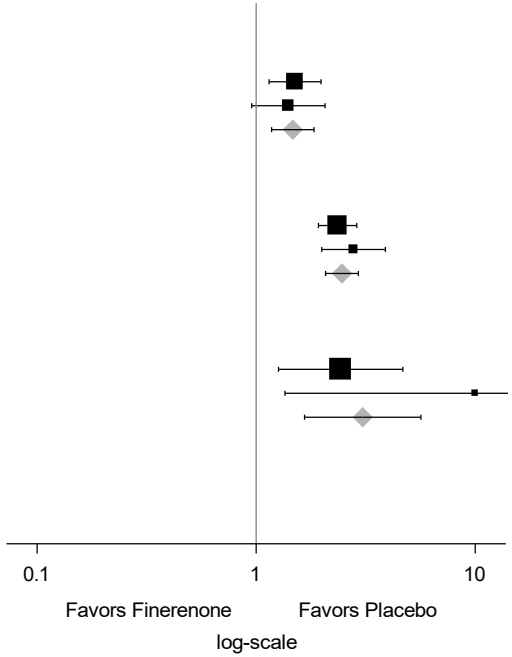


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.88.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

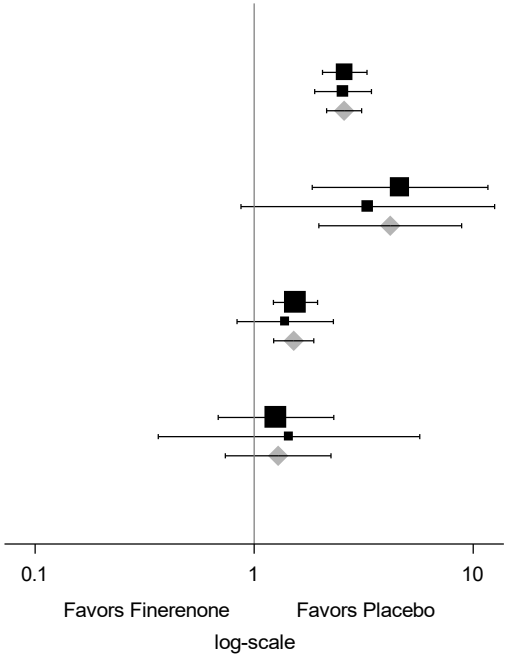
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	113 / 724	75 / 723	66.7	1.50 [1.14,1.98]	
FIGARO-DKD	56 / 494	40 / 495	33.3	1.40 [0.95,2.06]	
Total	169 / 1218	115 / 1218		1.47 [1.18,1.84]	Z=3.39, p=0.0007
Heterogeneity:	Q=0.08 (df=1)	p=0.7717	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	287 / 1759	122 / 1760	73.5	2.35 [1.92,2.88]	
FIGARO-DKD	120 / 829	43 / 827	26.5	2.78 [1.99,3.89]	
Total	407 / 2588	165 / 2587		2.46 [2.07,2.93]	Z=10.25, p=<.0001
Heterogeneity:	Q=0.71 (df=1)	p=0.3996	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 133	11 / 127	90.3	2.43 [1.26,4.67]	
FIGARO-DKD	10 / 34	1 / 34	9.7	10.00 [1.35,73.88]	
Total	38 / 167	12 / 161		3.07 [1.66,5.65]	Z=3.59, p=0.0003
Heterogeneity:	Q=1.83 (df=1)	p=0.1765	I^2=45.3%		
Subgroup Heterogeneity:	Q=14.57 (df=2)	p=0.0007	I^2=86.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.88.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

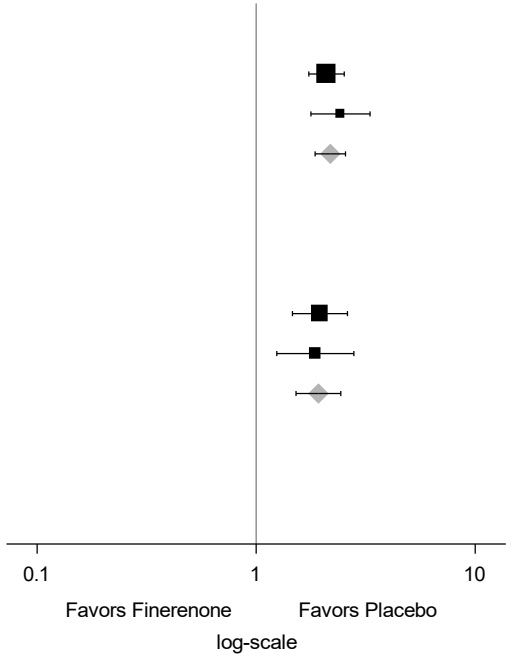
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	230 / 1634	90 / 1657	61.9	2.59 [2.05,3.27]	
FIGARO-DKD	143 / 1010	55 / 989	38.1	2.55 [1.89,3.43]	
Total	373 / 2644	145 / 2646		2.57 [2.14,3.09]	Z=10.07, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9269	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 129	5 / 115	67.6	4.64 [1.84,11.67]	
FIGARO-DKD	6 / 43	3 / 71	32.4	3.30 [0.87,12.53]	
Total	32 / 172	8 / 186		4.18 [1.97,8.85]	Z=3.74, p=0.0002
Heterogeneity:	Q=0.17 (df=1)	p=0.6816	I^2=0.0%		
Asian					
FIDELIO-DKD	150 / 678	97 / 677	82.6	1.54 [1.22,1.95]	
FIGARO-DKD	32 / 252	23 / 251	17.4	1.39 [0.84,2.30]	
Total	182 / 930	120 / 928		1.52 [1.23,1.87]	Z=3.87, p=0.0001
Heterogeneity:	Q=0.14 (df=1)	p=0.7035	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 176	16 / 161	83.7	1.26 [0.69,2.31]	
FIGARO-DKD	5 / 52	3 / 45	16.3	1.44 [0.36,5.70]	
Total	27 / 228	19 / 206		1.29 [0.74,2.24]	Z=0.89, p=0.3737
Heterogeneity:	Q=0.03 (df=1)	p=0.8583	I^2=0.0%		
Subgroup Heterogeneity:	Q=19.91 (df=3)	p=0.0002	I^2=84.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.88.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

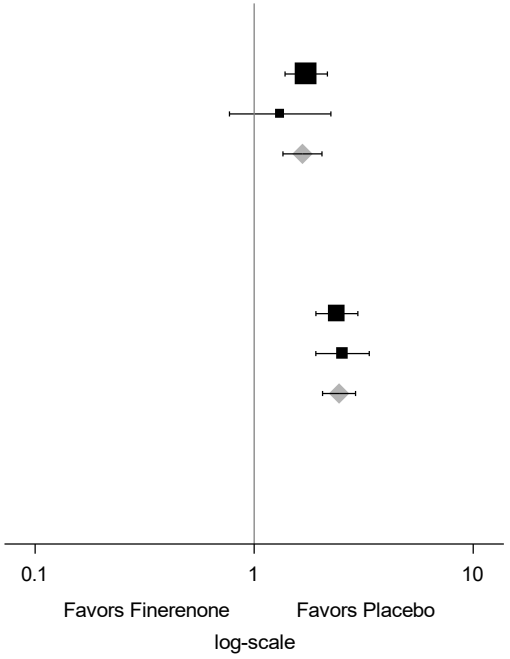
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	298 / 1797	148 / 1870	73.6	2.10 [1.74,2.52]	
FIGARO-DKD	124 / 917	52 / 933	26.4	2.43 [1.78,3.31]	
Total	422 / 2714	200 / 2803		2.18 [1.86,2.56]	Z=9.57, p=<.0001
Heterogeneity:	Q=0.63 (df=1)	p=0.4275	I^2=0.0%		
Female					
FIDELIO-DKD	130 / 820	60 / 740	66.2	1.96 [1.46,2.61]	
FIGARO-DKD	62 / 440	32 / 423	33.8	1.86 [1.24,2.79]	
Total	192 / 1260	92 / 1163		1.92 [1.52,2.43]	Z=5.45, p=<.0001
Heterogeneity:	Q=0.04 (df=1)	p=0.8485	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.74 (df=1)	p=0.3885	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.88.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

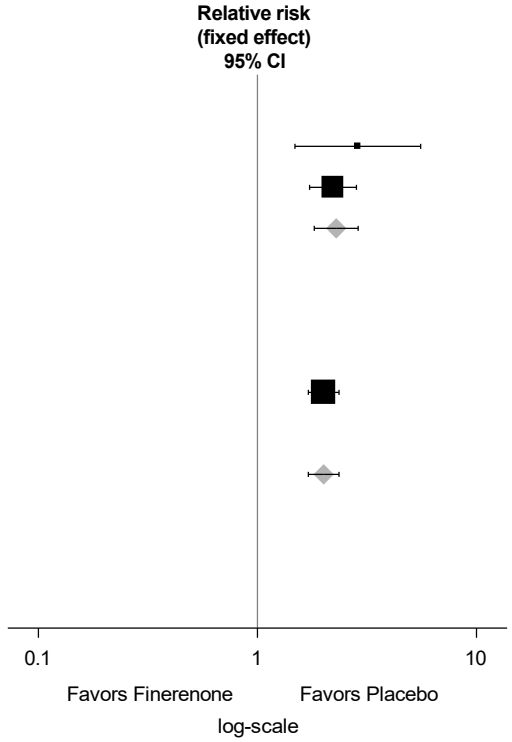
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	188 / 1103	106 / 1075	85.1	1.73 [1.38,2.16]	
FIGARO-DKD	29 / 336	22 / 335	14.9	1.31 [0.77,2.24]	
Total	217 / 1439	128 / 1410		1.66 [1.35,2.04]	Z=4.85, p=<.0001
Heterogeneity:	Q=0.86 (df=1)	p=0.3526	I^2=0.0%		
>= 65					
FIDELIO-DKD	240 / 1514	102 / 1535	61.9	2.39 [1.91,2.97]	
FIGARO-DKD	157 / 1021	62 / 1021	38.1	2.53 [1.91,3.35]	
Total	397 / 2535	164 / 2556		2.44 [2.05,2.90]	Z=10.08, p=<.0001
Heterogeneity:	Q=0.11 (df=1)	p=0.7433	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.88 (df=1)	p=0.0050	I^2=87.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.88.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

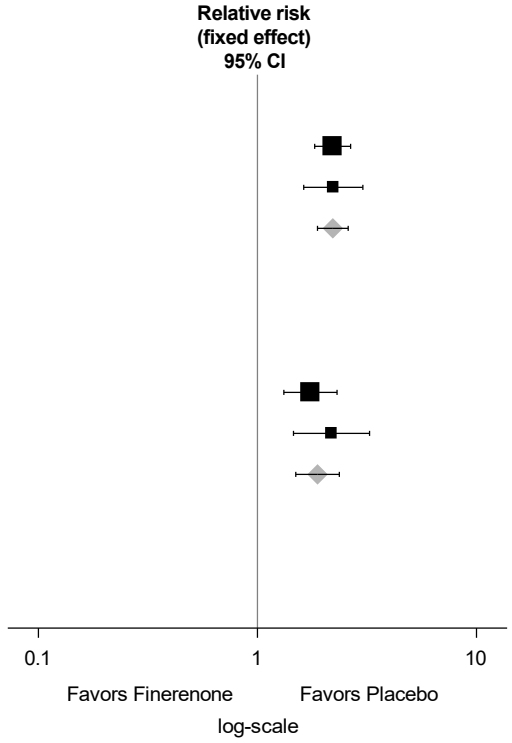
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	31 / 209	11 / 213	12.2	2.87 [1.48,5.56]	
FIGARO-DKD	186 / 1357	84 / 1356	87.8	2.21 [1.73,2.83]	
Total	217 / 1566	95 / 1569		2.29 [1.82,2.88]	Z=7.03, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4684	I^2=0.0%		
Very High					
FIDELIO-DKD	397 / 2408	197 / 2397	100.0	2.01 [1.71,2.36]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	397 / 2408	197 / 2397		2.01 [1.71,2.36]	Z=8.47, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.84 (df=1)	p=0.3586	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.88.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

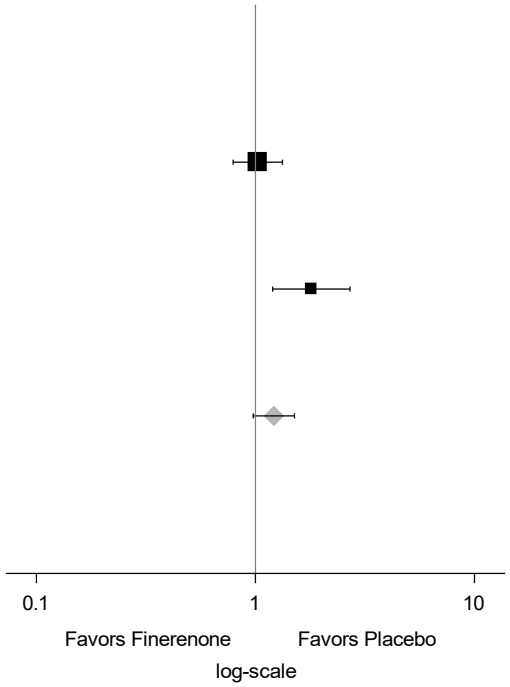
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	305 / 1556	137 / 1541	73.0	2.20 [1.83,2.66]	
FIGARO-DKD	115 / 637	51 / 627	27.0	2.22 [1.63,3.03]	
Total	420 / 2193	188 / 2168		2.21 [1.88,2.60]	Z=9.62, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9715	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	123 / 1061	71 / 1069	67.2	1.75 [1.32,2.31]	
FIGARO-DKD	71 / 720	33 / 729	32.8	2.18 [1.46,3.25]	
Total	194 / 1781	104 / 1798		1.88 [1.50,2.36]	Z=5.41, p=<.0001
Heterogeneity:	Q=0.79 (df=1)	p=0.3733	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.26 (df=1)	p=0.2609	I^2=20.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.89: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

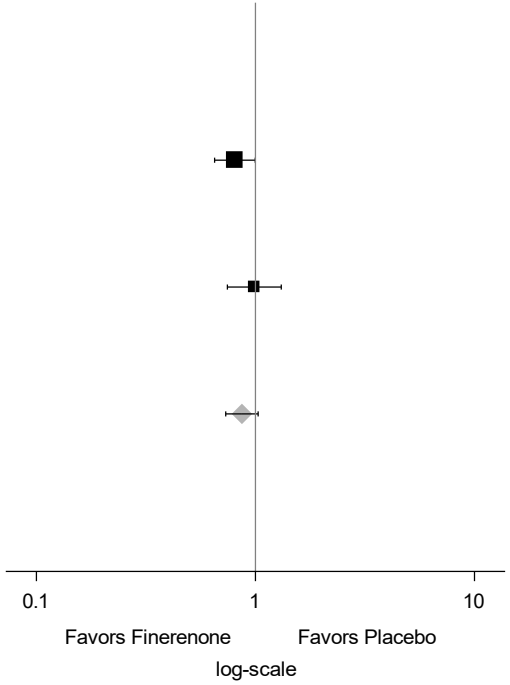
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2617	108 / 2610	71.1	1.03 [0.79,1.33]	
FIGARO-DKD	63 / 1357	35 / 1356	28.9	1.80 [1.20,2.70]	
Total	174 / 3974	143 / 3966		1.21 [0.98,1.51]	Z=1.75, p=0.0803
Heterogeneity:	Q=5.23 (df=1)	p=0.0222	I^2=80.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.90: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

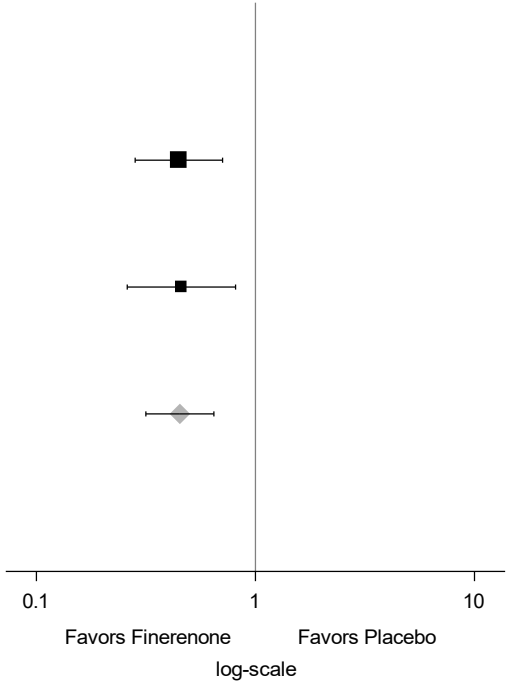
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	143 / 2617	177 / 2610	63.7	0.81 [0.65,1.00]	
FIGARO-DKD	89 / 1357	90 / 1356	36.3	0.99 [0.74,1.31]	
Total	232 / 3974	267 / 3966		0.87 [0.73,1.03]	Z=-1.64, p=0.1016
Heterogeneity:	Q=1.27 (df=1)	p=0.2595	I^2=21.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.91: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

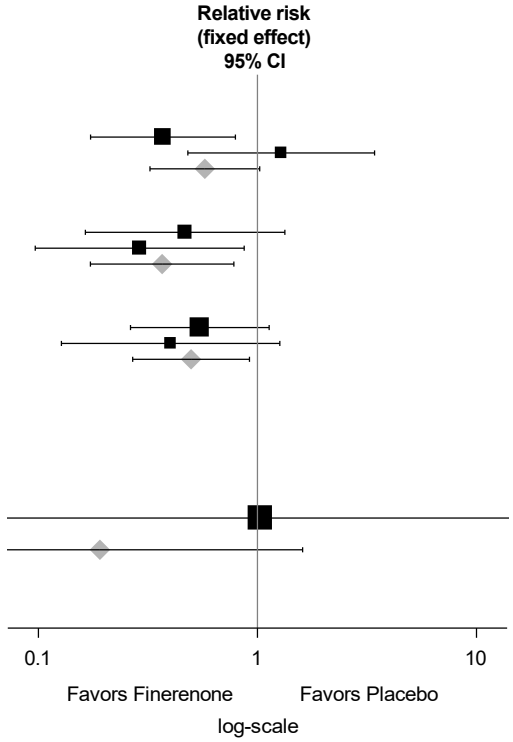
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	58 / 2610	60.6	0.45 [0.28,0.71]	
FIGARO-DKD	17 / 1357	37 / 1356	39.4	0.46 [0.26,0.81]	
Total	43 / 3974	95 / 3966		0.45 [0.32,0.65]	Z=-4.36, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.91.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

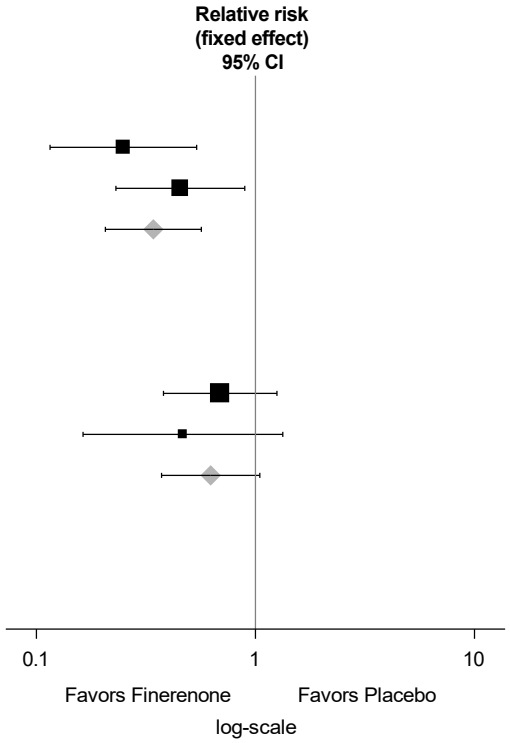
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	24 / 1062	62.4	0.37 [0.17,0.79]	
FIGARO-DKD	9 / 638	7 / 637	37.6	1.28 [0.48,3.43]	
Total	18 / 1713	31 / 1699		0.58 [0.32,1.02]	Z=-1.88, p=0.0602
Heterogeneity:	Q=3.85 (df=1)	p=0.0497	I^2=74.0%		
North America					
FIDELIO-DKD	5 / 424	11 / 436	52.3	0.47 [0.16,1.33]	
FIGARO-DKD	4 / 267	14 / 271	47.7	0.29 [0.10,0.87]	
Total	9 / 691	25 / 707		0.37 [0.17,0.78]	Z=-2.60, p=0.0092
Heterogeneity:	Q=0.38 (df=1)	p=0.5371	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 751	20 / 745	71.3	0.55 [0.26,1.13]	
FIGARO-DKD	4 / 289	10 / 290	28.7	0.40 [0.13,1.27]	
Total	15 / 1040	30 / 1035		0.50 [0.27,0.92]	Z=-2.23, p=0.0259
Heterogeneity:	Q=0.20 (df=1)	p=0.6580	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	2 / 270	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	0 / 102	2 / 101	0.0	0.00 [0.00,17E296]	
Total	0 / 375	4 / 371		0.00 [0.00,12E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	1 / 97	100.0	1.03 [0.07,16.26]	
FIGARO-DKD	0 / 61	4 / 57	0.0	0.00 [0.00,13E296]	
Total	1 / 155	5 / 154		0.19 [0.02,1.61]	Z=-1.52, p=0.1277
Heterogeneity:	Q=1.44 (df=1)	p=0.2302	I^2=30.5%		
Subgroup Heterogeneity:	Q=1.60 (df=4)	p=0.8096	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.91.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

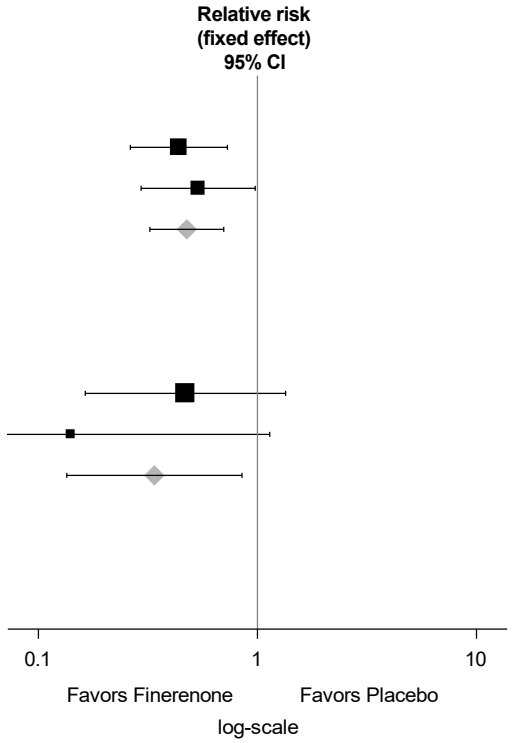
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	8 / 1213	32 / 1210	43.6	0.25 [0.12,0.54]	
FIGARO-DKD	12 / 862	26 / 848	56.4	0.45 [0.23,0.89]	
Total	20 / 2075	58 / 2058		0.34 [0.21,0.57]	Z=-4.17, p=<.0001
Heterogeneity:	Q=1.32 (df=1)	p=0.2510	I^2=24.1%		
Absent					
FIDELIO-DKD	18 / 1404	26 / 1400	75.6	0.69 [0.38,1.25]	
FIGARO-DKD	5 / 495	11 / 508	24.4	0.47 [0.16,1.33]	
Total	23 / 1899	37 / 1908		0.62 [0.37,1.05]	Z=-1.79, p=0.0741
Heterogeneity:	Q=0.41 (df=1)	p=0.5245	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.68 (df=1)	p=0.1018	I^2=62.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.91.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	21 / 1735	47 / 1700	58.0	0.44 [0.26,0.73]	
FIGARO-DKD	16 / 924	30 / 929	42.0	0.54 [0.29,0.98]	
Total	37 / 2659	77 / 2629		0.48 [0.32,0.70]	Z=-3.75, p=0.0002
Heterogeneity:	Q=0.25 (df=1)	p=0.6137	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 882	11 / 910	79.8	0.47 [0.16,1.34]	
FIGARO-DKD	1 / 433	7 / 426	20.2	0.14 [0.02,1.14]	
Total	6 / 1315	18 / 1336		0.34 [0.13,0.85]	Z=-2.31, p=0.0211
Heterogeneity:	Q=1.05 (df=1)	p=0.3062	I^2=4.5%		
Subgroup Heterogeneity:	Q=0.45 (df=1)	p=0.5039	I^2=0.0%		

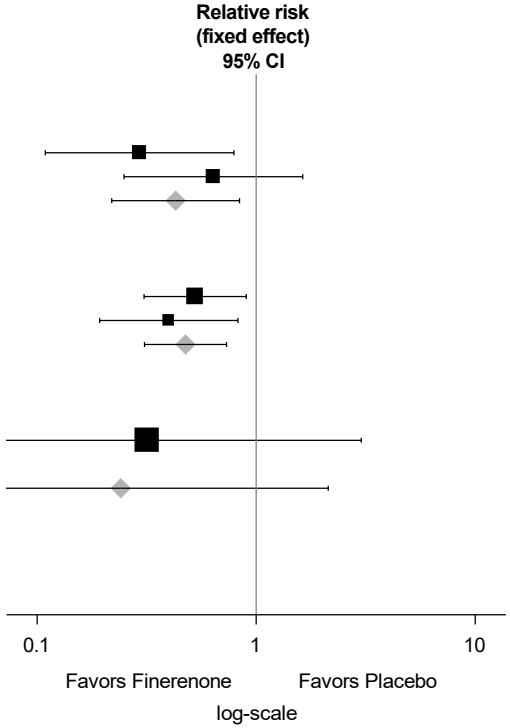


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.91.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

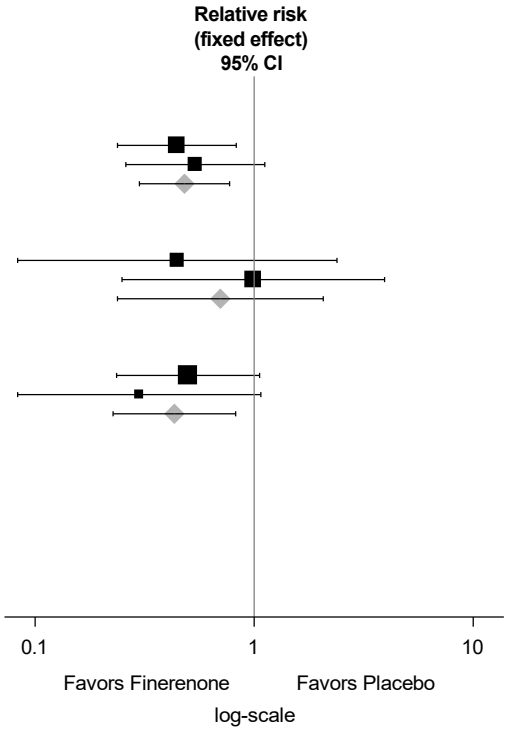
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	17 / 723	47.3	0.29 [0.11,0.79]	
FIGARO-DKD	7 / 494	11 / 495	52.7	0.64 [0.25,1.63]	
Total	12 / 1218	28 / 1218		0.43 [0.22,0.84]	Z=-2.47, p=0.0135
Heterogeneity:	Q=1.24 (df=1)	p=0.2646	I^2=19.6%		
130 - < 160					
FIDELIO-DKD	20 / 1759	38 / 1760	64.7	0.53 [0.31,0.90]	
FIGARO-DKD	10 / 829	25 / 827	35.3	0.40 [0.19,0.83]	
Total	30 / 2588	63 / 2587		0.48 [0.31,0.73]	Z=-3.38, p=0.0007
Heterogeneity:	Q=0.36 (df=1)	p=0.5474	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	3 / 127	100.0	0.32 [0.03,3.02]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,11E296]	
Total	1 / 167	4 / 161		0.24 [0.03,2.13]	Z=-1.28, p=0.2008
Heterogeneity:	Q=0.06 (df=1)	p=0.8084	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=2)	p=0.8198	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.91.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

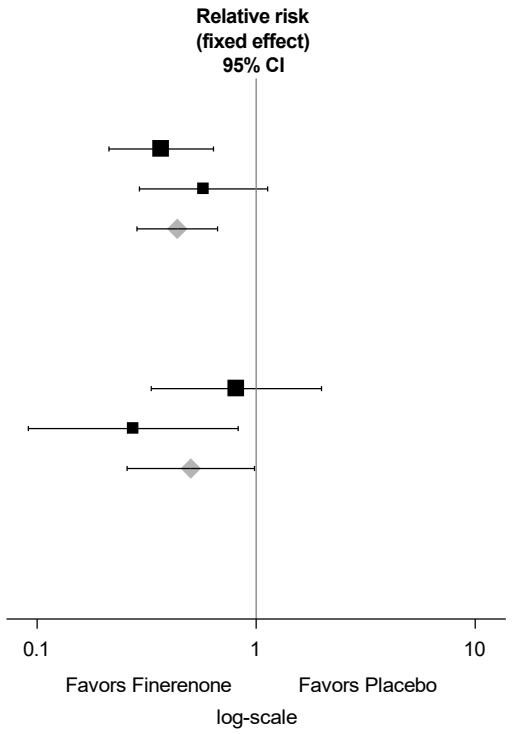
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1634	32 / 1657	57.8	0.44 [0.24,0.83]	
FIGARO-DKD	11 / 1010	20 / 989	42.2	0.54 [0.26,1.12]	
Total	25 / 2644	52 / 2646		0.48 [0.30,0.77]	Z=-3.03, p=0.0025
Heterogeneity:	Q=0.16 (df=1)	p=0.6925	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	4 / 115	40.3	0.45 [0.08,2.39]	
FIGARO-DKD	3 / 43	5 / 71	59.7	0.99 [0.25,3.94]	
Total	5 / 172	9 / 186		0.70 [0.24,2.07]	Z=-0.64, p=0.5196
Heterogeneity:	Q=0.52 (df=1)	p=0.4705	I^2=0.0%		
Asian					
FIDELIO-DKD	10 / 678	20 / 677	74.3	0.50 [0.24,1.06]	
FIGARO-DKD	3 / 252	10 / 251	25.7	0.30 [0.08,1.07]	
Total	13 / 930	30 / 928		0.43 [0.23,0.82]	Z=-2.55, p=0.0107
Heterogeneity:	Q=0.46 (df=1)	p=0.4968	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 176	2 / 161	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	0 / 52	2 / 45	0.0	0.00 [0.00,78E295]	
Total	0 / 228	4 / 206		0.00 [0.00,67E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.57 (df=3)	p=0.9034	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.91.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

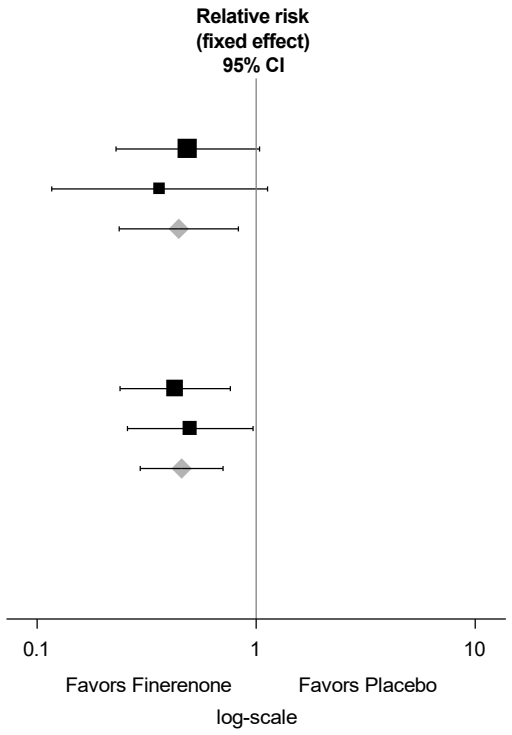
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	48 / 1870	60.1	0.37 [0.21,0.64]	
FIGARO-DKD	13 / 917	23 / 933	39.9	0.58 [0.29,1.13]	
Total	30 / 2714	71 / 2803		0.44 [0.29,0.67]	Z=-3.84, p=0.0001
Heterogeneity:	Q=1.01 (df=1)	p=0.3155	I^2=0.7%		
Female					
FIDELIO-DKD	9 / 820	10 / 740	60.3	0.81 [0.33,1.99]	
FIGARO-DKD	4 / 440	14 / 423	39.7	0.27 [0.09,0.83]	
Total	13 / 1260	24 / 1163		0.50 [0.26,0.98]	Z=-2.01, p=0.0444
Heterogeneity:	Q=2.26 (df=1)	p=0.1331	I^2=55.7%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7247	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.91.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

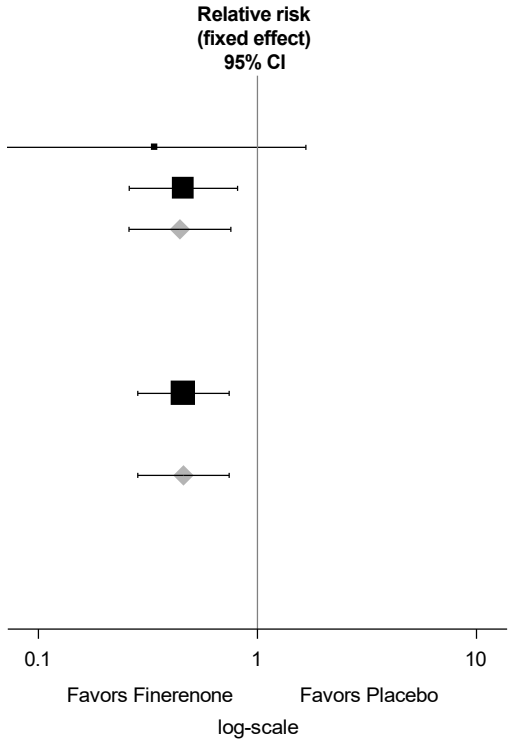
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1103	20 / 1075	69.3	0.49 [0.23,1.04]	
FIGARO-DKD	4 / 336	11 / 335	30.7	0.36 [0.12,1.13]	
Total	14 / 1439	31 / 1410		0.44 [0.24,0.83]	Z=-2.54, p=0.0109
Heterogeneity:	Q=0.18 (df=1)	p=0.6704	I^2=0.0%		
>= 65					
FIDELIO-DKD	16 / 1514	38 / 1535	56.5	0.43 [0.24,0.76]	
FIGARO-DKD	13 / 1021	26 / 1021	43.5	0.50 [0.26,0.97]	
Total	29 / 2535	64 / 2556		0.46 [0.30,0.71]	Z=-3.53, p=0.0004
Heterogeneity:	Q=0.12 (df=1)	p=0.7243	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9385	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.91.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

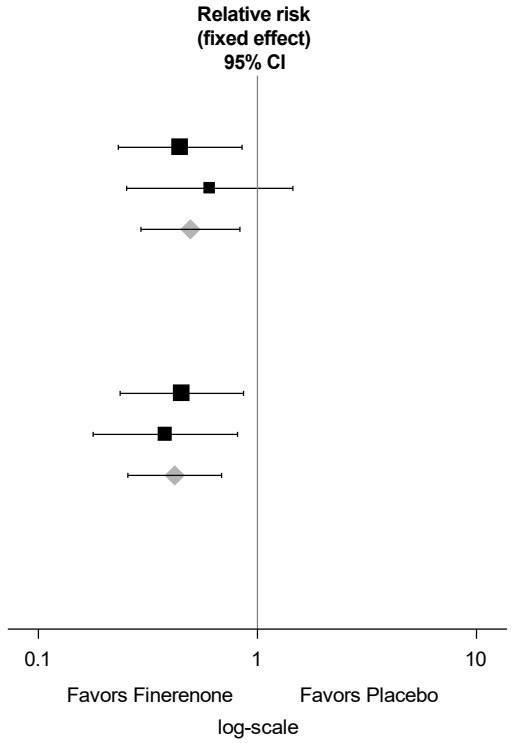
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	6 / 213	11.4	0.34 [0.07,1.66]	
FIGARO-DKD	17 / 1357	37 / 1356	88.6	0.46 [0.26,0.81]	
Total	19 / 1566	43 / 1569		0.44 [0.26,0.76]	Z=-2.98, p=0.0029
Heterogeneity:	Q=0.12 (df=1)	p=0.7264	I^2=0.0%		
Very High					
FIDELIO-DKD	24 / 2408	52 / 2397	100.0	0.46 [0.28,0.74]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	24 / 2408	52 / 2397		0.46 [0.28,0.74]	Z=-3.17, p=0.0015
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9193	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.91.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

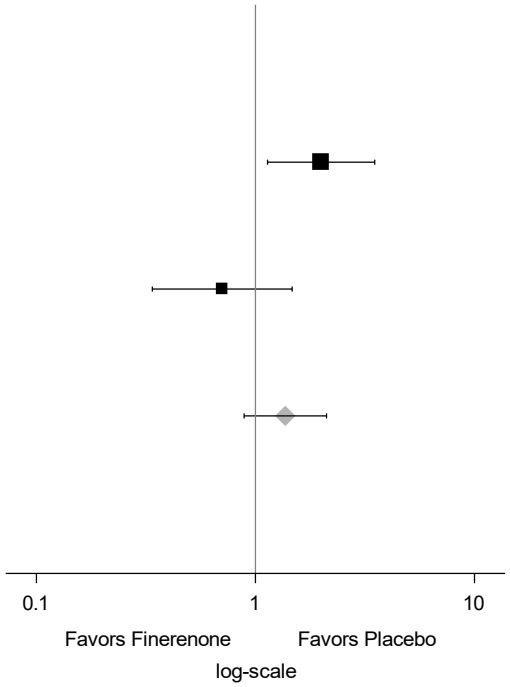
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	29 / 1541	64.3	0.44 [0.23,0.85]	
FIGARO-DKD	8 / 637	13 / 627	35.7	0.61 [0.25,1.45]	
Total	21 / 2193	42 / 2168		0.49 [0.29,0.83]	Z=-2.65, p=0.0080
Heterogeneity:	Q=0.31 (df=1)	p=0.5760	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	13 / 1061	29 / 1069	57.8	0.45 [0.24,0.86]	
FIGARO-DKD	9 / 720	24 / 729	42.2	0.38 [0.18,0.81]	
Total	22 / 1781	53 / 1798		0.42 [0.26,0.69]	Z=-3.46, p=0.0005
Heterogeneity:	Q=0.12 (df=1)	p=0.7333	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6518	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.92: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

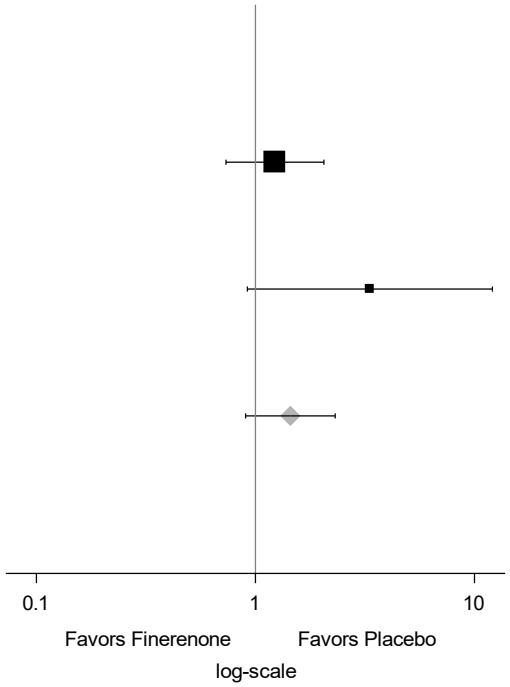
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	18 / 2610	63.0	1.99 [1.14,3.50]	
FIGARO-DKD	12 / 1357	17 / 1356	37.0	0.71 [0.34,1.47]	
Total	48 / 3974	35 / 3966		1.37 [0.89,2.11]	Z=1.42, p=0.1559
Heterogeneity:	Q=4.84 (df=1)	p=0.0278	I^2=79.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.93: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Metabolic acidosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

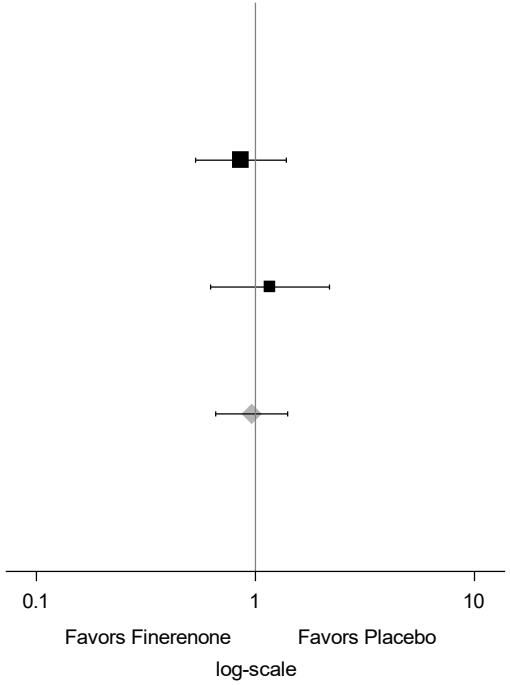
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	26 / 2610	86.2	1.23 [0.73,2.05]	
FIGARO-DKD	10 / 1357	3 / 1356	13.8	3.33 [0.92,12.08]	
Total	42 / 3974	29 / 3966		1.44 [0.90,2.31]	Z=1.53, p=0.1264
Heterogeneity:	Q=2.00 (df=1)	p=0.1573	I^2=50.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.94: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

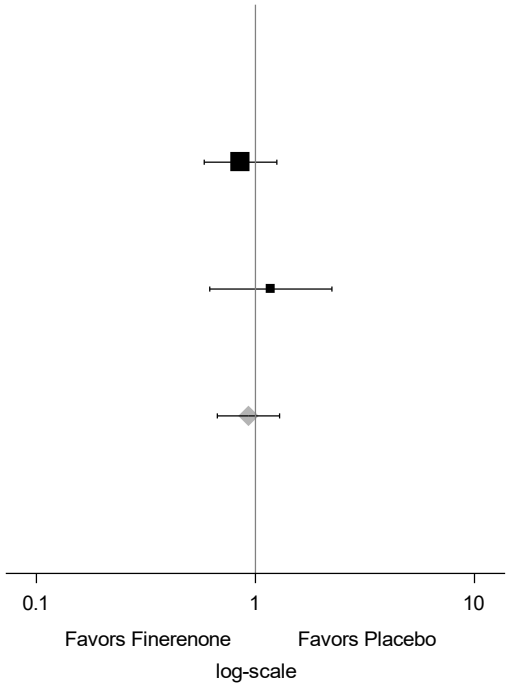
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	36 / 2610	63.2	0.86 [0.53,1.38]	
FIGARO-DKD	21 / 1357	18 / 1356	36.8	1.17 [0.62,2.18]	
Total	52 / 3974	54 / 3966		0.96 [0.66,1.40]	Z=-0.21, p=0.8374
Heterogeneity:	Q=0.58 (df=1)	p=0.4462	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.95: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

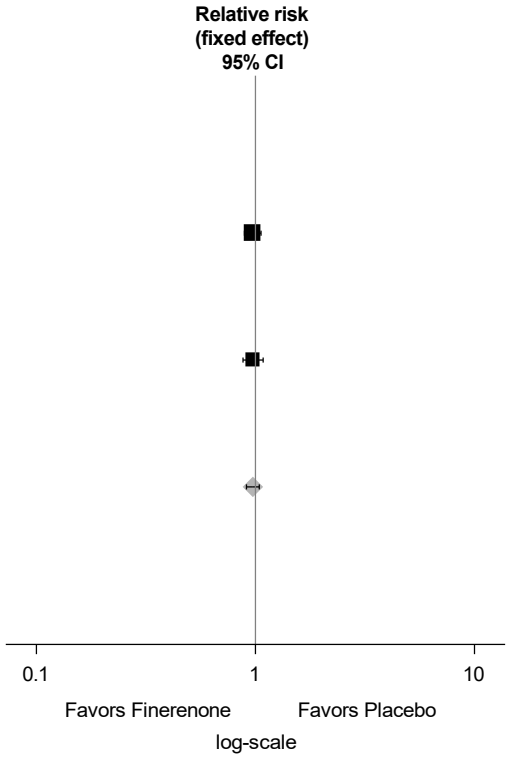
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 2617	56 / 2610	73.9	0.85 [0.58,1.25]	
FIGARO-DKD	20 / 1357	17 / 1356	26.1	1.18 [0.62,2.23]	
Total	68 / 3974	73 / 3966		0.93 [0.67,1.29]	Z=-0.44, p=0.6598
Heterogeneity:	Q=0.70 (df=1)	p=0.4032	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.96: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

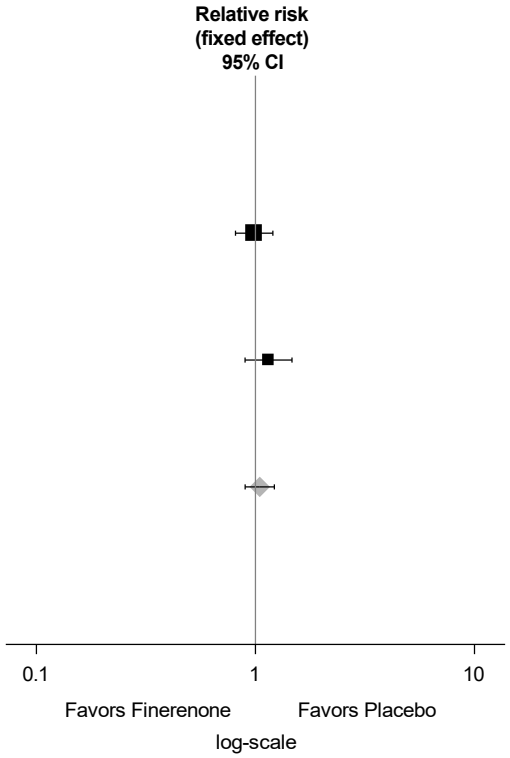
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	720 / 2617	739 / 2610	59.6	0.97 [0.89,1.06]	
FIGARO-DKD	450 / 1357	461 / 1356	40.4	0.98 [0.88,1.08]	
Total	1170 / 3974	1200 / 3966		0.97 [0.91,1.04]	Z=-0.79, p=0.4286
Heterogeneity:	Q=0.00 (df=1)	p=0.9563	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.97: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

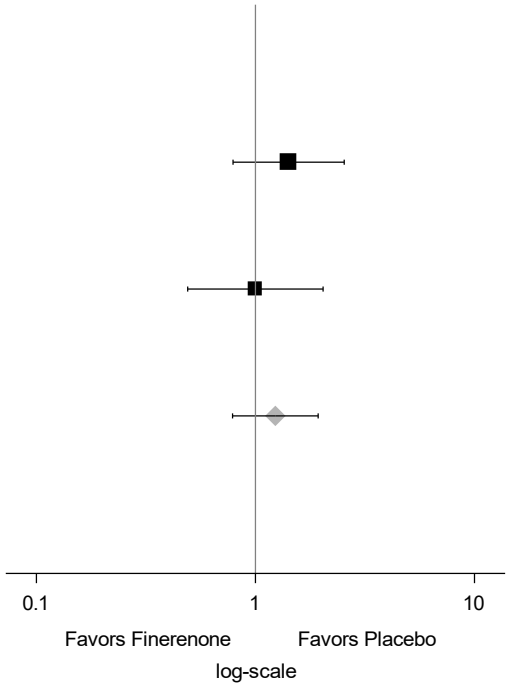
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	184 / 2617	186 / 2610	61.2	0.99 [0.81,1.20]	
FIGARO-DKD	124 / 1357	108 / 1356	38.8	1.15 [0.90,1.47]	
Total	308 / 3974	294 / 3966		1.05 [0.90,1.22]	Z=0.58, p=0.5644
Heterogeneity:	Q=0.88 (df=1)	p=0.3484	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.98: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

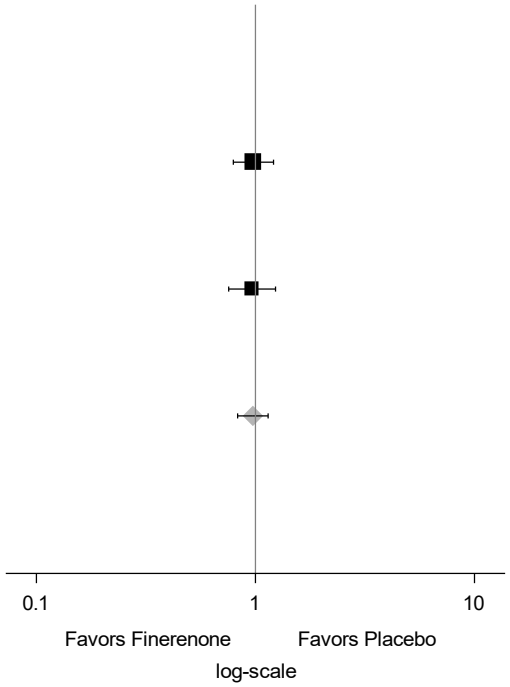
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	19 / 2610	59.7	1.42 [0.79,2.54]	
FIGARO-DKD	15 / 1357	15 / 1356	40.3	1.00 [0.49,2.04]	
Total	42 / 3974	34 / 3966		1.23 [0.79,1.93]	Z=0.91, p=0.3622
Heterogeneity:	Q=0.55 (df=1)	p=0.4570	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.99: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

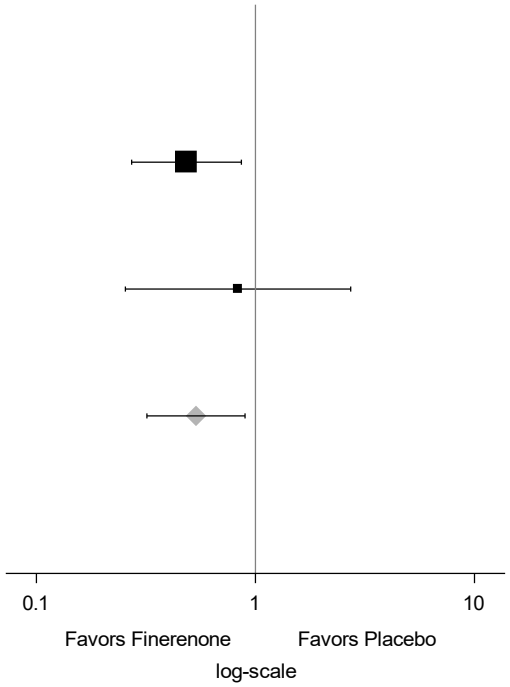
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	160 / 2617	163 / 2610	57.6	0.98 [0.79,1.21]	
FIGARO-DKD	114 / 1357	118 / 1356	42.4	0.97 [0.75,1.23]	
Total	274 / 3974	281 / 3966		0.97 [0.83,1.14]	Z=-0.33, p=0.7397
Heterogeneity:	Q=0.01 (df=1)	p=0.9327	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.100: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

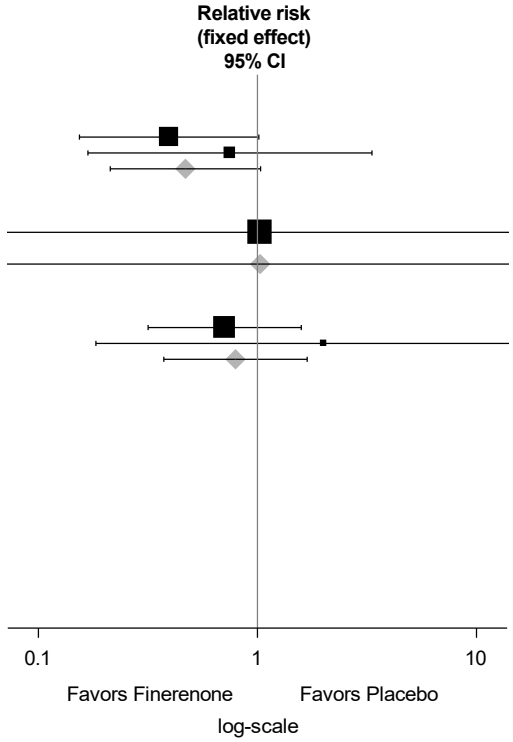
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 2617	35 / 2610	80.8	0.48 [0.27,0.86]	
FIGARO-DKD	5 / 1357	6 / 1356	19.2	0.83 [0.25,2.72]	
Total	22 / 3974	41 / 3966		0.54 [0.32,0.90]	Z=-2.38, p=0.0175
Heterogeneity:	Q=0.65 (df=1)	p=0.4202	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.100.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

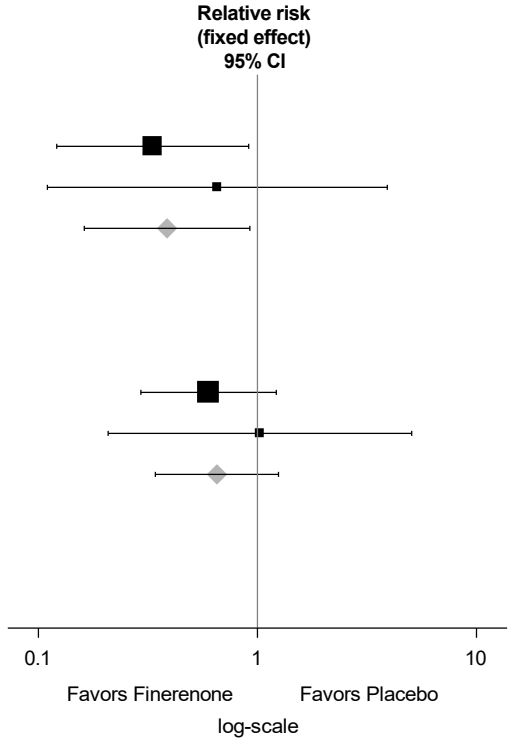
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 1075	15 / 1062	71.5	0.40 [0.15,1.01]	
FIGARO-DKD	3 / 638	4 / 637	28.5	0.75 [0.17,3.33]	
Total	9 / 1713	19 / 1699		0.47 [0.21,1.03]	Z=-1.88, p=0.0603
Heterogeneity:	Q=0.50 (df=1)	p=0.4777	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 424	1 / 436	100.0	1.03 [0.06,16.39]	
FIGARO-DKD	0 / 267	0 / 271	0.0	-	
Total	1 / 691	1 / 707		1.03 [0.06,16.39]	Z=0.02, p=0.9842
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	10 / 751	14 / 745	89.8	0.71 [0.32,1.59]	
FIGARO-DKD	2 / 289	1 / 290	10.2	2.01 [0.18,22.01]	
Total	12 / 1040	15 / 1035		0.79 [0.37,1.69]	Z=-0.60, p=0.5480
Heterogeneity:	Q=0.65 (df=1)	p=0.4192	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	3 / 270	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	0 / 375	3 / 371		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	0 / 61	1 / 57	0.0	0.00 [0.00,72E295]	
Total	0 / 155	3 / 154		0.00 [0.00,18E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.02 (df=4)	p=0.9071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.100.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

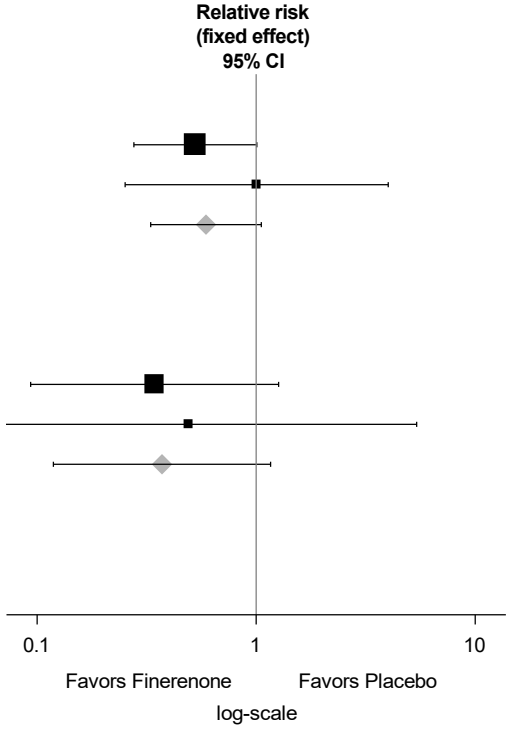
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	5 / 1213	15 / 1210	75.8	0.33 [0.12,0.91]	
FIGARO-DKD	2 / 862	3 / 848	24.2	0.66 [0.11,3.92]	
Total	7 / 2075	18 / 2058		0.39 [0.16,0.92]	Z=-2.14, p=0.0324
Heterogeneity:	Q=0.42 (df=1)	p=0.5160	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 1404	20 / 1400	83.4	0.60 [0.29,1.22]	
FIGARO-DKD	3 / 495	3 / 508	16.6	1.03 [0.21,5.06]	
Total	15 / 1899	23 / 1908		0.65 [0.34,1.25]	Z=-1.29, p=0.1969
Heterogeneity:	Q=0.37 (df=1)	p=0.5449	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.90 (df=1)	p=0.3437	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.100.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

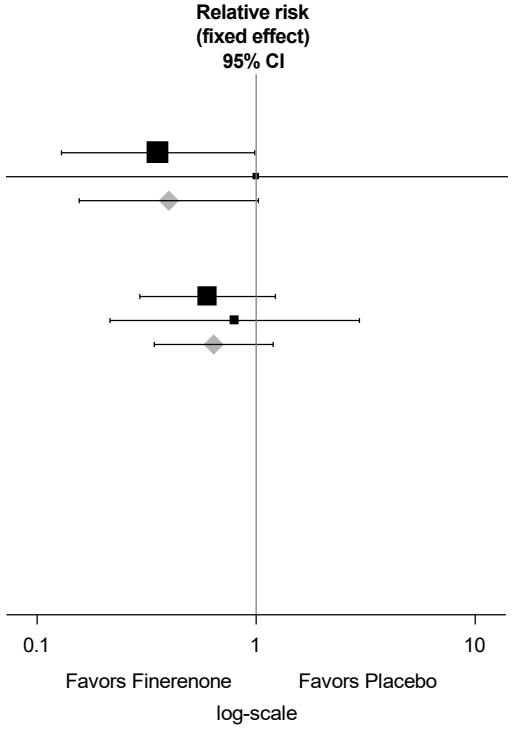
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	14 / 1735	26 / 1700	82.1	0.53 [0.28,1.01]	
FIGARO-DKD	4 / 924	4 / 929	17.9	1.01 [0.25,4.01]	
Total	18 / 2659	30 / 2629		0.59 [0.33,1.06]	Z=-1.78, p=0.0754
Heterogeneity:	Q=0.69 (df=1)	p=0.4077	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 882	9 / 910	77.2	0.34 [0.09,1.27]	
FIGARO-DKD	1 / 433	2 / 426	22.8	0.49 [0.04,5.40]	
Total	4 / 1315	11 / 1336		0.37 [0.12,1.16]	Z=-1.70, p=0.0892
Heterogeneity:	Q=0.07 (df=1)	p=0.7970	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4792	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.100.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

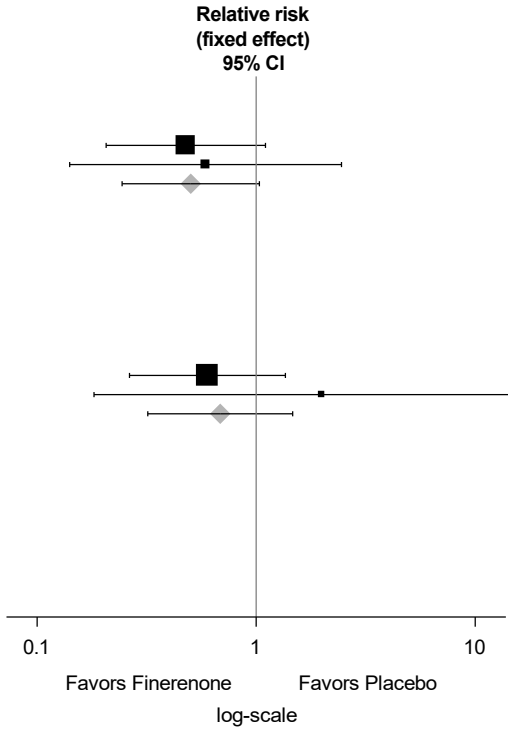
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	14 / 723	88.1	0.36 [0.13,0.99]	
FIGARO-DKD	1 / 494	1 / 495	11.9	1.00 [0.06,15.98]	
Total	6 / 1218	15 / 1218		0.40 [0.16,1.02]	Z=-1.91, p=0.0561
Heterogeneity:	Q=0.47 (df=1)	p=0.4922	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 1759	20 / 1760	77.2	0.60 [0.29,1.22]	
FIGARO-DKD	4 / 829	5 / 827	22.8	0.80 [0.22,2.96]	
Total	16 / 2588	25 / 2587		0.64 [0.34,1.20]	Z=-1.40, p=0.1614
Heterogeneity:	Q=0.14 (df=1)	p=0.7085	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	1 / 127	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	1 / 161		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.67 (df=2)	p=0.7158	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.100.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

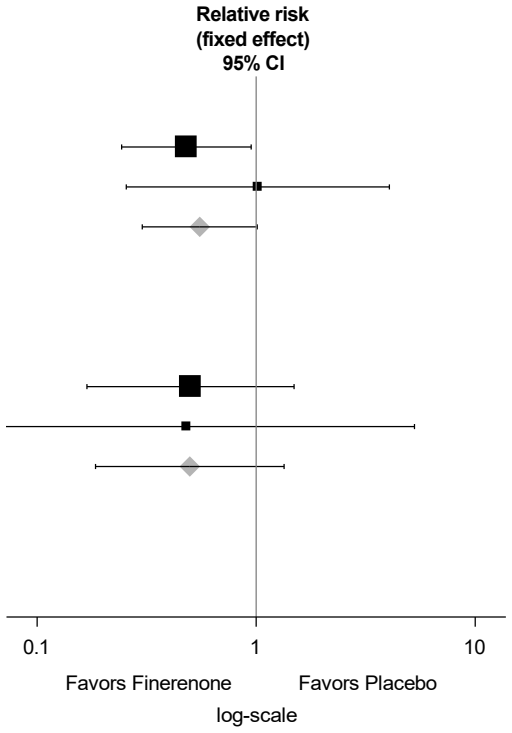
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 1634	17 / 1657	74.4	0.48 [0.21,1.10]	
FIGARO-DKD	3 / 1010	5 / 989	25.6	0.59 [0.14,2.45]	
Total	11 / 2644	22 / 2646		0.50 [0.24,1.03]	Z=-1.87, p=0.0617
Heterogeneity:	Q=0.06 (df=1)	p=0.8056	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	1 / 115	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	0 / 172	1 / 186		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	9 / 678	15 / 677	89.5	0.60 [0.26,1.36]	
FIGARO-DKD	2 / 252	1 / 251	10.5	1.99 [0.18,21.83]	
Total	11 / 930	16 / 928		0.69 [0.32,1.47]	Z=-0.97, p=0.3309
Heterogeneity:	Q=0.87 (df=1)	p=0.3519	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 176	2 / 161	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	0 / 228	2 / 206		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.34 (df=3)	p=0.9532	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.100.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

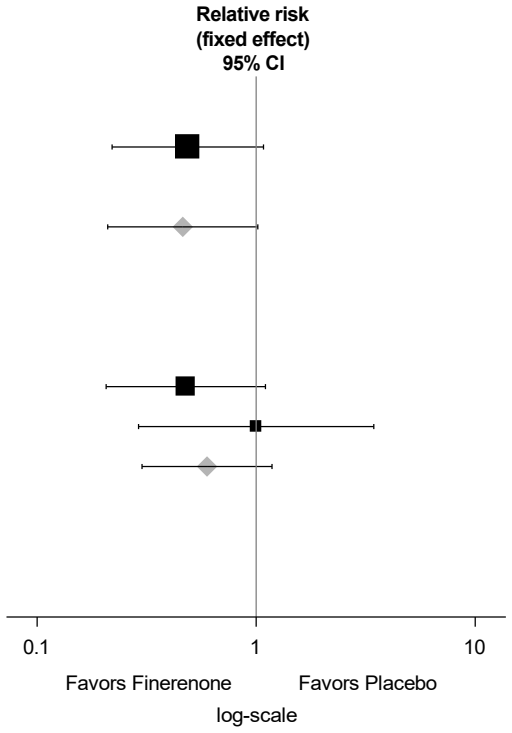
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	12 / 1797	26 / 1870	80.5	0.48 [0.24,0.95]	
FIGARO-DKD	4 / 917	4 / 933	19.5	1.02 [0.26,4.06]	
Total	16 / 2714	30 / 2803		0.55 [0.30,1.01]	Z=-1.92, p=0.0543
Heterogeneity:	Q=0.91 (df=1)	p=0.3397	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 820	9 / 740	82.9	0.50 [0.17,1.49]	
FIGARO-DKD	1 / 440	2 / 423	17.1	0.48 [0.04,5.28]	
Total	6 / 1260	11 / 1163		0.50 [0.18,1.34]	Z=-1.38, p=0.1677
Heterogeneity:	Q=0.00 (df=1)	p=0.9750	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8601	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.100.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1103	18 / 1075	100.0	0.49 [0.22,1.08]	
FIGARO-DKD	0 / 336	1 / 335	0.0	0.00 [0.00,16E296]	
Total	9 / 1439	19 / 1410		0.46 [0.21,1.02]	Z=-1.92, p=0.0552
Heterogeneity:	Q=0.02 (df=1)	p=0.8966	I^2=0.0%		
>= 65					
FIDELIO-DKD	8 / 1514	17 / 1535	68.6	0.48 [0.21,1.10]	
FIGARO-DKD	5 / 1021	5 / 1021	31.4	1.00 [0.29,3.44]	
Total	13 / 2535	22 / 2556		0.60 [0.30,1.18]	Z=-1.48, p=0.1383
Heterogeneity:	Q=0.94 (df=1)	p=0.3313	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6322	I^2=0.0%		

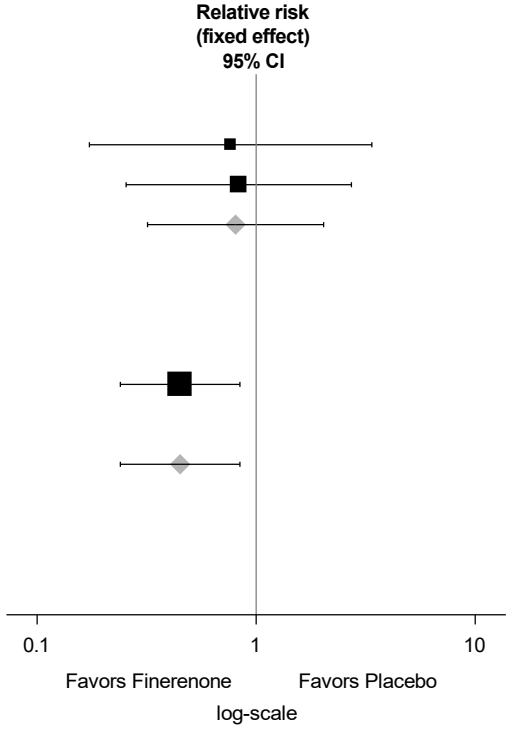


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.100.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Intervertebral disc protrusion (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

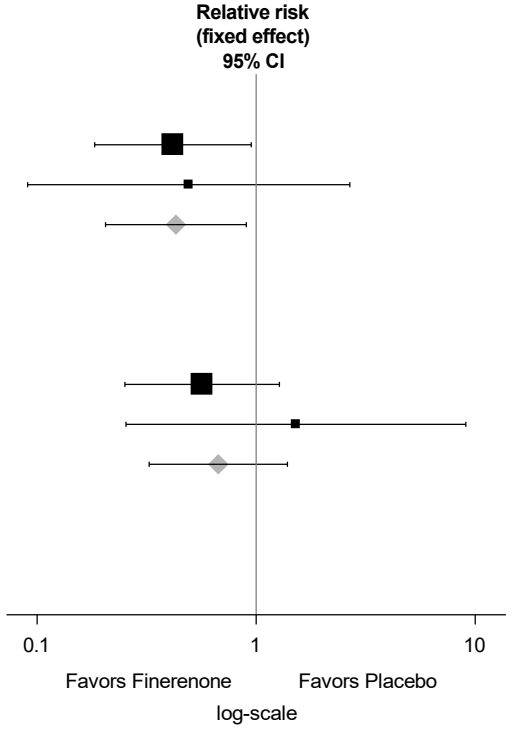
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	4 / 213	38.9	0.76 [0.17,3.37]	
FIGARO-DKD	5 / 1357	6 / 1356	61.1	0.83 [0.25,2.72]	
Total	8 / 1566	10 / 1569		0.81 [0.32,2.03]	Z=-0.46, p=0.6467
Heterogeneity:	Q=0.01 (df=1)	p=0.9296	I^2=0.0%		
Very High					
FIDELIO-DKD	14 / 2408	31 / 2397	100.0	0.45 [0.24,0.84]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	14 / 2408	31 / 2397		0.45 [0.24,0.84]	Z=-2.49, p=0.0127
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.04 (df=1)	p=0.3071	I^2=4.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.100.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

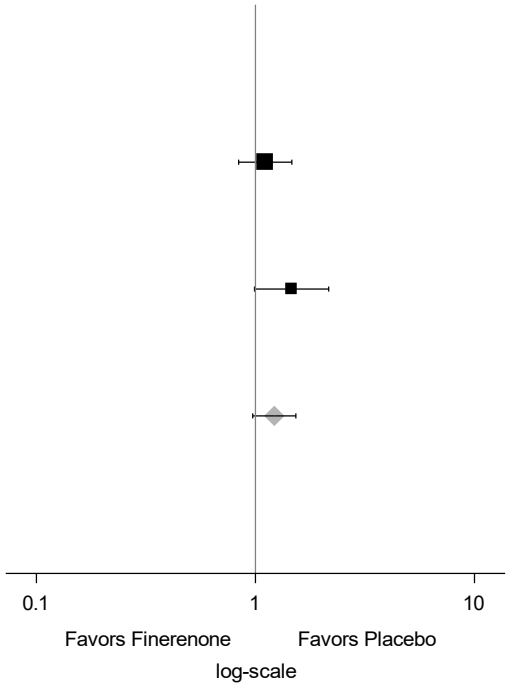
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	8 / 1556	19 / 1541	80.9	0.42 [0.18,0.95]	
FIGARO-DKD	2 / 637	4 / 627	19.1	0.49 [0.09,2.68]	
Total	10 / 2193	23 / 2168		0.43 [0.21,0.90]	Z=-2.24, p=0.0254
Heterogeneity:	Q=0.03 (df=1)	p=0.8631	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	16 / 1069	82.9	0.57 [0.25,1.28]	
FIGARO-DKD	3 / 720	2 / 729	17.1	1.52 [0.25,9.06]	
Total	12 / 1781	18 / 1798		0.67 [0.32,1.39]	Z=-1.07, p=0.2828
Heterogeneity:	Q=0.97 (df=1)	p=0.3248	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.71 (df=1)	p=0.3998	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.101: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

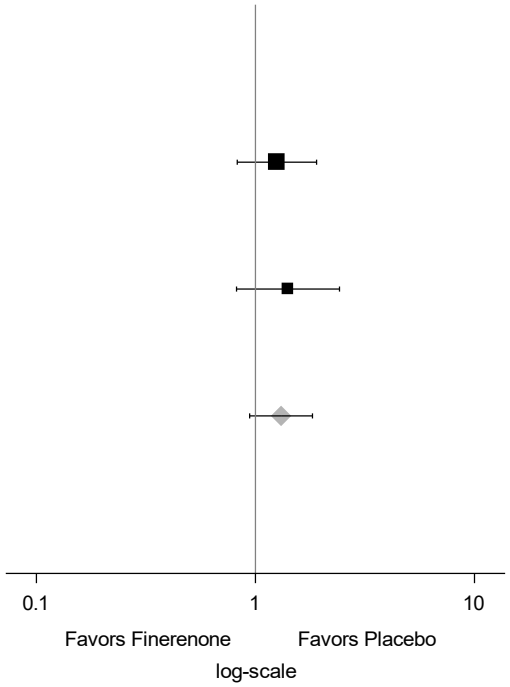
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	90 / 2610	66.0	1.11 [0.84,1.47]	
FIGARO-DKD	60 / 1357	41 / 1356	34.0	1.46 [0.99,2.16]	
Total	160 / 3974	131 / 3966		1.22 [0.97,1.53]	Z=1.71, p=0.0869
Heterogeneity:	Q=1.28 (df=1)	p=0.2572	I^2=22.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.102: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

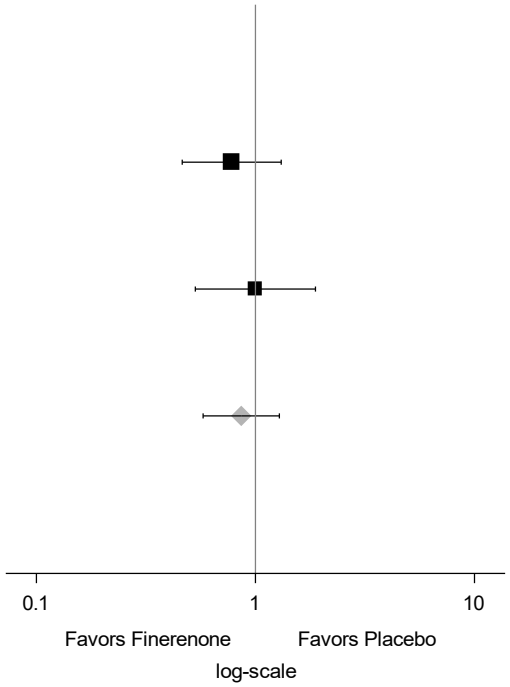
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2617	39 / 2610	62.7	1.25 [0.83,1.90]	
FIGARO-DKD	31 / 1357	22 / 1356	37.3	1.41 [0.82,2.42]	
Total	80 / 3974	61 / 3966		1.31 [0.94,1.82]	Z=1.60, p=0.1100
Heterogeneity:	Q=0.11 (df=1)	p=0.7380	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.103: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

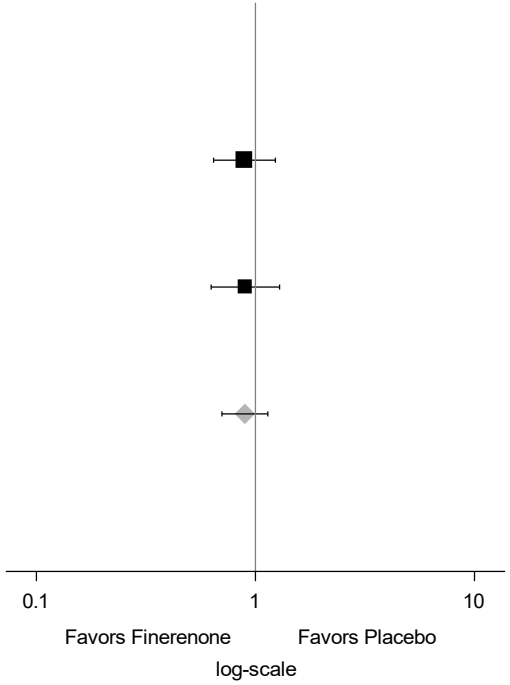
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	32 / 2610	59.6	0.78 [0.46,1.31]	
FIGARO-DKD	19 / 1357	19 / 1356	40.4	1.00 [0.53,1.88]	
Total	44 / 3974	51 / 3966		0.86 [0.58,1.29]	Z=-0.73, p=0.4652
Heterogeneity:	Q=0.36 (df=1)	p=0.5512	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.104: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

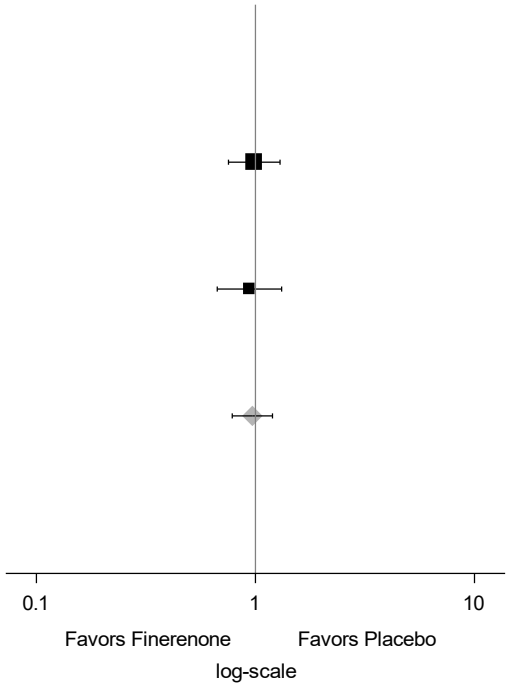
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 2617	75 / 2610	55.1	0.89 [0.64,1.23]	
FIGARO-DKD	54 / 1357	60 / 1356	44.9	0.90 [0.63,1.29]	
Total	121 / 3974	135 / 3966		0.89 [0.70,1.14]	Z=-0.90, p=0.3659
Heterogeneity:	Q=0.00 (df=1)	p=0.9698	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.105: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

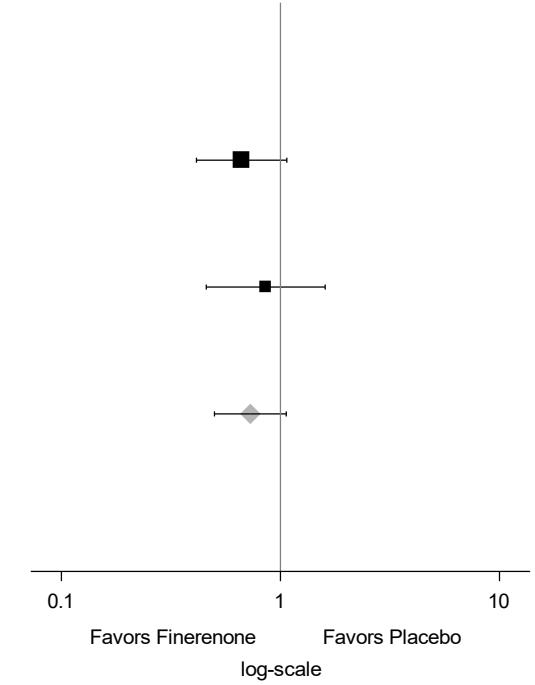
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	101 / 2610	60.9	0.99 [0.75,1.29]	
FIGARO-DKD	62 / 1357	66 / 1356	39.1	0.94 [0.67,1.32]	
Total	162 / 3974	167 / 3966		0.97 [0.78,1.20]	Z=-0.30, p=0.7638
Heterogeneity:	Q=0.05 (df=1)	p=0.8190	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.106: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

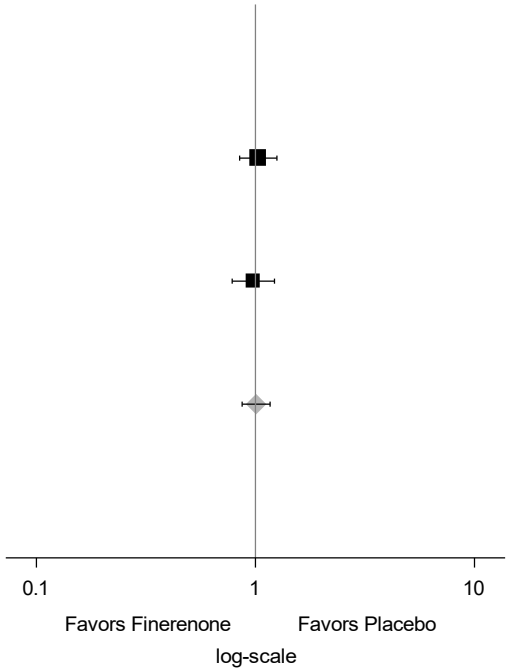
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	42 / 2610	63.4	0.66 [0.41,1.07]	
FIGARO-DKD	18 / 1357	21 / 1356	36.6	0.86 [0.46,1.60]	
Total	46 / 3974	63 / 3966		0.73 [0.50,1.06]	Z=-1.64, p=0.1005
Heterogeneity:	Q=0.40 (df=1)	p=0.5272	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.107: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

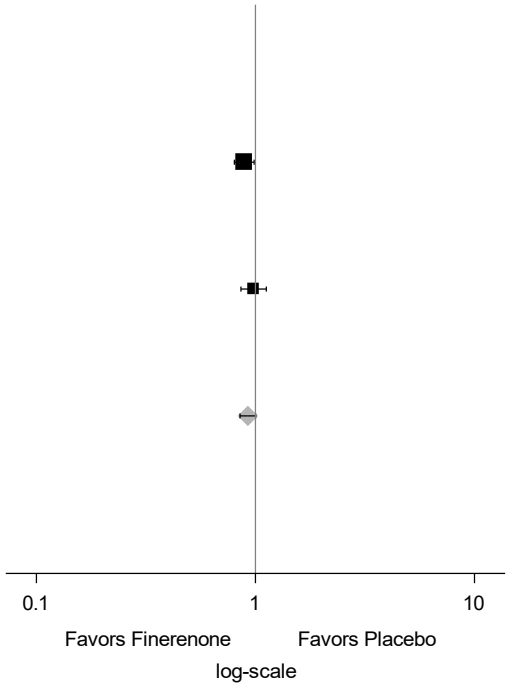
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	189 / 2617	183 / 2610	56.3	1.03 [0.85,1.25]	
FIGARO-DKD	138 / 1357	141 / 1356	43.7	0.98 [0.78,1.22]	
Total	327 / 3974	324 / 3966		1.01 [0.87,1.17]	Z=0.09, p=0.9264
Heterogeneity:	Q=0.12 (df=1)	p=0.7317	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.108: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

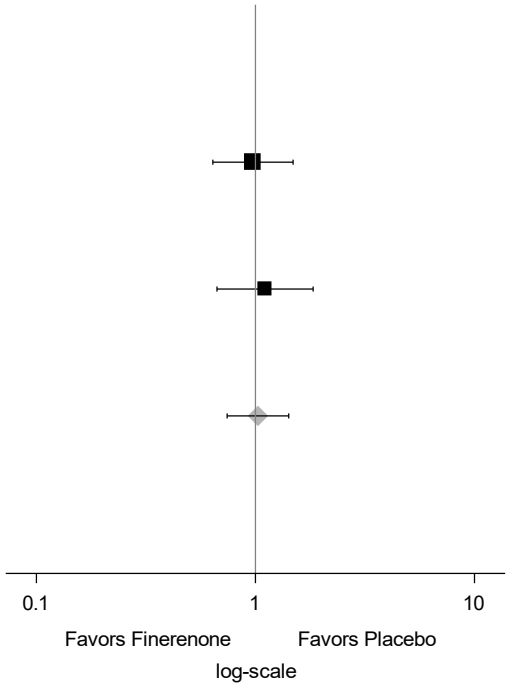
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	526 / 2617	590 / 2610	62.0	0.89 [0.80,0.99]	
FIGARO-DKD	325 / 1357	331 / 1356	38.0	0.98 [0.86,1.12]	
Total	851 / 3974	921 / 3966		0.92 [0.85,1.00]	Z=-1.91, p=0.0557
Heterogeneity:	Q=1.30 (df=1)	p=0.2541	I^2=23.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.109: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

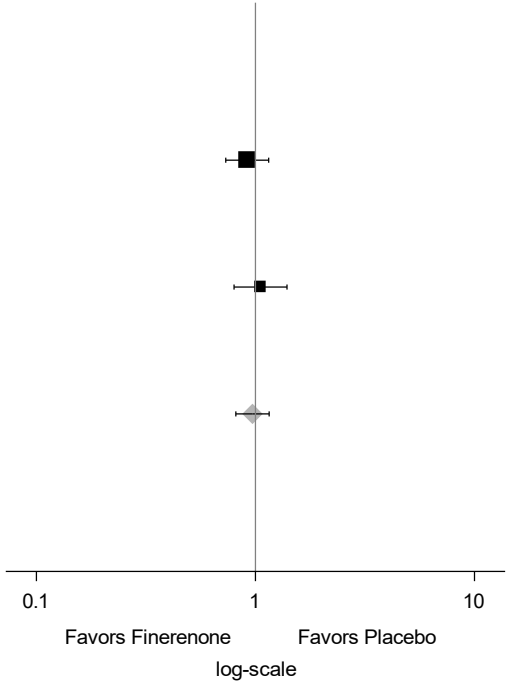
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2617	43 / 2610	59.0	0.97 [0.64,1.49]	
FIGARO-DKD	31 / 1357	28 / 1356	41.0	1.11 [0.67,1.83]	
Total	73 / 3974	71 / 3966		1.03 [0.74,1.42]	Z=0.16, p=0.8746
Heterogeneity:	Q=0.14 (df=1)	p=0.7048	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.110: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

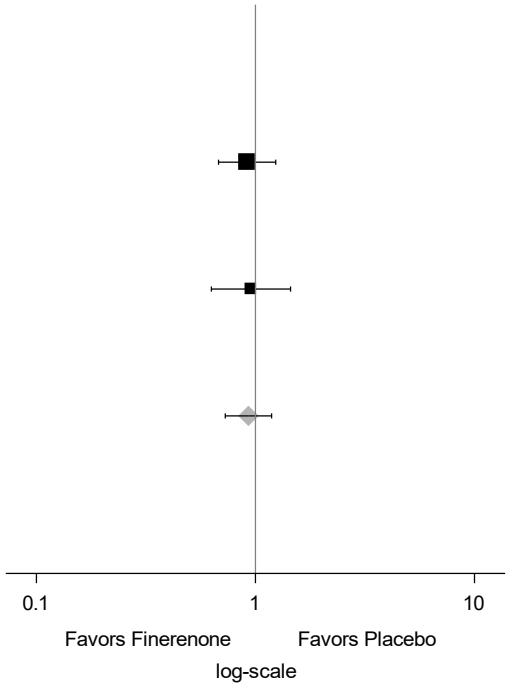
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	137 / 2617	149 / 2610	60.4	0.92 [0.73,1.15]	
FIGARO-DKD	95 / 1357	90 / 1356	39.6	1.05 [0.80,1.39]	
Total	232 / 3974	239 / 3966		0.97 [0.81,1.15]	Z=-0.35, p=0.7273
Heterogeneity:	Q=0.59 (df=1)	p=0.4438	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.111: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

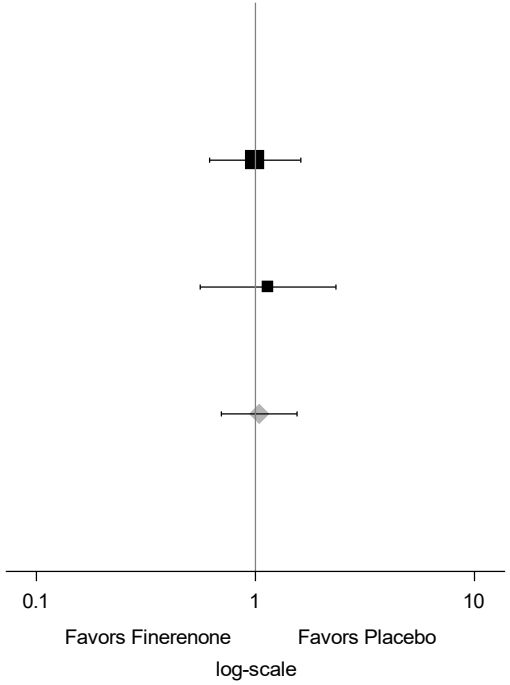
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	79 / 2617	86 / 2610	65.7	0.92 [0.68,1.24]	
FIGARO-DKD	42 / 1357	44 / 1356	34.3	0.95 [0.63,1.45]	
Total	121 / 3974	130 / 3966		0.93 [0.73,1.19]	Z=-0.59, p=0.5530
Heterogeneity:	Q=0.02 (df=1)	p=0.8776	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.112: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

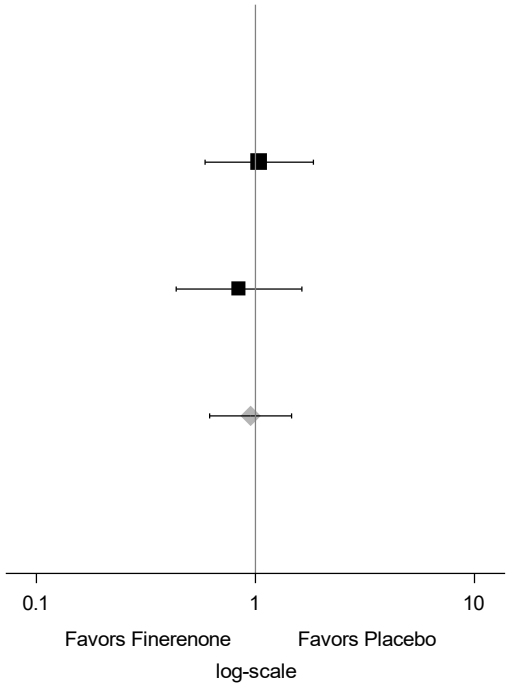
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2617	33 / 2610	68.9	1.00 [0.62,1.61]	
FIGARO-DKD	16 / 1357	14 / 1356	31.1	1.14 [0.56,2.33]	
Total	49 / 3974	47 / 3966		1.04 [0.70,1.55]	Z=0.19, p=0.8455
Heterogeneity:	Q=0.10 (df=1)	p=0.7574	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.113: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

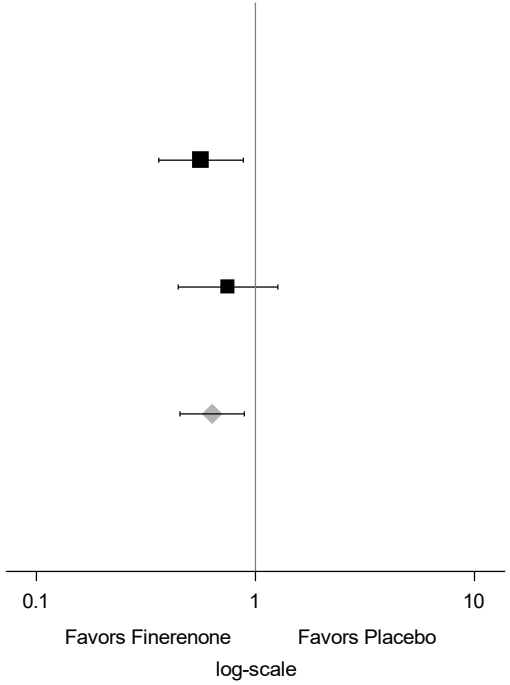
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2617	23 / 2610	57.4	1.04 [0.59,1.84]	
FIGARO-DKD	16 / 1357	19 / 1356	42.6	0.84 [0.43,1.63]	
Total	40 / 3974	42 / 3966		0.95 [0.62,1.46]	Z=-0.23, p=0.8170
Heterogeneity:	Q=0.23 (df=1)	p=0.6330	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.114: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

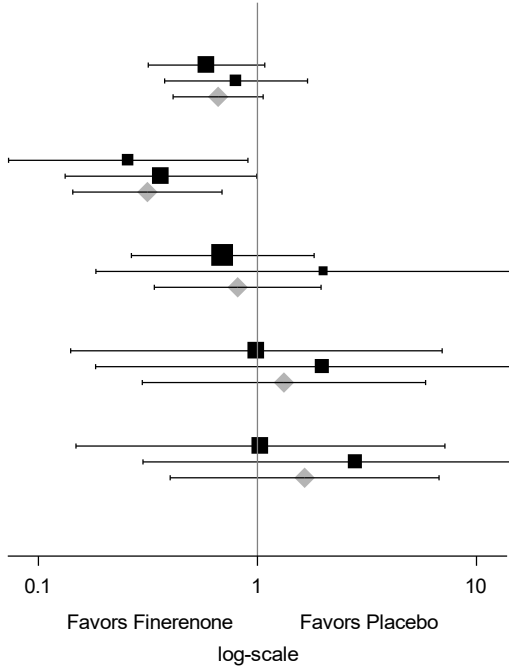
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	53 / 2610	58.1	0.56 [0.36,0.88]	
FIGARO-DKD	24 / 1357	32 / 1356	41.9	0.75 [0.44,1.27]	
Total	54 / 3974	85 / 3966		0.63 [0.45,0.89]	Z=-2.64, p=0.0083
Heterogeneity:	Q=0.65 (df=1)	p=0.4188	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.114.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

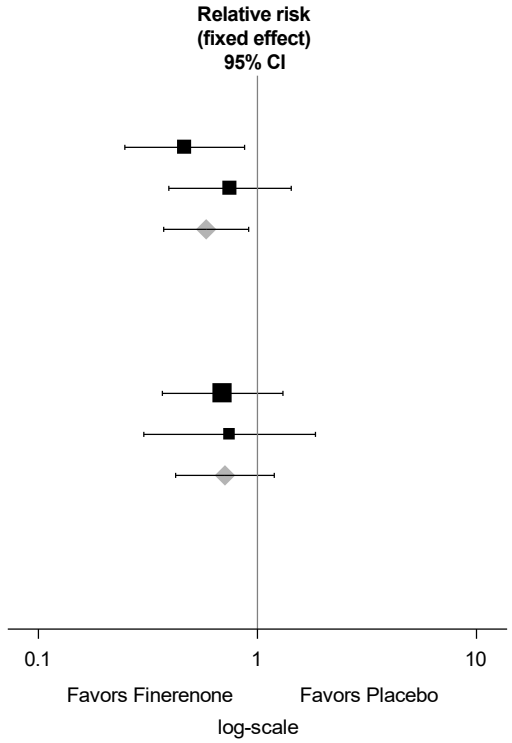
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	27 / 1062	60.1	0.59 [0.32,1.08]	
FIGARO-DKD	12 / 638	15 / 637	39.9	0.80 [0.38,1.69]	
Total	28 / 1713	42 / 1699		0.66 [0.41,1.06]	Z=-1.71, p=0.0870
Heterogeneity:	Q=0.39 (df=1)	p=0.5298	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	12 / 436	39.1	0.26 [0.07,0.90]	
FIGARO-DKD	5 / 267	14 / 271	60.9	0.36 [0.13,0.99]	
Total	8 / 691	26 / 707		0.31 [0.14,0.69]	Z=-2.89, p=0.0038
Heterogeneity:	Q=0.18 (df=1)	p=0.6756	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 751	10 / 745	86.1	0.69 [0.27,1.81]	
FIGARO-DKD	2 / 289	1 / 290	13.9	2.01 [0.18,22.01]	
Total	9 / 1040	11 / 1035		0.81 [0.34,1.95]	Z=-0.46, p=0.6421
Heterogeneity:	Q=0.65 (df=1)	p=0.4200	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	2 / 270	59.9	0.99 [0.14,6.97]	
FIGARO-DKD	2 / 102	1 / 101	40.1	1.98 [0.18,21.50]	
Total	4 / 375	3 / 371		1.32 [0.30,5.86]	Z=0.37, p=0.7141
Heterogeneity:	Q=0.20 (df=1)	p=0.6587	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	2 / 97	57.0	1.03 [0.15,7.18]	
FIGARO-DKD	3 / 61	1 / 57	43.0	2.80 [0.30,26.18]	
Total	5 / 155	3 / 154		1.64 [0.40,6.75]	Z=0.69, p=0.4917
Heterogeneity:	Q=0.44 (df=1)	p=0.5069	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.07 (df=4)	p=0.1942	I^2=34.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.114.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

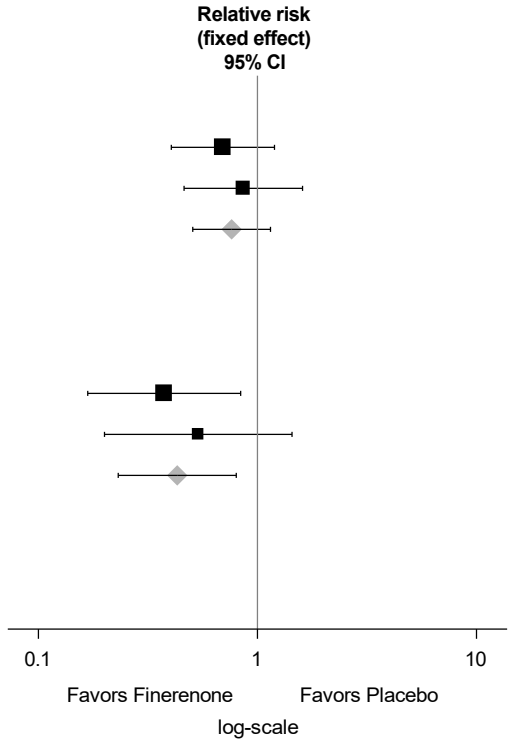
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	14 / 1213	30 / 1210	51.1	0.47 [0.25,0.87]	
FIGARO-DKD	16 / 862	21 / 848	48.9	0.75 [0.39,1.43]	
Total	30 / 2075	51 / 2058		0.58 [0.37,0.91]	Z=-2.36, p=0.0180
Heterogeneity:	Q=1.08 (df=1)	p=0.2994	I^2=7.1%		
Absent					
FIDELIO-DKD	16 / 1404	23 / 1400	67.0	0.69 [0.37,1.31]	
FIGARO-DKD	8 / 495	11 / 508	33.0	0.75 [0.30,1.84]	
Total	24 / 1899	34 / 1908		0.71 [0.42,1.19]	Z=-1.29, p=0.1966
Heterogeneity:	Q=0.02 (df=1)	p=0.8964	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.32 (df=1)	p=0.5719	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.114.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

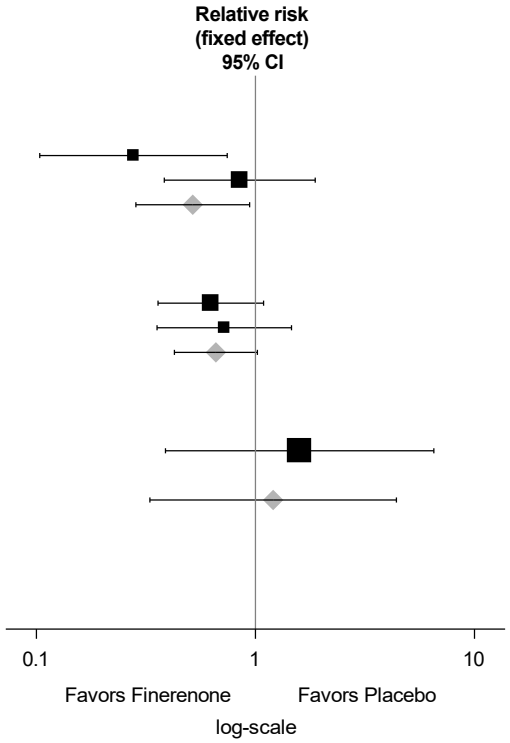
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 1735	31 / 1700	56.9	0.70 [0.40,1.20]	
FIGARO-DKD	18 / 924	21 / 929	43.1	0.86 [0.46,1.61]	
Total	40 / 2659	52 / 2629		0.76 [0.51,1.15]	Z=-1.30, p=0.1927
Heterogeneity:	Q=0.26 (df=1)	p=0.6106	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	22 / 910	60.1	0.38 [0.17,0.84]	
FIGARO-DKD	6 / 433	11 / 426	39.9	0.54 [0.20,1.44]	
Total	14 / 1315	33 / 1336		0.43 [0.23,0.80]	Z=-2.66, p=0.0077
Heterogeneity:	Q=0.30 (df=1)	p=0.5811	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.28 (df=1)	p=0.1315	I^2=56.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.114.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

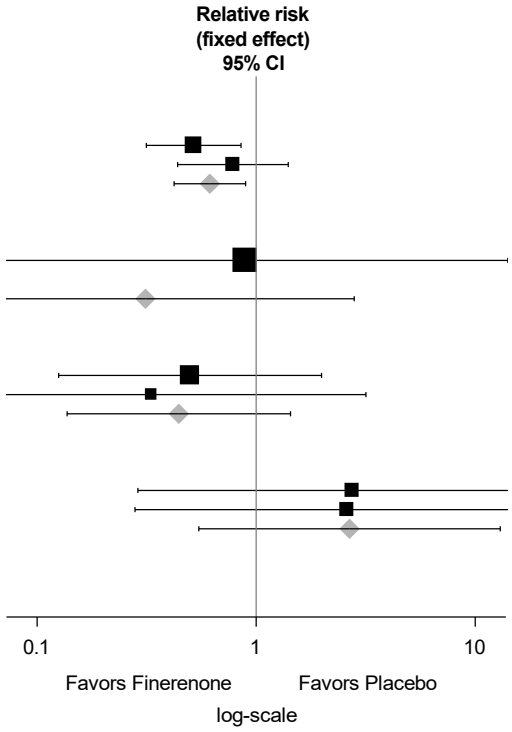
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	18 / 723	39.3	0.28 [0.10,0.74]	
FIGARO-DKD	11 / 494	13 / 495	60.7	0.85 [0.38,1.87]	
Total	16 / 1218	31 / 1218		0.52 [0.28,0.94]	Z=-2.16, p=0.0307
Heterogeneity:	Q=3.03 (df=1)	p=0.0819	I^2=67.0%		
130 - < 160					
FIDELIO-DKD	20 / 1759	32 / 1760	61.9	0.63 [0.36,1.09]	
FIGARO-DKD	13 / 829	18 / 827	38.1	0.72 [0.36,1.46]	
Total	33 / 2588	50 / 2587		0.66 [0.43,1.02]	Z=-1.87, p=0.0616
Heterogeneity:	Q=0.10 (df=1)	p=0.7574	I^2=0.0%		
>= 160					
FIDELIO-DKD	5 / 133	3 / 127	100.0	1.59 [0.39,6.52]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,11E296]	
Total	5 / 167	4 / 161		1.20 [0.33,4.40]	Z=0.28, p=0.7784
Heterogeneity:	Q=0.15 (df=1)	p=0.6987	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.42 (df=2)	p=0.4921	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.114.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

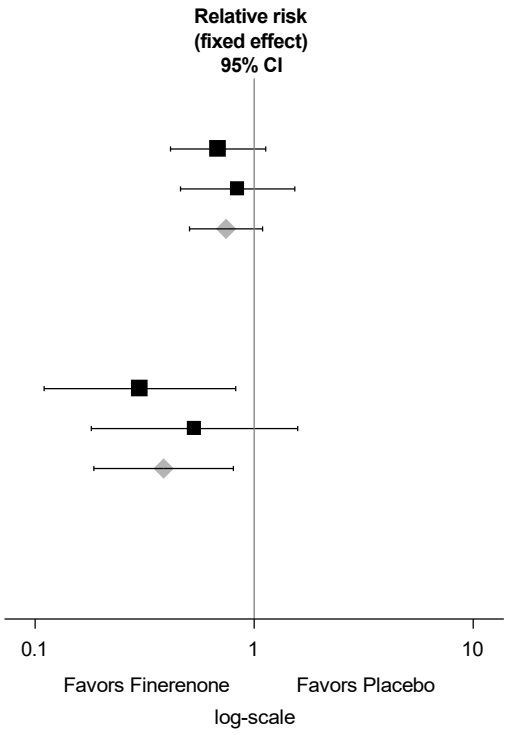
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	23 / 1634	45 / 1657	57.7	0.52 [0.32,0.85]	
FIGARO-DKD	20 / 1010	25 / 989	42.3	0.78 [0.44,1.40]	
Total	43 / 2644	70 / 2646		0.61 [0.42,0.89]	Z=-2.54, p=0.0111
Heterogeneity:	Q=1.12 (df=1)	p=0.2901	I^2=10.7%		
Black					
FIDELIO-DKD	1 / 129	1 / 115	100.0	0.89 [0.06,14.09]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,22E296]	
Total	1 / 172	4 / 186		0.31 [0.03,2.80]	Z=-1.04, p=0.2985
Heterogeneity:	Q=0.56 (df=1)	p=0.4563	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 678	6 / 677	72.7	0.50 [0.13,1.99]	
FIGARO-DKD	1 / 252	3 / 251	27.3	0.33 [0.03,3.17]	
Total	4 / 930	9 / 928		0.44 [0.14,1.43]	Z=-1.36, p=0.1746
Heterogeneity:	Q=0.09 (df=1)	p=0.7623	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 176	1 / 161	49.4	2.74 [0.29,26.12]	
FIGARO-DKD	3 / 52	1 / 45	50.6	2.60 [0.28,24.09]	
Total	6 / 228	2 / 206		2.67 [0.55,13.02]	Z=1.21, p=0.2246
Heterogeneity:	Q=0.00 (df=1)	p=0.9726	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.94 (df=3)	p=0.2677	I^2=23.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.114.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

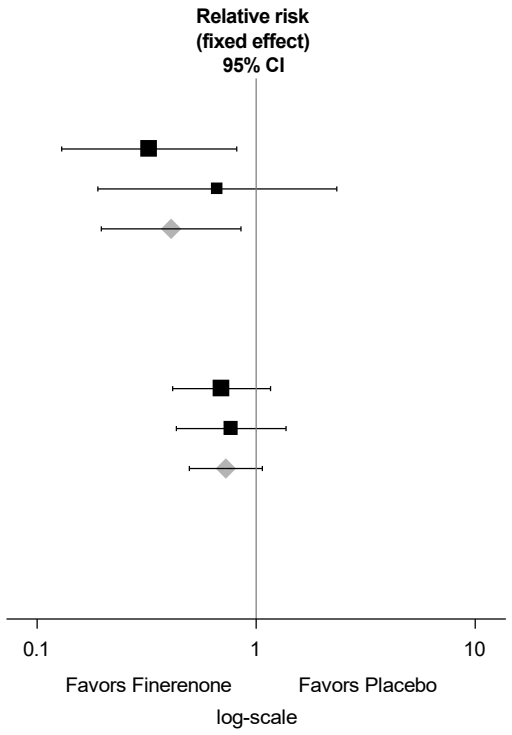
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1797	38 / 1870	59.0	0.68 [0.42,1.13]	
FIGARO-DKD	19 / 917	23 / 933	41.0	0.84 [0.46,1.53]	
Total	44 / 2714	61 / 2803		0.74 [0.51,1.09]	Z=-1.51, p=0.1313
Heterogeneity:	Q=0.26 (df=1)	p=0.6071	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 820	15 / 740	53.7	0.30 [0.11,0.82]	
FIGARO-DKD	5 / 440	9 / 423	46.3	0.53 [0.18,1.58]	
Total	10 / 1260	24 / 1163		0.39 [0.19,0.80]	Z=-2.54, p=0.0110
Heterogeneity:	Q=0.58 (df=1)	p=0.4465	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.41 (df=1)	p=0.1202	I^2=58.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.114.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

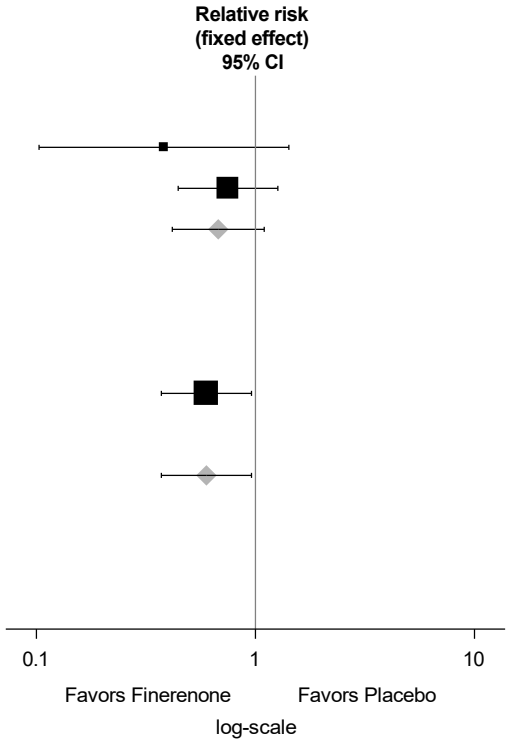
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	6 / 1103	18 / 1075	65.1	0.32 [0.13,0.82]	
FIGARO-DKD	4 / 336	6 / 335	34.9	0.66 [0.19,2.33]	
Total	10 / 1439	24 / 1410		0.41 [0.20,0.85]	Z=-2.39, p=0.0170
Heterogeneity:	Q=0.81 (df=1)	p=0.3667	I^2=0.0%		
>= 65					
FIDELIO-DKD	24 / 1514	35 / 1535	55.7	0.70 [0.42,1.16]	
FIGARO-DKD	20 / 1021	26 / 1021	44.3	0.77 [0.43,1.37]	
Total	44 / 2535	61 / 2556		0.73 [0.50,1.07]	Z=-1.63, p=0.1034
Heterogeneity:	Q=0.07 (df=1)	p=0.7975	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.85 (df=1)	p=0.1735	I^2=46.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.114.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

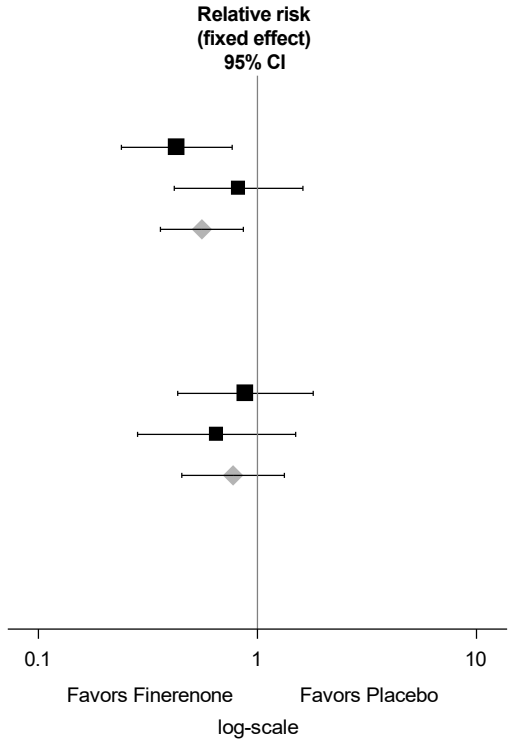
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	8 / 213	13.7	0.38 [0.10,1.42]	
FIGARO-DKD	24 / 1357	32 / 1356	86.3	0.75 [0.44,1.27]	
Total	27 / 1566	40 / 1569		0.68 [0.42,1.10]	Z=-1.59, p=0.1127
Heterogeneity:	Q=0.87 (df=1)	p=0.3500	I^2=0.0%		
Very High					
FIDELIO-DKD	27 / 2408	45 / 2397	100.0	0.60 [0.37,0.96]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	27 / 2408	45 / 2397		0.60 [0.37,0.96]	Z=-2.13, p=0.0330
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7186	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.114.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

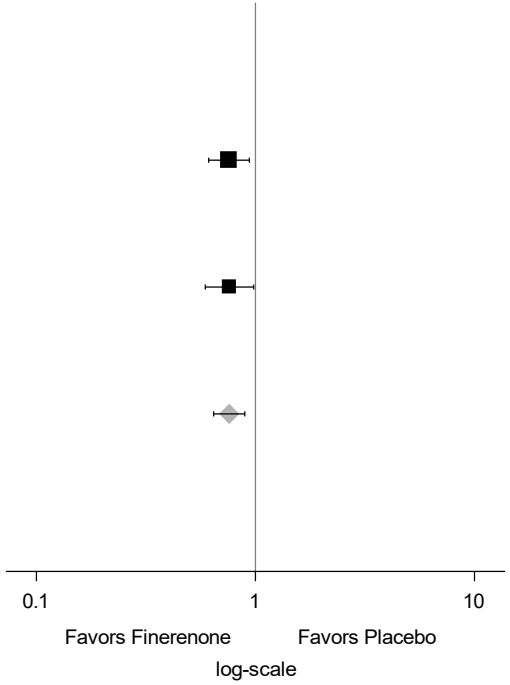
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	16 / 1556	37 / 1541	57.4	0.43 [0.24,0.77]	
FIGARO-DKD	15 / 637	18 / 627	42.6	0.82 [0.42,1.61]	
Total	31 / 2193	55 / 2168		0.56 [0.36,0.86]	Z=-2.63, p=0.0086
Heterogeneity:	Q=2.04 (df=1)	p=0.1532	I^2=51.0%		
45 - < 60					
FIDELIO-DKD	14 / 1061	16 / 1069	57.7	0.88 [0.43,1.80]	
FIGARO-DKD	9 / 720	14 / 729	42.3	0.65 [0.28,1.49]	
Total	23 / 1781	30 / 1798		0.77 [0.45,1.33]	Z=-0.93, p=0.3517
Heterogeneity:	Q=0.30 (df=1)	p=0.5869	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.86 (df=1)	p=0.3541	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

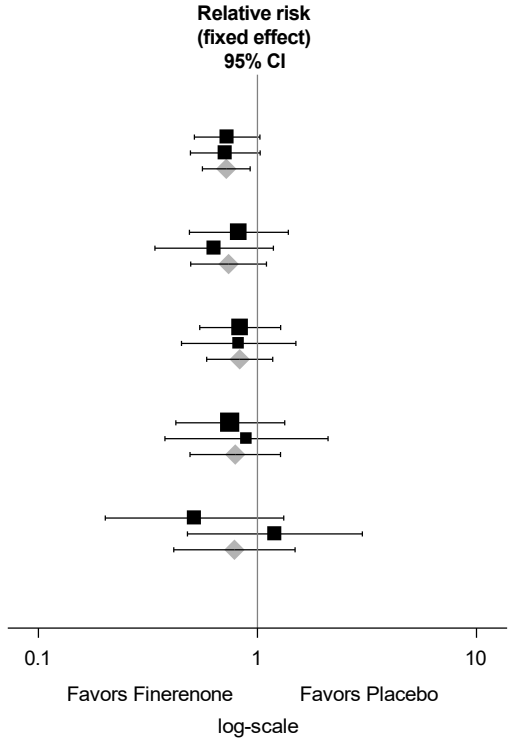
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	139 / 2617	183 / 2610	58.7	0.76 [0.61,0.94]	
FIGARO-DKD	96 / 1357	126 / 1356	41.3	0.76 [0.59,0.98]	
Total	235 / 3974	309 / 3966		0.76 [0.64,0.89]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.00 (df=1)	p=0.9764	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.115.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

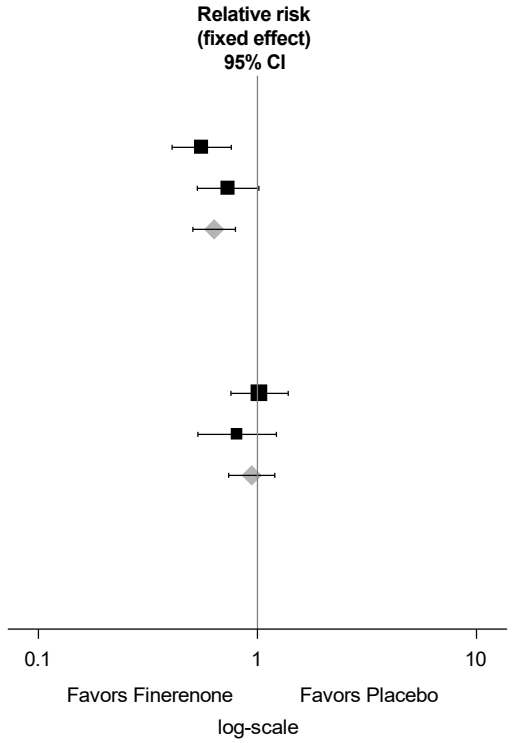
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	53 / 1075	72 / 1062	53.1	0.73 [0.52,1.03]	
FIGARO-DKD	45 / 638	63 / 637	46.9	0.71 [0.49,1.03]	
Total	98 / 1713	135 / 1699		0.72 [0.56,0.93]	Z=-2.56, p=0.0105
Heterogeneity:	Q=0.01 (df=1)	p=0.9394	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 424	30 / 436	58.9	0.82 [0.49,1.38]	
FIGARO-DKD	15 / 267	24 / 271	41.1	0.63 [0.34,1.18]	
Total	39 / 691	54 / 707		0.74 [0.50,1.10]	Z=-1.49, p=0.1351
Heterogeneity:	Q=0.39 (df=1)	p=0.5299	I^2=0.0%		
Asia					
FIDELIO-DKD	37 / 751	44 / 745	66.7	0.83 [0.55,1.28]	
FIGARO-DKD	18 / 289	22 / 290	33.3	0.82 [0.45,1.50]	
Total	55 / 1040	66 / 1035		0.83 [0.59,1.17]	Z=-1.05, p=0.2921
Heterogeneity:	Q=0.00 (df=1)	p=0.9662	I^2=0.0%		
Latin America					
FIDELIO-DKD	19 / 273	25 / 270	69.2	0.75 [0.42,1.33]	
FIGARO-DKD	9 / 102	10 / 101	30.8	0.89 [0.38,2.10]	
Total	28 / 375	35 / 371		0.79 [0.49,1.27]	Z=-0.96, p=0.3363
Heterogeneity:	Q=0.10 (df=1)	p=0.7461	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 94	12 / 97	49.0	0.52 [0.20,1.32]	
FIGARO-DKD	9 / 61	7 / 57	51.0	1.20 [0.48,3.01]	
Total	15 / 155	19 / 154		0.78 [0.41,1.49]	Z=-0.74, p=0.4568
Heterogeneity:	Q=1.59 (df=1)	p=0.2070	I^2=37.2%		
Subgroup Heterogeneity:	Q=0.48 (df=4)	p=0.9756	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	58 / 1213	104 / 1210	52.0	0.56 [0.41,0.76]	
FIGARO-DKD	59 / 862	79 / 848	48.0	0.73 [0.53,1.02]	
Total	117 / 2075	183 / 2058		0.63 [0.51,0.79]	Z=-3.99, p=<.0001
Heterogeneity:	Q=1.47 (df=1)	p=0.2246	I^2=32.2%		
Absent					
FIDELIO-DKD	81 / 1404	79 / 1400	65.3	1.02 [0.76,1.38]	
FIGARO-DKD	37 / 495	47 / 508	34.7	0.81 [0.53,1.22]	
Total	118 / 1899	126 / 1908		0.94 [0.74,1.20]	Z=-0.49, p=0.6275
Heterogeneity:	Q=0.82 (df=1)	p=0.3662	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.51 (df=1)	p=0.0190	I^2=81.8%		

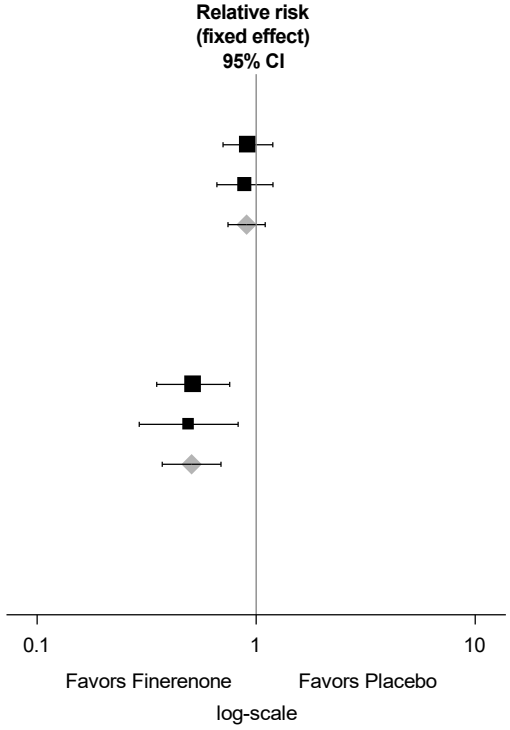


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

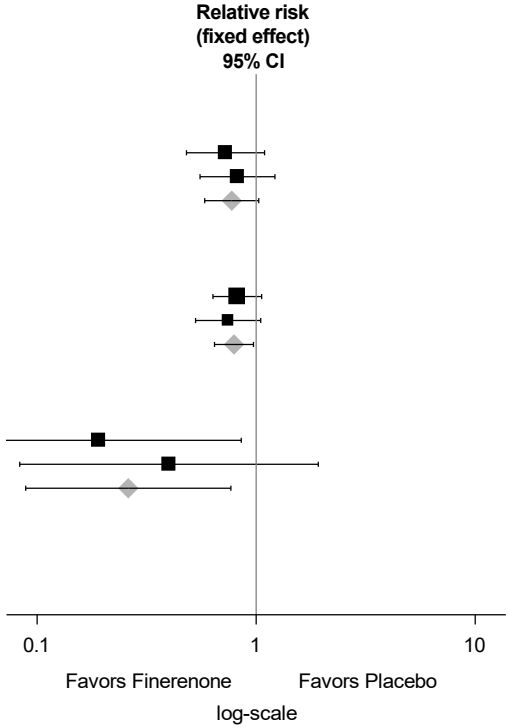
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	102 / 1735	109 / 1700	56.0	0.92 [0.71,1.19]	
FIGARO-DKD	76 / 924	86 / 929	44.0	0.89 [0.66,1.19]	
Total	178 / 2659	195 / 2629		0.90 [0.74,1.10]	Z=-1.01, p=0.3135
Heterogeneity:	Q=0.02 (df=1)	p=0.8757	I^2=0.0%		
> 4.5					
FIDELIO-DKD	37 / 882	74 / 910	64.7	0.52 [0.35,0.76]	
FIGARO-DKD	20 / 433	40 / 426	35.3	0.49 [0.29,0.83]	
Total	57 / 1315	114 / 1336		0.51 [0.37,0.69]	Z=-4.31, p=<.0001
Heterogeneity:	Q=0.02 (df=1)	p=0.8853	I^2=0.0%		
Subgroup Heterogeneity:	Q=9.61 (df=1)	p=0.0019	I^2=89.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

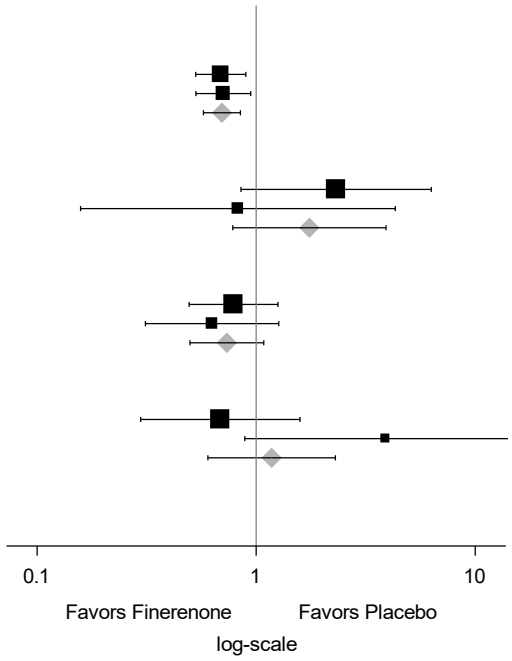
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	37 / 724	51 / 723	47.9	0.72 [0.48,1.09]	
FIGARO-DKD	41 / 494	50 / 495	52.1	0.82 [0.55,1.22]	
Total	78 / 1218	101 / 1218		0.77 [0.58,1.03]	Z=-1.77, p=0.0761
Heterogeneity:	Q=0.19 (df=1)	p=0.6645	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	100 / 1759	122 / 1760	64.2	0.82 [0.63,1.06]	
FIGARO-DKD	53 / 829	71 / 827	35.8	0.74 [0.53,1.05]	
Total	153 / 2588	193 / 2587		0.79 [0.65,0.97]	Z=-2.23, p=0.0259
Heterogeneity:	Q=0.20 (df=1)	p=0.6582	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 133	10 / 127	52.3	0.19 [0.04,0.85]	
FIGARO-DKD	2 / 34	5 / 34	47.7	0.40 [0.08,1.92]	
Total	4 / 167	15 / 161		0.26 [0.09,0.77]	Z=-2.44, p=0.0146
Heterogeneity:	Q=0.45 (df=1)	p=0.5016	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.94 (df=2)	p=0.1392	I^2=49.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

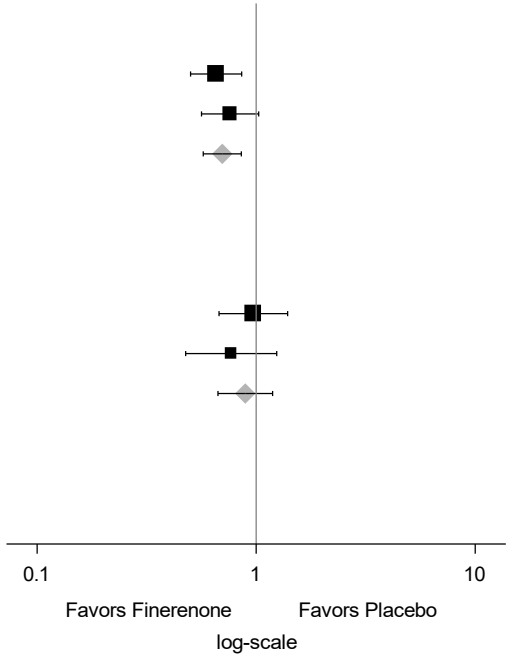
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	87 / 1634	128 / 1657	54.4	0.69 [0.53,0.90]	
FIGARO-DKD	73 / 1010	101 / 989	45.6	0.71 [0.53,0.94]	
Total	160 / 2644	229 / 2646		0.70 [0.57,0.85]	Z=-3.63, p=0.0003
Heterogeneity:	Q=0.02 (df=1)	p=0.8943	I^2=0.0%		
Black					
FIDELIO-DKD	13 / 129	5 / 115	73.2	2.32 [0.85,6.30]	
FIGARO-DKD	2 / 43	4 / 71	26.8	0.83 [0.16,4.32]	
Total	15 / 172	9 / 186		1.75 [0.78,3.92]	Z=1.36, p=0.1733
Heterogeneity:	Q=1.10 (df=1)	p=0.2953	I^2=8.7%		
Asian					
FIDELIO-DKD	30 / 678	38 / 677	69.3	0.79 [0.49,1.26]	
FIGARO-DKD	12 / 252	19 / 251	30.7	0.63 [0.31,1.27]	
Total	42 / 930	57 / 928		0.73 [0.50,1.08]	Z=-1.56, p=0.1194
Heterogeneity:	Q=0.28 (df=1)	p=0.5995	I^2=0.0%		
Others					
FIDELIO-DKD	9 / 176	12 / 161	75.7	0.69 [0.30,1.59]	
FIGARO-DKD	9 / 52	2 / 45	24.3	3.89 [0.89,17.10]	
Total	18 / 228	14 / 206		1.18 [0.60,2.30]	Z=0.48, p=0.6347
Heterogeneity:	Q=4.11 (df=1)	p=0.0427	I^2=75.7%		
Subgroup Heterogeneity:	Q=6.52 (df=3)	p=0.0889	I^2=54.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.115.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

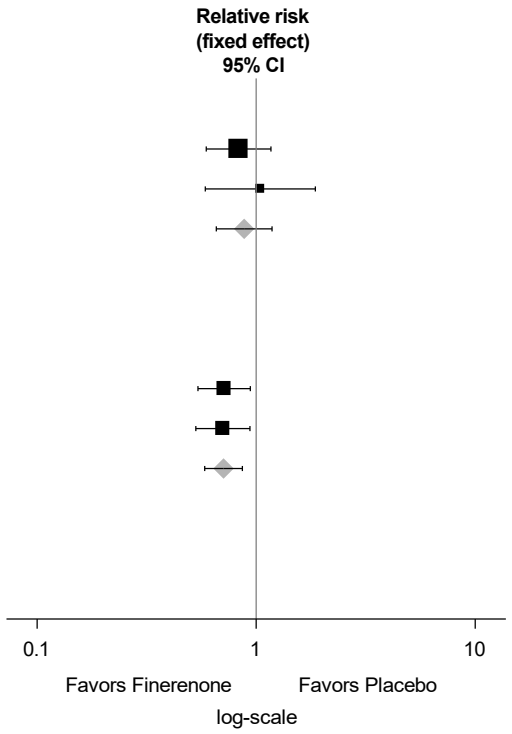
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	82 / 1797	130 / 1870	55.6	0.66 [0.50,0.86]	
FIGARO-DKD	68 / 917	91 / 933	44.4	0.76 [0.56,1.03]	
Total	150 / 2714	221 / 2803		0.70 [0.57,0.86]	Z=-3.49, p=0.0005
Heterogeneity:	Q=0.51 (df=1)	p=0.4751	I^2=0.0%		
Female					
FIDELIO-DKD	57 / 820	53 / 740	63.8	0.97 [0.68,1.39]	
FIGARO-DKD	28 / 440	35 / 423	36.2	0.77 [0.48,1.24]	
Total	85 / 1260	88 / 1163		0.89 [0.67,1.19]	Z=-0.78, p=0.4348
Heterogeneity:	Q=0.58 (df=1)	p=0.4467	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1758	I^2=45.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.115.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

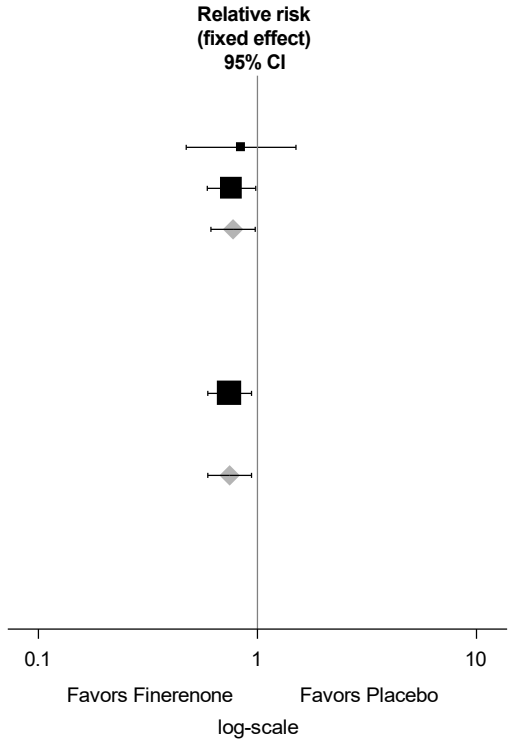
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	58 / 1103	68 / 1075	74.3	0.83 [0.59,1.17]	
FIGARO-DKD	22 / 336	21 / 335	25.7	1.04 [0.59,1.86]	
Total	80 / 1439	89 / 1410		0.88 [0.66,1.18]	Z=-0.84, p=0.3982
Heterogeneity:	Q=0.44 (df=1)	p=0.5049	I^2=0.0%		
>= 65					
FIDELIO-DKD	81 / 1514	115 / 1535	51.7	0.71 [0.54,0.94]	
FIGARO-DKD	74 / 1021	105 / 1021	48.3	0.70 [0.53,0.94]	
Total	155 / 2535	220 / 2556		0.71 [0.58,0.86]	Z=-3.40, p=0.0007
Heterogeneity:	Q=0.00 (df=1)	p=0.9479	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.45 (df=1)	p=0.2292	I^2=30.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.115.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	19 / 209	23 / 213	16.3	0.84 [0.47,1.50]	
FIGARO-DKD	96 / 1357	126 / 1356	83.7	0.76 [0.59,0.98]	
Total	115 / 1566	149 / 1569		0.77 [0.61,0.98]	Z=-2.16, p=0.0310
Heterogeneity:	Q=0.10 (df=1)	p=0.7546	I^2=0.0%		
Very High					
FIDELIO-DKD	120 / 2408	160 / 2397	100.0	0.75 [0.59,0.94]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	120 / 2408	160 / 2397		0.75 [0.59,0.94]	Z=-2.49, p=0.0127
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8298	I^2=0.0%		

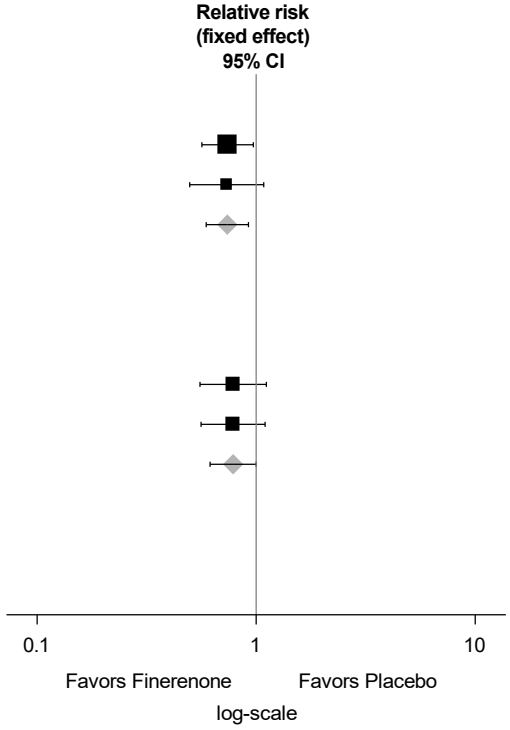


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.115.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Psychiatric Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

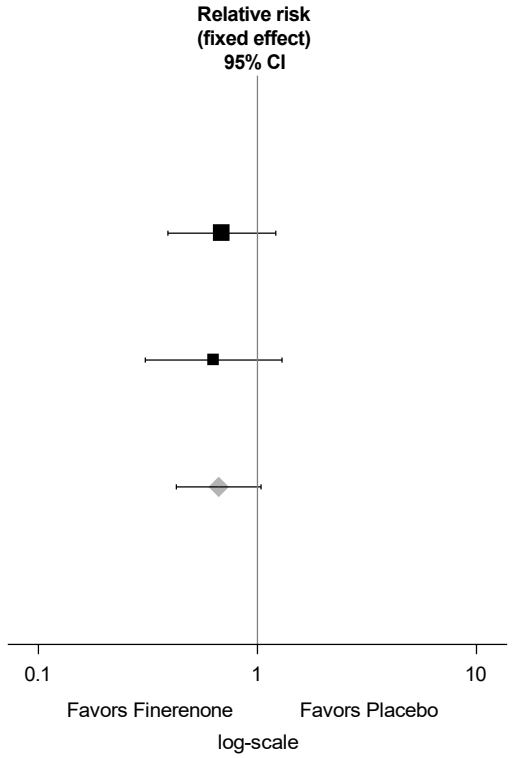
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	86 / 1556	115 / 1541	67.4	0.74 [0.57,0.97]	
FIGARO-DKD	41 / 637	55 / 627	32.6	0.73 [0.50,1.08]	
Total	127 / 2193	170 / 2168		0.74 [0.59,0.92]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.00 (df=1)	p=0.9693	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	53 / 1061	68 / 1069	48.2	0.79 [0.55,1.11]	
FIGARO-DKD	55 / 720	71 / 729	51.8	0.78 [0.56,1.10]	
Total	108 / 1781	139 / 1798		0.78 [0.62,1.00]	Z=-1.96, p=0.0499
Heterogeneity:	Q=0.00 (df=1)	p=0.9961	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7161	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.116: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

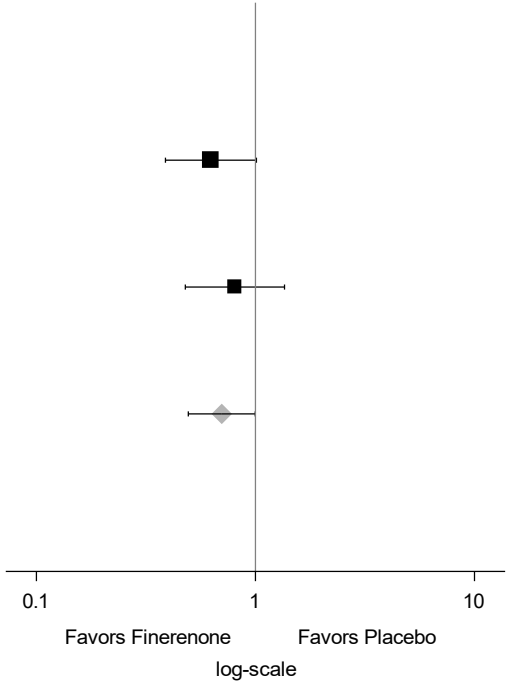
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	29 / 2610	61.6	0.69 [0.39,1.21]	
FIGARO-DKD	12 / 1357	19 / 1356	38.4	0.63 [0.31,1.29]	
Total	32 / 3974	48 / 3966		0.67 [0.43,1.04]	Z=-1.79, p=0.0728
Heterogeneity:	Q=0.03 (df=1)	p=0.8539	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.117: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

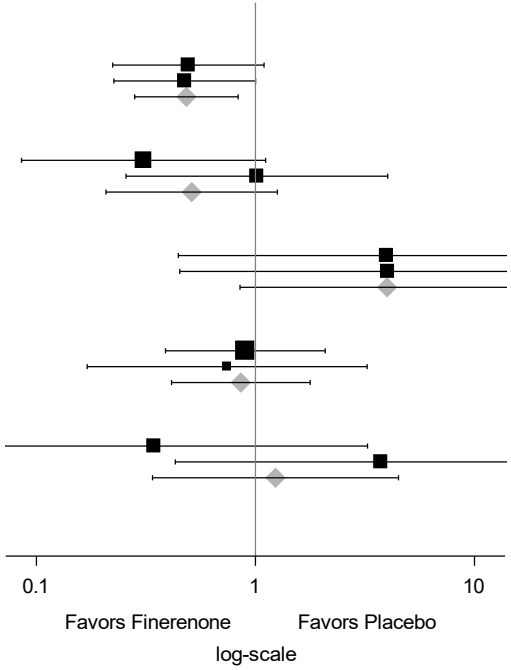
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	43 / 2610	54.3	0.63 [0.39,1.01]	
FIGARO-DKD	25 / 1357	31 / 1356	45.7	0.81 [0.48,1.36]	
Total	52 / 3974	74 / 3966		0.70 [0.49,1.00]	Z=-1.97, p=0.0485
Heterogeneity:	Q=0.49 (df=1)	p=0.4848	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.117.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

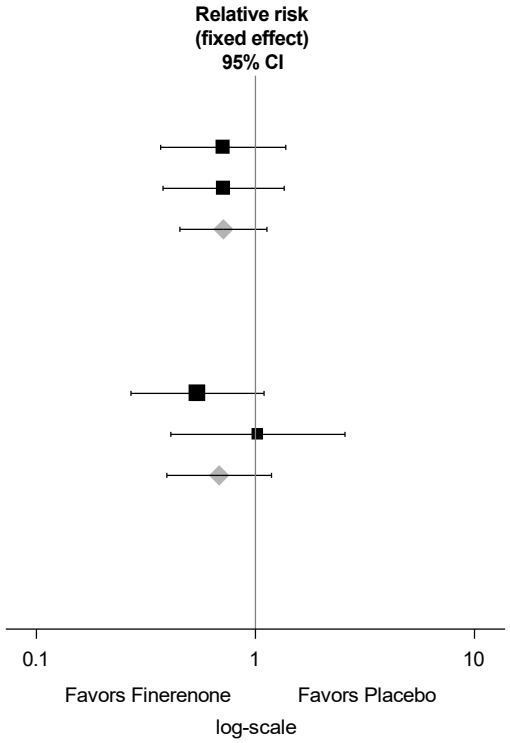
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	18 / 1062	46.7	0.49 [0.22,1.09]	
FIGARO-DKD	10 / 638	21 / 637	53.3	0.48 [0.23,1.00]	
Total	19 / 1713	39 / 1699		0.48 [0.28,0.83]	Z=-2.62, p=0.0089
Heterogeneity:	Q=0.00 (df=1)	p=0.9452	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	10 / 436	53.5	0.31 [0.09,1.11]	
FIGARO-DKD	4 / 267	4 / 271	46.5	1.01 [0.26,4.02]	
Total	7 / 691	14 / 707		0.51 [0.21,1.26]	Z=-1.46, p=0.1449
Heterogeneity:	Q=1.55 (df=1)	p=0.2132	I^2=35.5%		
Asia					
FIDELIO-DKD	4 / 751	1 / 745	49.9	3.97 [0.44,35.42]	
FIGARO-DKD	4 / 289	1 / 290	50.1	4.01 [0.45,35.69]	
Total	8 / 1040	2 / 1035		3.99 [0.85,18.74]	Z=1.75, p=0.0794
Heterogeneity:	Q=0.00 (df=1)	p=0.9942	I^2=0.0%		
Latin America					
FIDELIO-DKD	10 / 273	11 / 270	75.4	0.90 [0.39,2.08]	
FIGARO-DKD	3 / 102	4 / 101	24.6	0.74 [0.17,3.23]	
Total	13 / 375	15 / 371		0.86 [0.41,1.78]	Z=-0.41, p=0.6793
Heterogeneity:	Q=0.05 (df=1)	p=0.8250	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	48.1	0.34 [0.04,3.25]	
FIGARO-DKD	4 / 61	1 / 57	51.9	3.74 [0.43,32.45]	
Total	5 / 155	4 / 154		1.23 [0.34,4.50]	Z=0.32, p=0.7492
Heterogeneity:	Q=2.25 (df=1)	p=0.1333	I^2=55.6%		
Subgroup Heterogeneity:	Q=8.12 (df=4)	p=0.0872	I^2=50.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.117.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

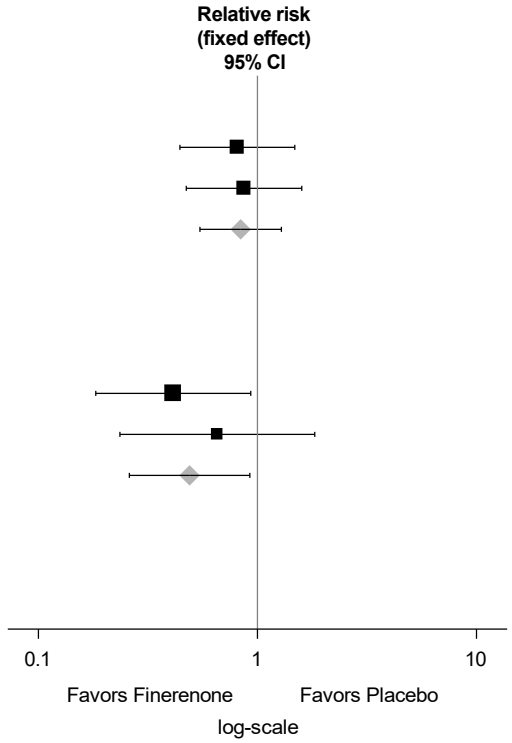
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 1213	21 / 1210	48.4	0.71 [0.37,1.38]	
FIGARO-DKD	16 / 862	22 / 848	51.6	0.72 [0.38,1.35]	
Total	31 / 2075	43 / 2058		0.71 [0.45,1.13]	Z=-1.44, p=0.1491
Heterogeneity:	Q=0.00 (df=1)	p=0.9930	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 1404	22 / 1400	63.1	0.54 [0.27,1.09]	
FIGARO-DKD	9 / 495	9 / 508	36.9	1.03 [0.41,2.56]	
Total	21 / 1899	31 / 1908		0.68 [0.39,1.18]	Z=-1.36, p=0.1741
Heterogeneity:	Q=1.17 (df=1)	p=0.2800	I^2=14.3%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.9025	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.117.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

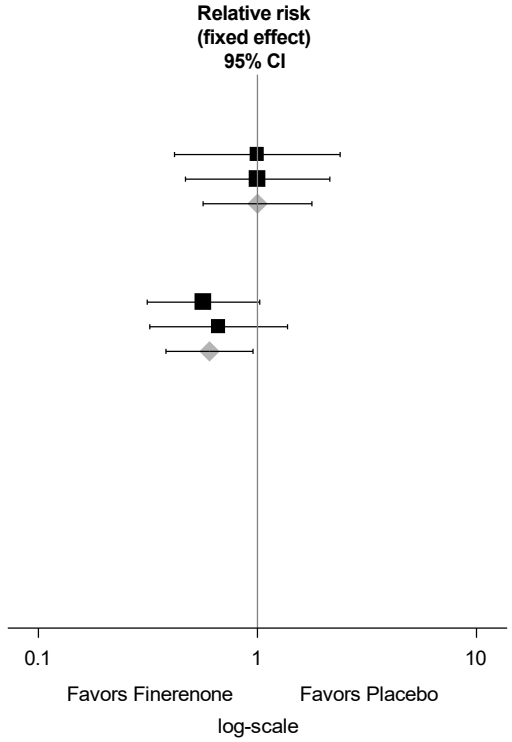
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 1735	23 / 1700	50.3	0.81 [0.44,1.48]	
FIGARO-DKD	19 / 924	22 / 929	49.7	0.87 [0.47,1.59]	
Total	38 / 2659	45 / 2629		0.84 [0.55,1.29]	Z=-0.81, p=0.4189
Heterogeneity:	Q=0.03 (df=1)	p=0.8723	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	20 / 910	61.3	0.41 [0.18,0.93]	
FIGARO-DKD	6 / 433	9 / 426	38.7	0.66 [0.24,1.83]	
Total	14 / 1315	29 / 1336		0.49 [0.26,0.92]	Z=-2.21, p=0.0272
Heterogeneity:	Q=0.48 (df=1)	p=0.4875	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.90 (df=1)	p=0.1686	I^2=47.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.117.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

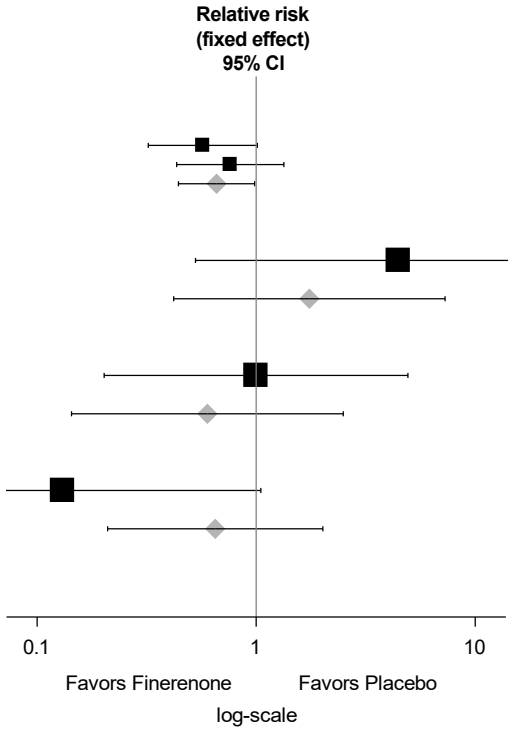
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	10 / 724	10 / 723	43.2	1.00 [0.42,2.38]	
FIGARO-DKD	13 / 494	13 / 495	56.8	1.00 [0.47,2.14]	
Total	23 / 1218	23 / 1218		1.00 [0.56,1.77]	Z=0.00, p=0.9985
Heterogeneity:	Q=0.00 (df=1)	p=0.9954	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	17 / 1759	30 / 1760	60.0	0.57 [0.31,1.02]	
FIGARO-DKD	12 / 829	18 / 827	40.0	0.67 [0.32,1.37]	
Total	29 / 2588	48 / 2587		0.60 [0.38,0.95]	Z=-2.16, p=0.0308
Heterogeneity:	Q=0.11 (df=1)	p=0.7380	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	3 / 127	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	3 / 161		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.83 (df=2)	p=0.4015	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.117.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

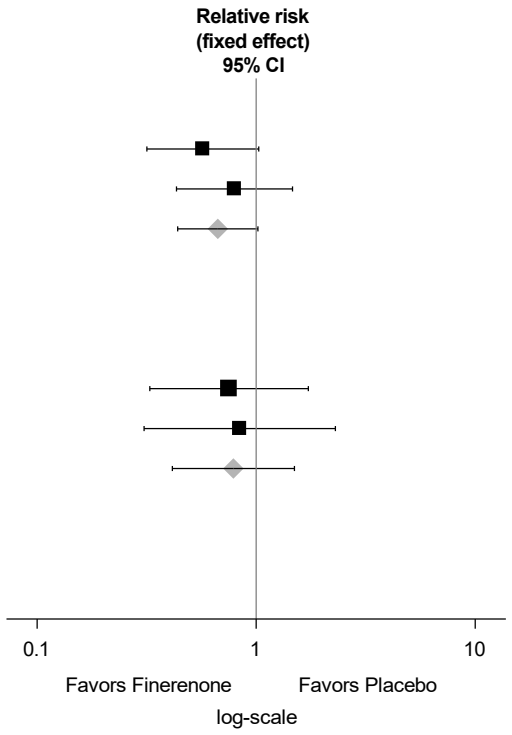
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	18 / 1634	32 / 1657	49.1	0.57 [0.32,1.01]	
FIGARO-DKD	21 / 1010	27 / 989	50.9	0.76 [0.43,1.34]	
Total	39 / 2644	59 / 2646		0.66 [0.44,0.98]	Z=-2.04, p=0.0416
Heterogeneity:	Q=0.50 (df=1)	p=0.4809	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	1 / 115	100.0	4.46 [0.53,37.59]	
FIGARO-DKD	0 / 43	2 / 71	0.0	0.00 [0.00,12E296]	
Total	5 / 172	3 / 186		1.75 [0.42,7.29]	Z=0.77, p=0.4421
Heterogeneity:	Q=0.74 (df=1)	p=0.3900	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 678	3 / 677	100.0	1.00 [0.20,4.93]	
FIGARO-DKD	0 / 252	2 / 251	0.0	0.00 [0.00,16E296]	
Total	3 / 930	5 / 928		0.60 [0.14,2.50]	Z=-0.70, p=0.4817
Heterogeneity:	Q=0.39 (df=1)	p=0.5303	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	7 / 161	100.0	0.13 [0.02,1.05]	
FIGARO-DKD	4 / 52	0 / 45	0.0	147E9 [147E9,147E9]	
Total	5 / 228	7 / 206		0.65 [0.21,2.02]	Z=-0.75, p=0.4560
Heterogeneity:	Q=2.28 (df=1)	p=0.1313	I^2=56.1%		
Subgroup Heterogeneity:	Q=1.73 (df=3)	p=0.6301	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.117.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

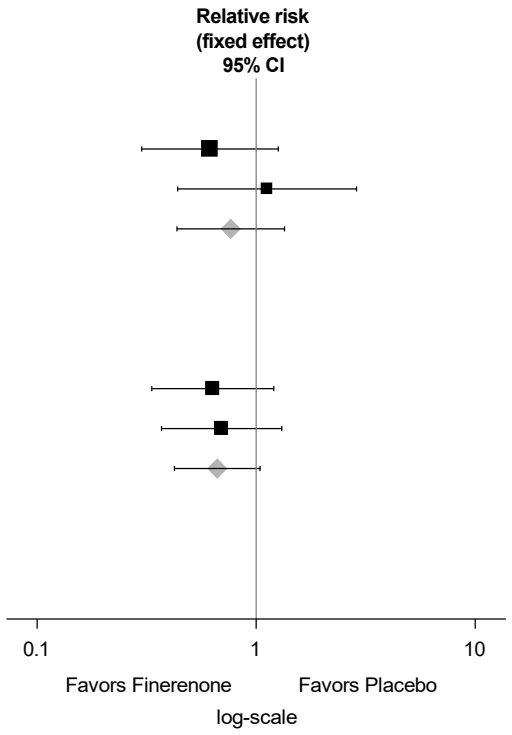
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	31 / 1870	51.8	0.57 [0.32,1.03]	
FIGARO-DKD	18 / 917	23 / 933	48.2	0.80 [0.43,1.47]	
Total	35 / 2714	54 / 2803		0.67 [0.44,1.02]	Z=-1.87, p=0.0608
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	12 / 740	59.3	0.75 [0.33,1.73]	
FIGARO-DKD	7 / 440	8 / 423	40.7	0.84 [0.31,2.30]	
Total	17 / 1260	20 / 1163		0.79 [0.41,1.50]	Z=-0.73, p=0.4645
Heterogeneity:	Q=0.03 (df=1)	p=0.8665	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6755	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.117.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

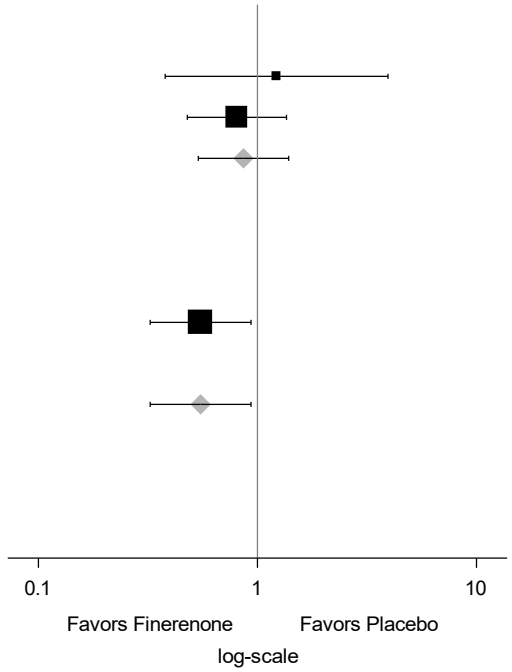
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	12 / 1103	19 / 1075	63.2	0.62 [0.30,1.26]	
FIGARO-DKD	9 / 336	8 / 335	36.8	1.12 [0.44,2.87]	
Total	21 / 1439	27 / 1410		0.77 [0.43,1.35]	Z=-0.93, p=0.3536
Heterogeneity:	Q=0.99 (df=1)	p=0.3201	I^2=0.0%		
>= 65					
FIDELIO-DKD	15 / 1514	24 / 1535	49.3	0.63 [0.33,1.20]	
FIGARO-DKD	16 / 1021	23 / 1021	50.7	0.70 [0.37,1.31]	
Total	31 / 2535	47 / 2556		0.66 [0.42,1.04]	Z=-1.78, p=0.0748
Heterogeneity:	Q=0.04 (df=1)	p=0.8390	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7007	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.117.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

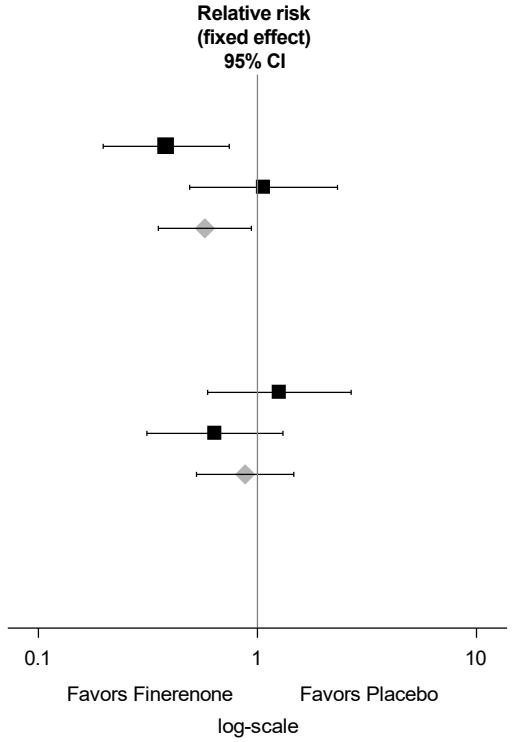
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	6 / 209	5 / 213	16.5	1.22 [0.38,3.95]	
FIGARO-DKD	25 / 1357	31 / 1356	83.5	0.81 [0.48,1.36]	
Total	31 / 1566	36 / 1569		0.86 [0.54,1.39]	Z=-0.61, p=0.5450
Heterogeneity:	Q=0.41 (df=1)	p=0.5237	I^2=0.0%		
Very High					
FIDELIO-DKD	21 / 2408	38 / 2397	100.0	0.55 [0.32,0.93]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	21 / 2408	38 / 2397		0.55 [0.32,0.93]	Z=-2.21, p=0.0271
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.54 (df=1)	p=0.2143	I^2=35.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.117.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

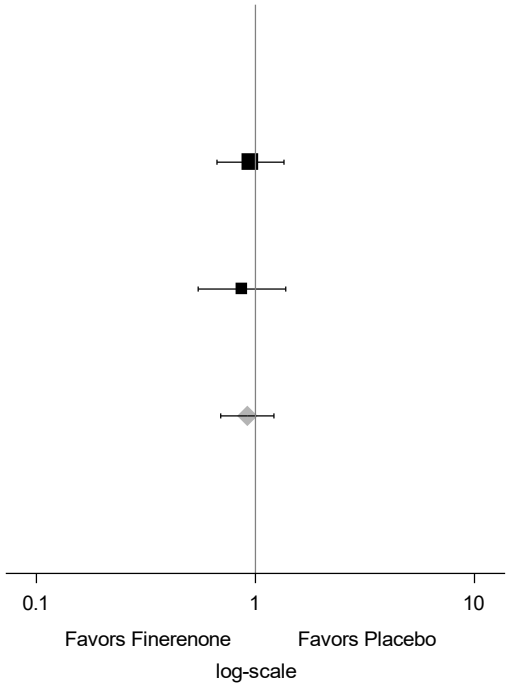
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	12 / 1556	31 / 1541	57.9	0.38 [0.20,0.74]	
FIGARO-DKD	13 / 637	12 / 627	42.1	1.07 [0.49,2.32]	
Total	25 / 2193	43 / 2168		0.58 [0.35,0.94]	Z=-2.22, p=0.0268
Heterogeneity:	Q=3.87 (df=1)	p=0.0493	I^2=74.1%		
45 - < 60					
FIDELIO-DKD	15 / 1061	12 / 1069	47.3	1.26 [0.59,2.68]	
FIGARO-DKD	12 / 720	19 / 729	52.7	0.64 [0.31,1.31]	
Total	27 / 1781	31 / 1798		0.88 [0.53,1.47]	Z=-0.50, p=0.6197
Heterogeneity:	Q=1.63 (df=1)	p=0.2013	I^2=38.8%		
Subgroup Heterogeneity:	Q=1.37 (df=1)	p=0.2410	I^2=27.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.118: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

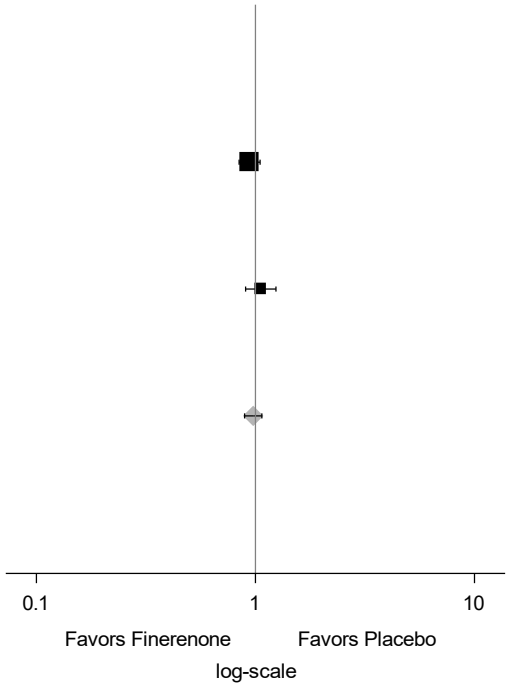
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	59 / 2617	62 / 2610	63.1	0.95 [0.67,1.35]	
FIGARO-DKD	33 / 1357	38 / 1356	36.9	0.87 [0.55,1.37]	
Total	92 / 3974	100 / 3966		0.92 [0.69,1.21]	Z=-0.60, p=0.5495
Heterogeneity:	Q=0.09 (df=1)	p=0.7621	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.119: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

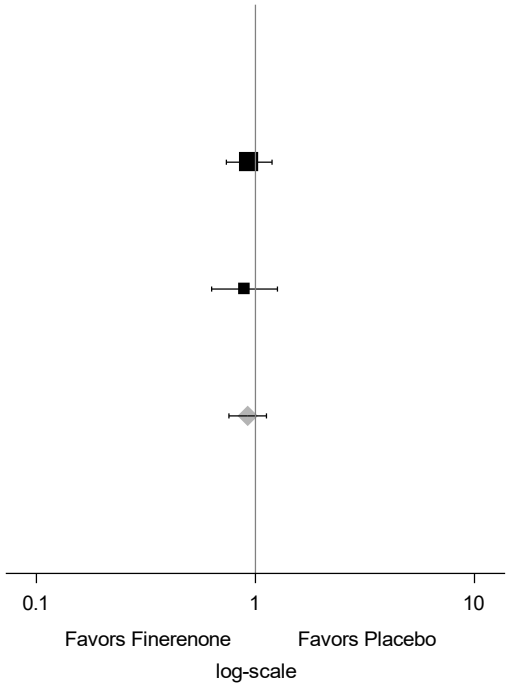
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	494 / 2617	524 / 2610	67.7	0.94 [0.84,1.05]	
FIGARO-DKD	254 / 1357	240 / 1356	32.3	1.06 [0.90,1.24]	
Total	748 / 3974	764 / 3966		0.98 [0.89,1.07]	Z=-0.51, p=0.6099
Heterogeneity:	Q=1.41 (df=1)	p=0.2348	I^2=29.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.120: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

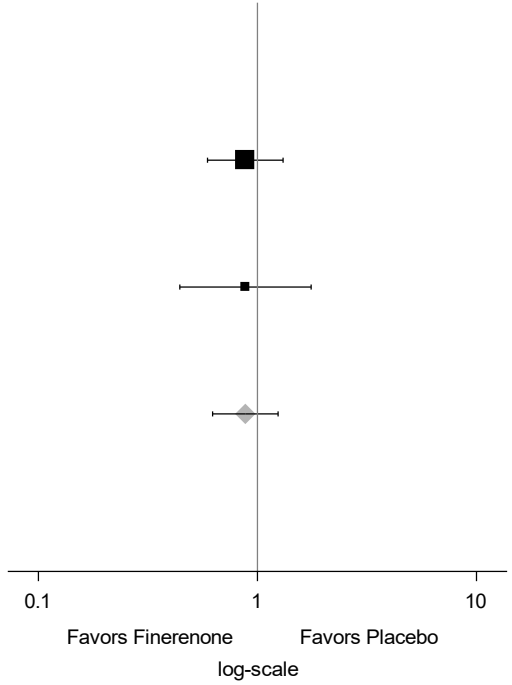
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	123 / 2617	131 / 2610	67.5	0.94 [0.74,1.19]	
FIGARO-DKD	58 / 1357	65 / 1356	32.5	0.89 [0.63,1.26]	
Total	181 / 3974	196 / 3966		0.92 [0.76,1.12]	Z=-0.81, p=0.4172
Heterogeneity:	Q=0.05 (df=1)	p=0.8196	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.121: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

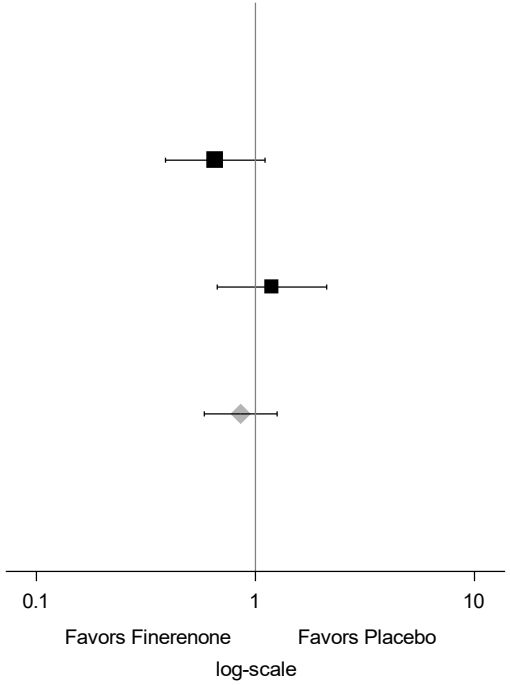
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	51 / 2610	75.1	0.88 [0.59,1.31]	
FIGARO-DKD	15 / 1357	17 / 1356	24.9	0.88 [0.44,1.76]	
Total	60 / 3974	68 / 3966		0.88 [0.62,1.24]	Z=-0.73, p=0.4684
Heterogeneity:	Q=0.00 (df=1)	p=0.9962	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.122: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

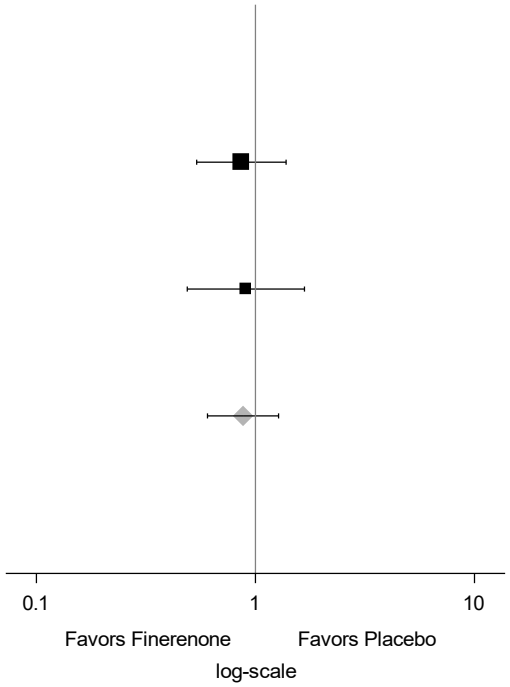
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	35 / 2610	54.7	0.66 [0.39,1.11]	
FIGARO-DKD	25 / 1357	21 / 1356	45.3	1.19 [0.67,2.11]	
Total	48 / 3974	56 / 3966		0.86 [0.58,1.26]	Z=-0.79, p=0.4272
Heterogeneity:	Q=2.26 (df=1)	p=0.1330	I^2=55.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.123: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

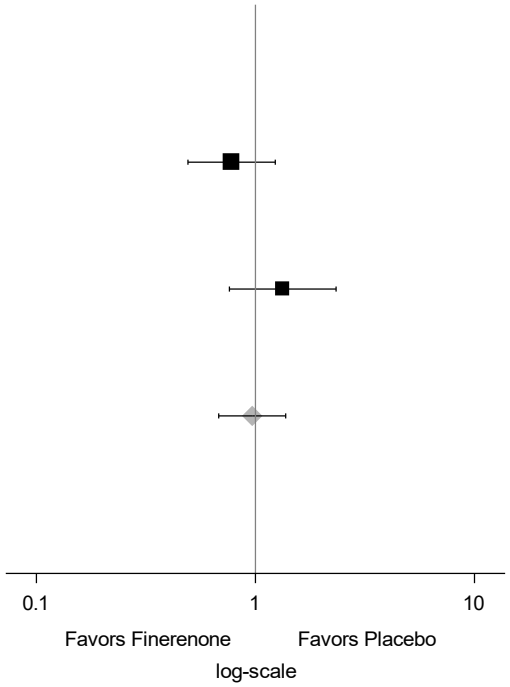
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	37 / 2610	63.2	0.86 [0.54,1.38]	
FIGARO-DKD	19 / 1357	21 / 1356	36.8	0.90 [0.49,1.67]	
Total	51 / 3974	58 / 3966		0.88 [0.60,1.28]	Z=-0.68, p=0.4934
Heterogeneity:	Q=0.01 (df=1)	p=0.9053	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.124: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

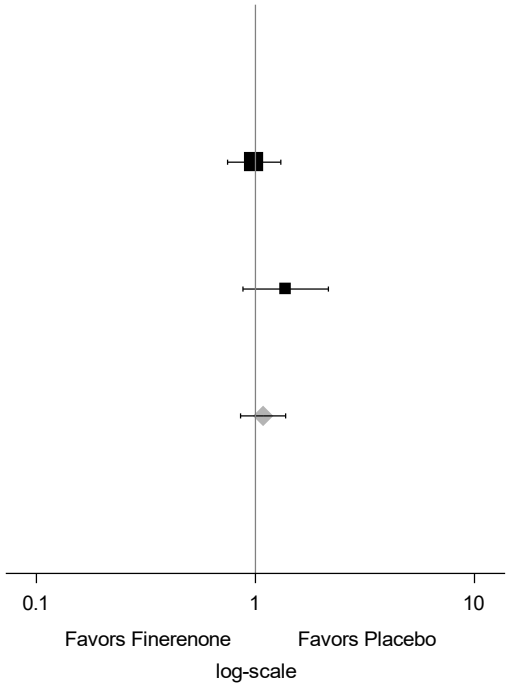
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	41 / 2610	59.9	0.78 [0.49,1.23]	
FIGARO-DKD	28 / 1357	21 / 1356	40.1	1.33 [0.76,2.33]	
Total	60 / 3974	62 / 3966		0.97 [0.68,1.37]	Z=-0.19, p=0.8492
Heterogeneity:	Q=2.11 (df=1)	p=0.1461	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.125: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

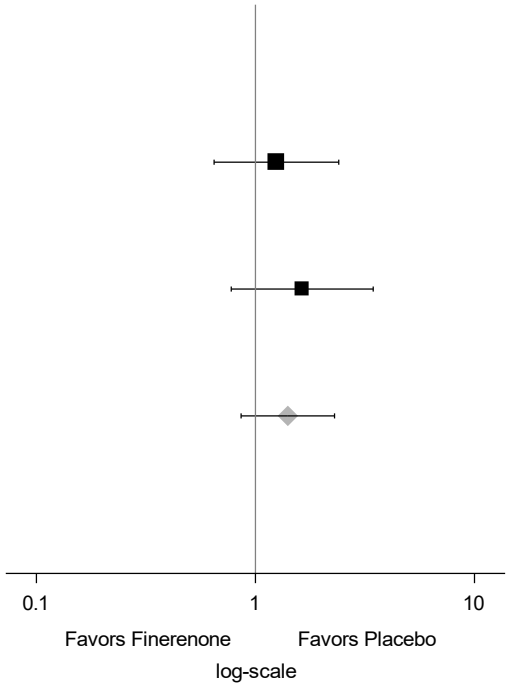
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2617	95 / 2610	72.0	0.99 [0.75,1.31]	
FIGARO-DKD	44 / 1357	32 / 1356	28.0	1.37 [0.88,2.15]	
Total	138 / 3974	127 / 3966		1.08 [0.86,1.37]	Z=0.67, p=0.5060
Heterogeneity:	Q=1.50 (df=1)	p=0.2203	I^2=33.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.126: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Urinary incontinence (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

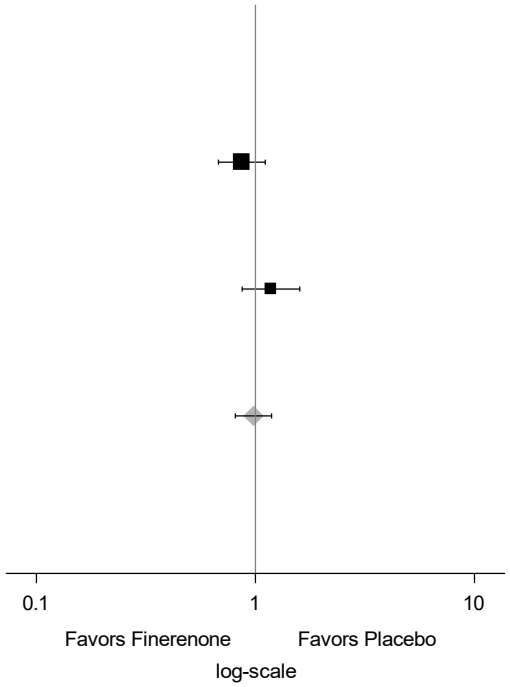
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	16 / 2610	56.5	1.25 [0.65,2.40]	
FIGARO-DKD	18 / 1357	11 / 1356	43.5	1.64 [0.78,3.45]	
Total	38 / 3974	27 / 3966		1.41 [0.86,2.30]	Z=1.36, p=0.1747
Heterogeneity:	Q=0.29 (df=1)	p=0.5923	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.127: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

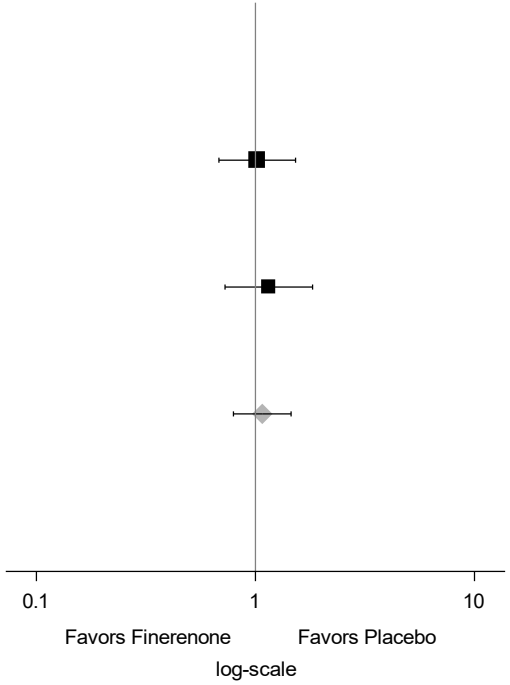
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2617	130 / 2610	60.2	0.87 [0.68,1.11]	
FIGARO-DKD	86 / 1357	73 / 1356	39.8	1.18 [0.87,1.59]	
Total	199 / 3974	203 / 3966		0.98 [0.81,1.18]	Z=-0.21, p=0.8299
Heterogeneity:	Q=2.36 (df=1)	p=0.1243	I^2=57.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.128: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

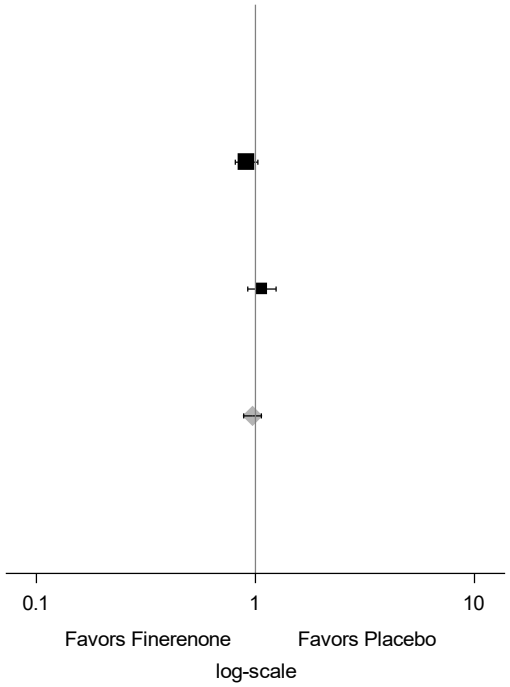
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2617	46 / 2610	56.6	1.02 [0.68,1.52]	
FIGARO-DKD	38 / 1357	33 / 1356	43.4	1.15 [0.73,1.82]	
Total	85 / 3974	79 / 3966		1.07 [0.79,1.45]	Z=0.46, p=0.6432
Heterogeneity:	Q=0.15 (df=1)	p=0.6970	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.129: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

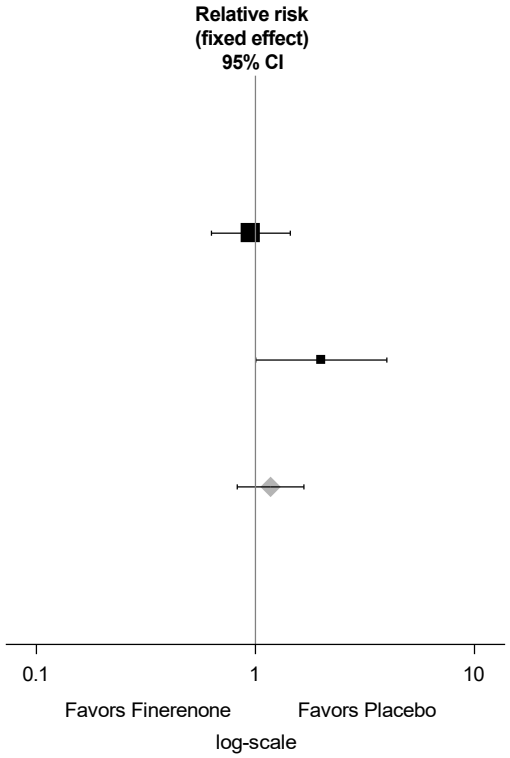
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	432 / 2617	473 / 2610	61.2	0.91 [0.81,1.03]	
FIGARO-DKD	286 / 1357	267 / 1356	38.8	1.07 [0.92,1.24]	
Total	718 / 3974	740 / 3966		0.97 [0.88,1.06]	Z=-0.65, p=0.5165
Heterogeneity:	Q=2.76 (df=1)	p=0.0966	I^2=63.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.130: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

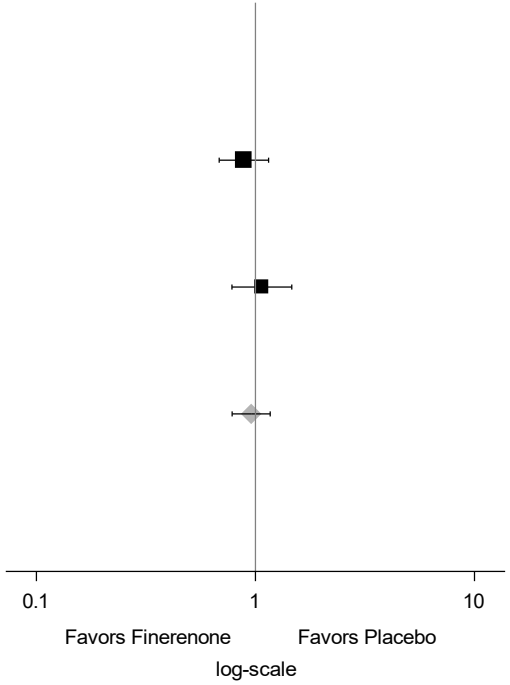
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	45 / 2610	73.4	0.95 [0.63,1.44]	
FIGARO-DKD	24 / 1357	12 / 1356	26.6	2.00 [1.00,3.98]	
Total	67 / 3974	57 / 3966		1.17 [0.83,1.66]	Z=0.89, p=0.3738
Heterogeneity:	Q=3.26 (df=1)	p=0.0709	I^2=69.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.131: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

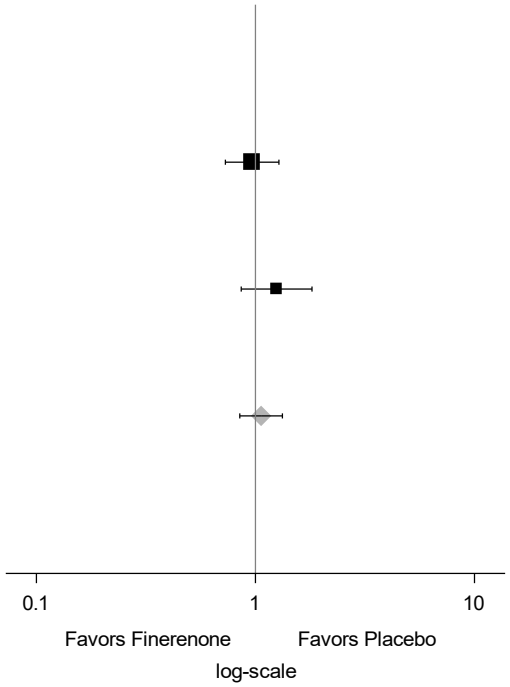
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	103 / 2617	116 / 2610	59.5	0.89 [0.68,1.15]	
FIGARO-DKD	76 / 1357	71 / 1356	40.5	1.07 [0.78,1.47]	
Total	179 / 3974	187 / 3966		0.96 [0.78,1.17]	Z=-0.44, p=0.6591
Heterogeneity:	Q=0.82 (df=1)	p=0.3643	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.132: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

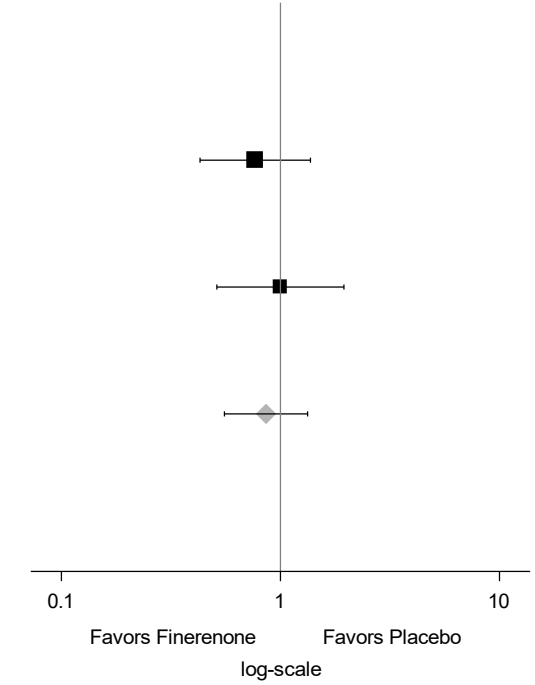
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	92 / 2617	95 / 2610	63.6	0.97 [0.73,1.28]	
FIGARO-DKD	60 / 1357	48 / 1356	36.4	1.25 [0.86,1.81]	
Total	152 / 3974	143 / 3966		1.06 [0.85,1.33]	Z=0.52, p=0.6038
Heterogeneity:	Q=1.17 (df=1)	p=0.2799	I^2=14.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.133: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Dyspnoea exertional (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

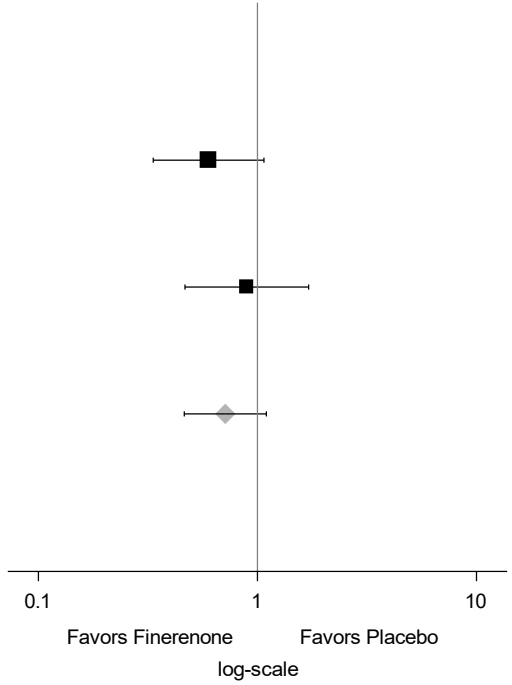
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	26 / 2610	57.0	0.77 [0.43,1.37]	
FIGARO-DKD	17 / 1357	17 / 1356	43.0	1.00 [0.51,1.95]	
Total	37 / 3974	43 / 3966		0.86 [0.55,1.33]	Z=-0.68, p=0.4959
Heterogeneity:	Q=0.34 (df=1)	p=0.5583	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.134: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

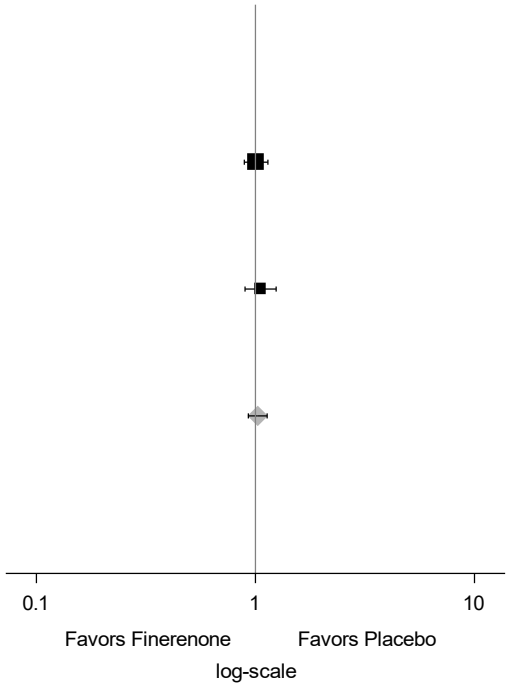
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	30 / 2610	55.5	0.60 [0.33,1.07]	
FIGARO-DKD	17 / 1357	19 / 1356	44.5	0.89 [0.47,1.71]	
Total	35 / 3974	49 / 3966		0.71 [0.46,1.10]	Z=-1.54, p=0.1248
Heterogeneity:	Q=0.81 (df=1)	p=0.3669	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.135: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

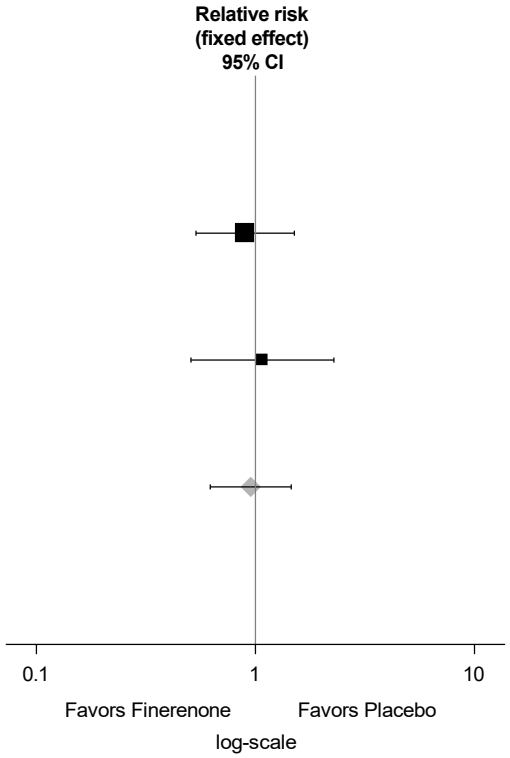
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	422 / 2617	418 / 2610	63.5	1.01 [0.89,1.14]	
FIGARO-DKD	244 / 1357	231 / 1356	36.5	1.06 [0.90,1.24]	
Total	666 / 3974	649 / 3966		1.02 [0.93,1.13]	Z=0.48, p=0.6328
Heterogeneity:	Q=0.20 (df=1)	p=0.6522	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.136: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

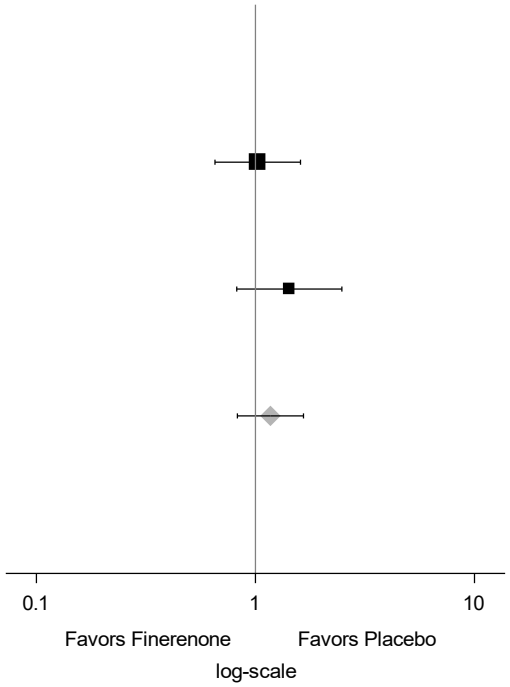
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	30 / 2610	67.8	0.90 [0.54,1.51]	
FIGARO-DKD	14 / 1357	13 / 1356	32.2	1.08 [0.51,2.28]	
Total	41 / 3974	43 / 3966		0.95 [0.62,1.46]	Z=-0.23, p=0.8189
Heterogeneity:	Q=0.15 (df=1)	p=0.6966	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.137: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

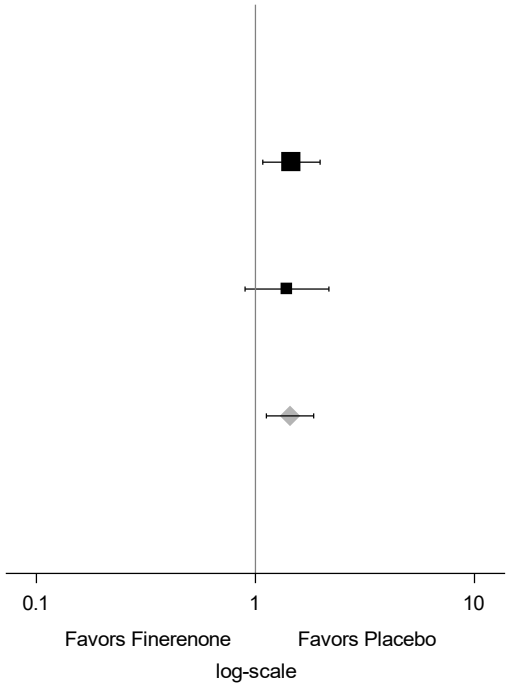
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	37 / 2610	60.2	1.02 [0.65,1.61]	
FIGARO-DKD	30 / 1357	21 / 1356	39.8	1.43 [0.82,2.48]	
Total	68 / 3974	58 / 3966		1.17 [0.83,1.66]	Z=0.89, p=0.3743
Heterogeneity:	Q=0.83 (df=1)	p=0.3610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.138: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

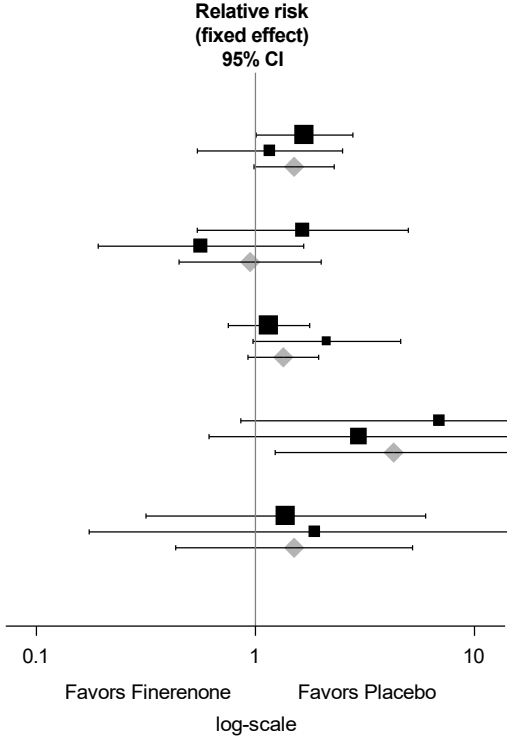
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	101 / 2617	69 / 2610	68.2	1.46 [1.08,1.97]	
FIGARO-DKD	46 / 1357	33 / 1356	31.8	1.39 [0.90,2.16]	
Total	147 / 3974	102 / 3966		1.44 [1.12,1.84]	Z=2.86, p=0.0042
Heterogeneity:	Q=0.03 (df=1)	p=0.8632	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.138.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

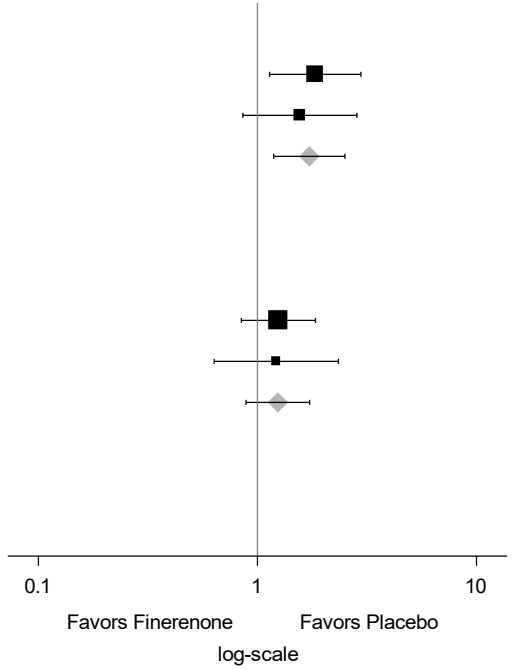
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	39 / 1075	23 / 1062	69.3	1.68 [1.01,2.78]	
FIGARO-DKD	14 / 638	12 / 637	30.7	1.16 [0.54,2.50]	
Total	53 / 1713	35 / 1699		1.50 [0.99,2.29]	Z=1.89, p=0.0587
Heterogeneity:	Q=0.60 (df=1)	p=0.4374	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	5 / 436	48.7	1.65 [0.54,4.99]	
FIGARO-DKD	5 / 267	9 / 271	51.3	0.56 [0.19,1.66]	
Total	13 / 691	14 / 707		0.95 [0.45,2.00]	Z=-0.15, p=0.8835
Heterogeneity:	Q=1.84 (df=1)	p=0.1752	I^2=45.6%		
Asia					
FIDELIO-DKD	43 / 751	37 / 745	76.7	1.15 [0.75,1.77]	
FIGARO-DKD	19 / 289	9 / 290	23.3	2.12 [0.97,4.60]	
Total	62 / 1040	46 / 1035		1.34 [0.92,1.94]	Z=1.54, p=0.1224
Heterogeneity:	Q=1.81 (df=1)	p=0.1782	I^2=44.8%		
Latin America					
FIDELIO-DKD	7 / 273	1 / 270	36.3	6.92 [0.86,55.89]	
FIGARO-DKD	6 / 102	2 / 101	63.7	2.97 [0.61,14.37]	
Total	13 / 375	3 / 371		4.27 [1.23,14.85]	Z=2.29, p=0.0222
Heterogeneity:	Q=0.41 (df=1)	p=0.5222	I^2=0.0%		
Others					
FIDELIO-DKD	4 / 94	3 / 97	72.3	1.38 [0.32,5.98]	
FIGARO-DKD	2 / 61	1 / 57	27.7	1.87 [0.17,20.05]	
Total	6 / 155	4 / 154		1.50 [0.43,5.22]	Z=0.64, p=0.5221
Heterogeneity:	Q=0.05 (df=1)	p=0.8297	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.31 (df=4)	p=0.3651	I^2=7.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.138.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

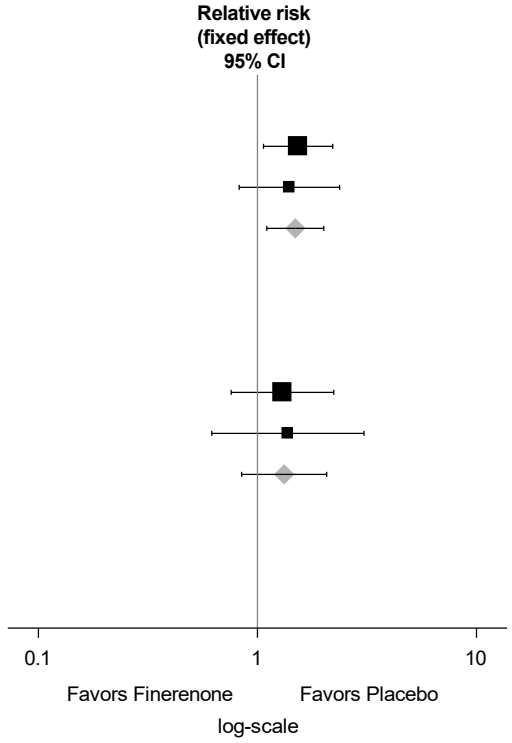
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	46 / 1213	25 / 1210	60.9	1.84 [1.14,2.97]	
FIGARO-DKD	27 / 862	17 / 848	39.1	1.56 [0.86,2.85]	
Total	73 / 2075	42 / 2058		1.72 [1.19,2.51]	Z=2.85, p=0.0043
Heterogeneity:	Q=0.17 (df=1)	p=0.6811	I^2=0.0%		
Absent					
FIDELIO-DKD	55 / 1404	44 / 1400	73.8	1.25 [0.84,1.84]	
FIGARO-DKD	19 / 495	16 / 508	26.2	1.22 [0.63,2.34]	
Total	74 / 1899	60 / 1908		1.24 [0.89,1.73]	Z=1.26, p=0.2091
Heterogeneity:	Q=0.00 (df=1)	p=0.9537	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.67 (df=1)	p=0.1968	I^2=40.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.138.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

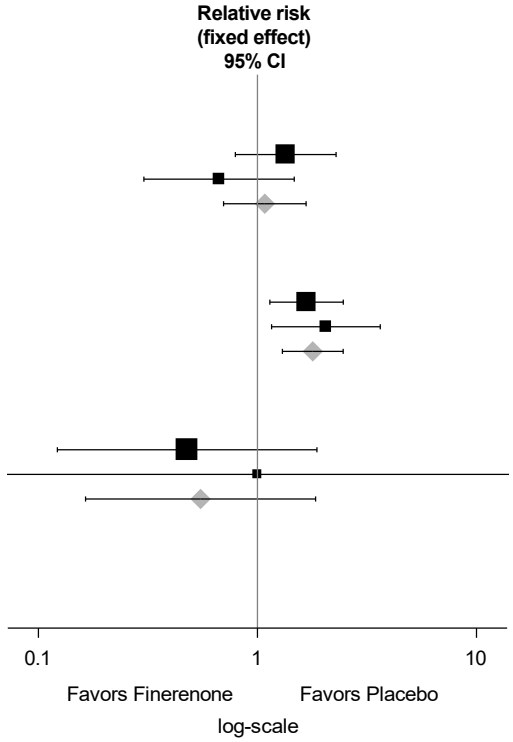
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	72 / 1735	46 / 1700	67.8	1.53 [1.07,2.21]	
FIGARO-DKD	32 / 924	23 / 929	32.2	1.40 [0.83,2.37]	
Total	104 / 2659	69 / 2629		1.49 [1.10,2.01]	Z=2.61, p=0.0092
Heterogeneity:	Q=0.08 (df=1)	p=0.7785	I^2=0.0%		
> 4.5					
FIDELIO-DKD	29 / 882	23 / 910	68.8	1.30 [0.76,2.23]	
FIGARO-DKD	14 / 433	10 / 426	31.2	1.38 [0.62,3.07]	
Total	43 / 1315	33 / 1336		1.32 [0.85,2.07]	Z=1.23, p=0.2182
Heterogeneity:	Q=0.01 (df=1)	p=0.9077	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6694	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.138.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

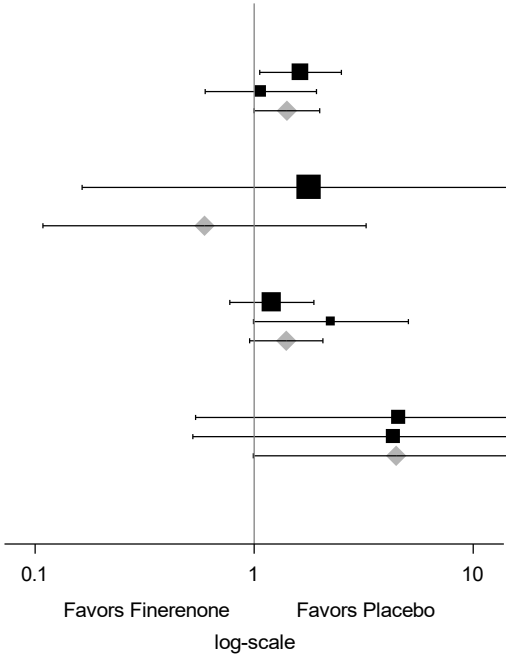
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	31 / 724	23 / 723	69.0	1.35 [0.79,2.29]	
FIGARO-DKD	10 / 494	15 / 495	31.0	0.67 [0.30,1.47]	
Total	41 / 1218	38 / 1218		1.08 [0.70,1.67]	Z=0.35, p=0.7261
Heterogeneity:	Q=2.08 (df=1)	p=0.1489	I^2=52.0%		
130 - < 160					
FIDELIO-DKD	67 / 1759	40 / 1760	68.7	1.68 [1.14,2.47]	
FIGARO-DKD	35 / 829	17 / 827	31.3	2.05 [1.16,3.64]	
Total	102 / 2588	57 / 2587		1.79 [1.30,2.46]	Z=3.57, p=0.0004
Heterogeneity:	Q=0.33 (df=1)	p=0.5632	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 133	6 / 127	80.0	0.48 [0.12,1.87]	
FIGARO-DKD	1 / 34	1 / 34	20.0	1.00 [0.07,15.34]	
Total	4 / 167	7 / 161		0.55 [0.16,1.84]	Z=-0.97, p=0.3324
Heterogeneity:	Q=0.23 (df=1)	p=0.6349	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.89 (df=2)	p=0.0527	I^2=66.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.138.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

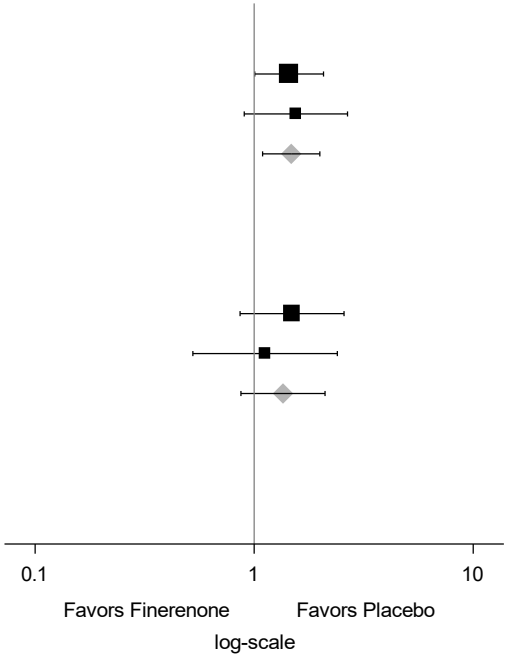
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	53 / 1634	33 / 1657	65.0	1.63 [1.06,2.50]	
FIGARO-DKD	23 / 1010	21 / 989	35.0	1.07 [0.60,1.93]	
Total	76 / 2644	54 / 2646		1.41 [1.00,1.99]	Z=1.96, p=0.0502
Heterogeneity:	Q=1.27 (df=1)	p=0.2590	I^2=21.5%		
Black					
FIDELIO-DKD	2 / 129	1 / 115	100.0	1.78 [0.16,19.40]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,22E296]	
Total	2 / 172	4 / 186		0.59 [0.11,3.24]	Z=-0.60, p=0.5470
Heterogeneity:	Q=0.82 (df=1)	p=0.3664	I^2=0.0%		
Asian					
FIDELIO-DKD	41 / 678	34 / 677	77.2	1.20 [0.77,1.87]	
FIGARO-DKD	18 / 252	8 / 251	22.8	2.24 [0.99,5.06]	
Total	59 / 930	42 / 928		1.40 [0.95,2.06]	Z=1.72, p=0.0860
Heterogeneity:	Q=1.73 (df=1)	p=0.1885	I^2=42.2%		
Others					
FIDELIO-DKD	5 / 176	1 / 161	49.4	4.57 [0.54,38.73]	
FIGARO-DKD	5 / 52	1 / 45	50.6	4.33 [0.52,35.68]	
Total	10 / 228	2 / 206		4.45 [0.99,19.97]	Z=1.95, p=0.0514
Heterogeneity:	Q=0.00 (df=1)	p=0.9711	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.24 (df=3)	p=0.3560	I^2=7.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.138.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

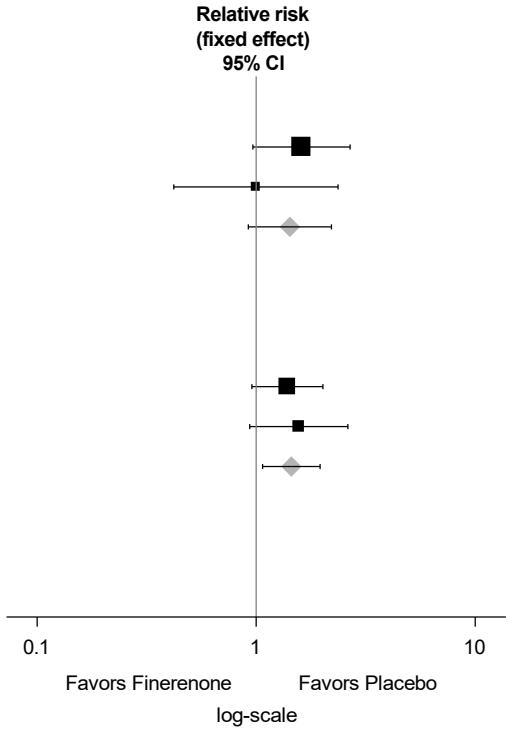
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	68 / 1797	49 / 1870	69.3	1.44 [1.01,2.07]	
FIGARO-DKD	32 / 917	21 / 933	30.7	1.55 [0.90,2.67]	
Total	100 / 2714	70 / 2803		1.48 [1.09,1.99]	Z=2.54, p=0.0112
Heterogeneity:	Q=0.05 (df=1)	p=0.8310	I^2=0.0%		
Female					
FIDELIO-DKD	33 / 820	20 / 740	65.9	1.49 [0.86,2.57]	
FIGARO-DKD	14 / 440	12 / 423	34.1	1.12 [0.52,2.40]	
Total	47 / 1260	32 / 1163		1.35 [0.87,2.11]	Z=1.34, p=0.1793
Heterogeneity:	Q=0.35 (df=1)	p=0.5527	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7511	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.138.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

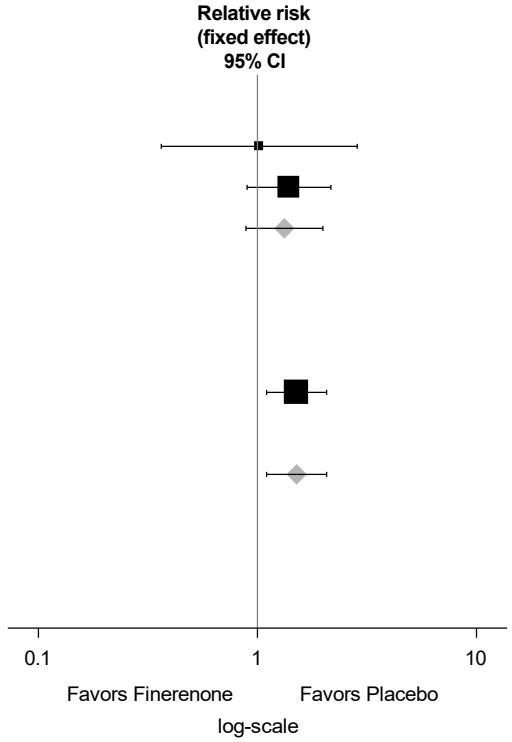
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	38 / 1103	23 / 1075	74.1	1.61 [0.97,2.68]	
FIGARO-DKD	10 / 336	10 / 335	25.9	1.00 [0.42,2.36]	
Total	48 / 1439	33 / 1410		1.43 [0.92,2.21]	Z=1.59, p=0.1120
Heterogeneity:	Q=0.88 (df=1)	p=0.3490	I^2=0.0%		
>= 65					
FIDELIO-DKD	63 / 1514	46 / 1535	65.6	1.39 [0.96,2.02]	
FIGARO-DKD	36 / 1021	23 / 1021	34.4	1.57 [0.93,2.62]	
Total	99 / 2535	69 / 2556		1.45 [1.07,1.96]	Z=2.40, p=0.0165
Heterogeneity:	Q=0.14 (df=1)	p=0.7125	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9549	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.138.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

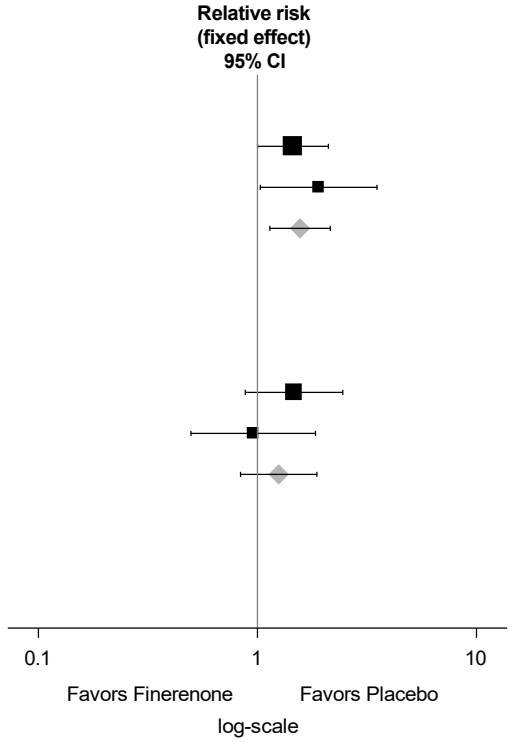
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	7 / 213	15.5	1.02 [0.36,2.86]	
FIGARO-DKD	46 / 1357	33 / 1356	84.5	1.39 [0.90,2.16]	
Total	53 / 1566	40 / 1569		1.33 [0.89,1.99]	Z=1.37, p=0.1696
Heterogeneity:	Q=0.30 (df=1)	p=0.5847	I^2=0.0%		
Very High					
FIDELIO-DKD	94 / 2408	62 / 2397	100.0	1.51 [1.10,2.07]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	94 / 2408	62 / 2397		1.51 [1.10,2.07]	Z=2.56, p=0.0106
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6246	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.138.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

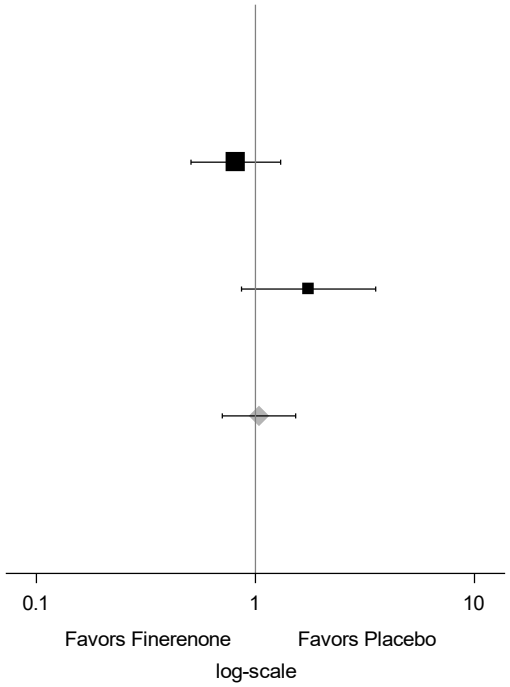
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	66 / 1556	45 / 1541	73.1	1.45 [1.00,2.11]	
FIGARO-DKD	29 / 637	15 / 627	26.9	1.90 [1.03,3.51]	
Total	95 / 2193	60 / 2168		1.57 [1.14,2.15]	Z=2.76, p=0.0057
Heterogeneity:	Q=0.54 (df=1)	p=0.4606	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	24 / 1069	62.0	1.47 [0.88,2.45]	
FIGARO-DKD	17 / 720	18 / 729	38.0	0.96 [0.50,1.84]	
Total	52 / 1781	42 / 1798		1.25 [0.84,1.87]	Z=1.09, p=0.2755
Heterogeneity:	Q=1.03 (df=1)	p=0.3113	I^2=2.5%		
Subgroup Heterogeneity:	Q=0.74 (df=1)	p=0.3894	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.139: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

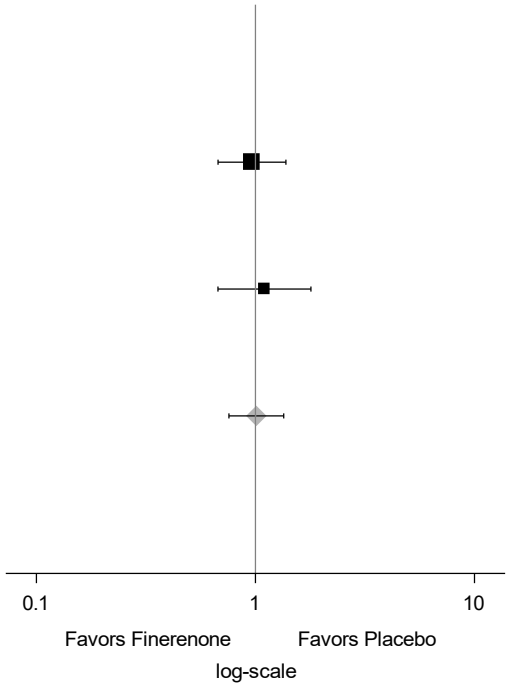
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	38 / 2610	69.1	0.81 [0.51,1.30]	
FIGARO-DKD	21 / 1357	12 / 1356	30.9	1.75 [0.86,3.54]	
Total	52 / 3974	50 / 3966		1.04 [0.71,1.53]	Z=0.19, p=0.8509
Heterogeneity:	Q=3.13 (df=1)	p=0.0770	I^2=68.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.140: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

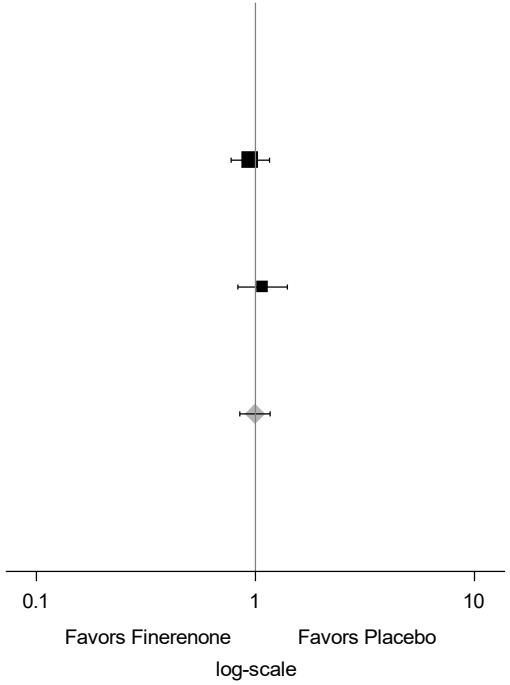
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	58 / 2617	60 / 2610	65.2	0.96 [0.67,1.38]	
FIGARO-DKD	33 / 1357	30 / 1356	34.8	1.10 [0.67,1.79]	
Total	91 / 3974	90 / 3966		1.01 [0.76,1.35]	Z=0.06, p=0.9508
Heterogeneity:	Q=0.18 (df=1)	p=0.6710	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.141: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

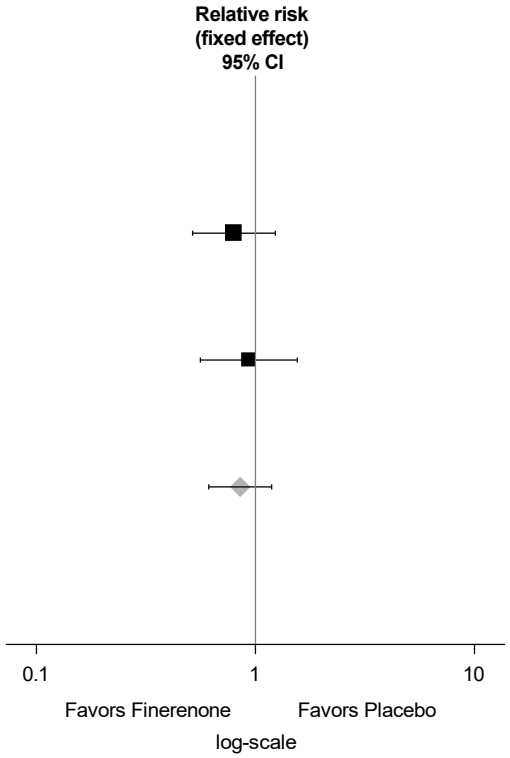
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	172 / 2617	181 / 2610	62.5	0.95 [0.77,1.16]	
FIGARO-DKD	109 / 1357	101 / 1356	37.5	1.08 [0.83,1.40]	
Total	281 / 3974	282 / 3966		0.99 [0.85,1.17]	Z=-0.06, p=0.9491
Heterogeneity:	Q=0.59 (df=1)	p=0.4416	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.142: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

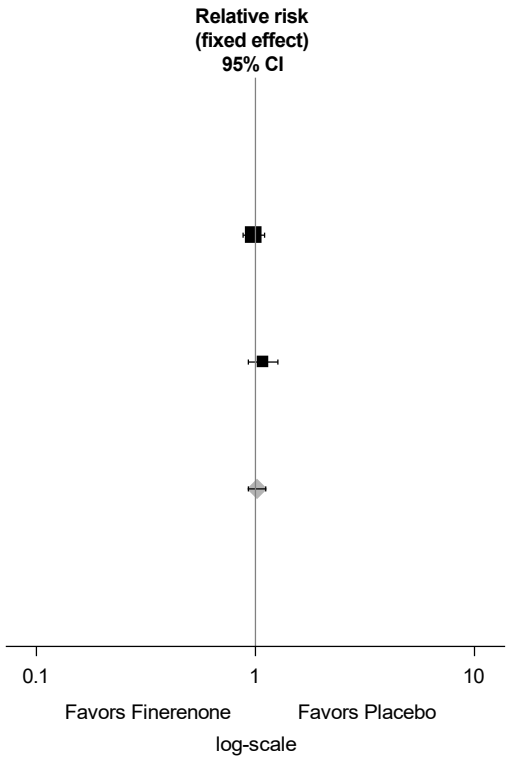
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	45 / 2610	57.8	0.80 [0.52,1.23]	
FIGARO-DKD	28 / 1357	30 / 1356	42.2	0.93 [0.56,1.55]	
Total	64 / 3974	75 / 3966		0.85 [0.61,1.19]	Z=-0.95, p=0.3420
Heterogeneity:	Q=0.21 (df=1)	p=0.6479	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.143: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

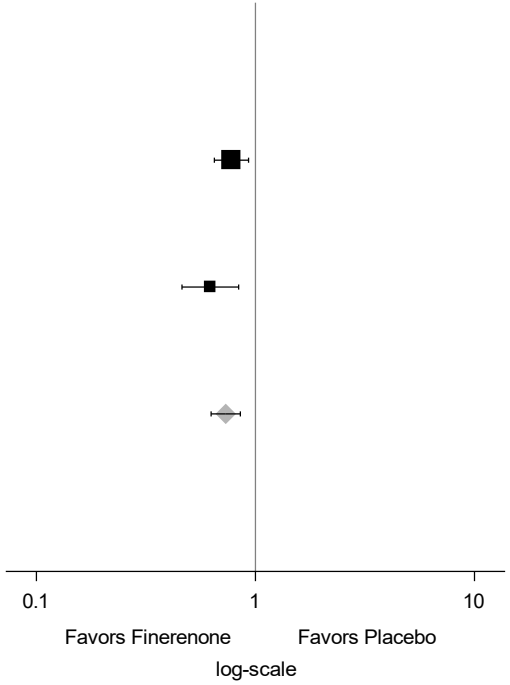
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	485 / 2617	492 / 2610	65.3	0.98 [0.88,1.10]	
FIGARO-DKD	269 / 1357	248 / 1356	34.7	1.08 [0.93,1.27]	
Total	754 / 3974	740 / 3966		1.02 [0.93,1.11]	Z=0.36, p=0.7180
Heterogeneity:	Q=0.99 (df=1)	p=0.3195	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.144: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

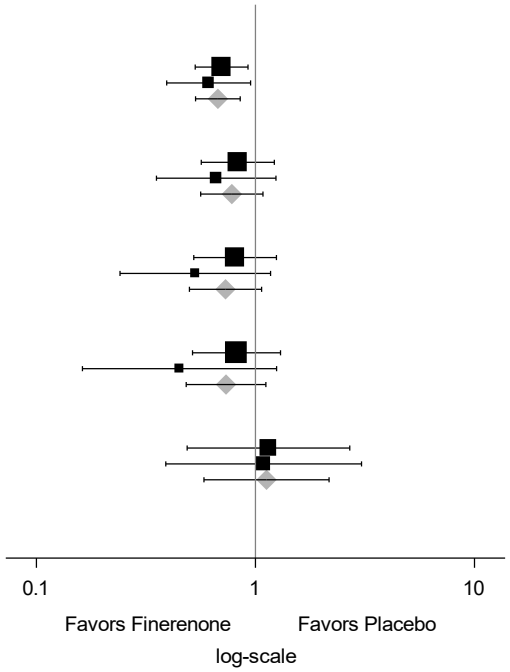
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194 / 2617	249 / 2610	73.3	0.78 [0.65,0.93]	
FIGARO-DKD	66 / 1357	106 / 1356	26.7	0.62 [0.46,0.84]	
Total	260 / 3974	355 / 3966		0.73 [0.63,0.85]	Z=-3.99, p=<.0001
Heterogeneity:	Q=1.57 (df=1)	p=0.2106	I^2=36.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.144.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

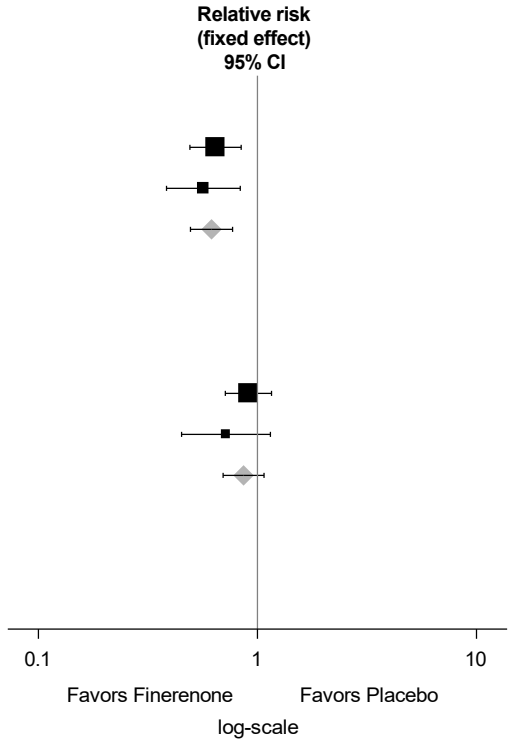
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	78 / 1075	110 / 1062	71.6	0.70 [0.53,0.92]	
FIGARO-DKD	30 / 638	49 / 637	28.4	0.61 [0.39,0.95]	
Total	108 / 1713	159 / 1699		0.67 [0.53,0.85]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.26 (df=1)	p=0.6082	I^2=0.0%		
North America					
FIDELIO-DKD	42 / 424	52 / 436	72.8	0.83 [0.57,1.22]	
FIGARO-DKD	15 / 267	23 / 271	27.2	0.66 [0.35,1.24]	
Total	57 / 691	75 / 707		0.78 [0.56,1.08]	Z=-1.49, p=0.1370
Heterogeneity:	Q=0.36 (df=1)	p=0.5458	I^2=0.0%		
Asia					
FIDELIO-DKD	35 / 751	43 / 745	76.8	0.81 [0.52,1.25]	
FIGARO-DKD	9 / 289	17 / 290	23.2	0.53 [0.24,1.17]	
Total	44 / 1040	60 / 1035		0.73 [0.50,1.07]	Z=-1.63, p=0.1039
Heterogeneity:	Q=0.83 (df=1)	p=0.3633	I^2=0.0%		
Latin America					
FIDELIO-DKD	29 / 273	35 / 270	83.0	0.82 [0.52,1.30]	
FIGARO-DKD	5 / 102	11 / 101	17.0	0.45 [0.16,1.25]	
Total	34 / 375	46 / 371		0.73 [0.48,1.12]	Z=-1.45, p=0.1477
Heterogeneity:	Q=1.10 (df=1)	p=0.2943	I^2=9.1%		
Others					
FIDELIO-DKD	10 / 94	9 / 97	59.2	1.15 [0.49,2.70]	
FIGARO-DKD	7 / 61	6 / 57	40.8	1.09 [0.39,3.05]	
Total	17 / 155	15 / 154		1.12 [0.58,2.17]	Z=0.35, p=0.7291
Heterogeneity:	Q=0.01 (df=1)	p=0.9411	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.25 (df=4)	p=0.6891	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.144.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

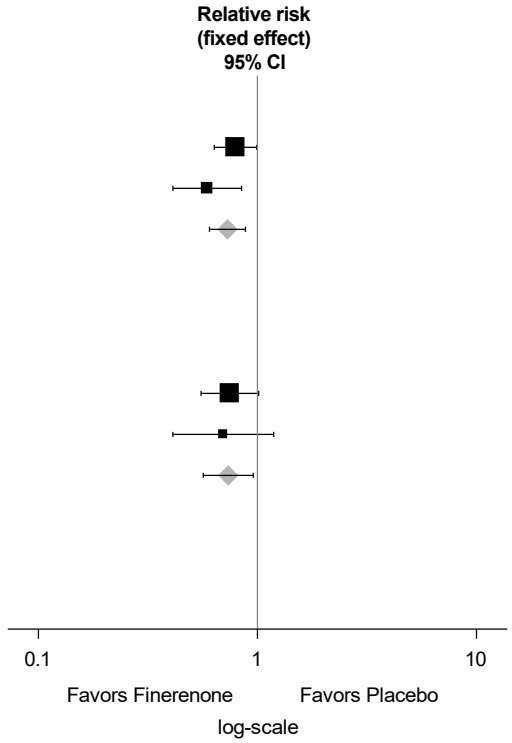
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	80 / 1213	124 / 1210	67.4	0.64 [0.49,0.84]	
FIGARO-DKD	38 / 862	66 / 848	32.6	0.57 [0.38,0.83]	
Total	118 / 2075	190 / 2058		0.62 [0.49,0.77]	Z=-4.28, p=<.0001
Heterogeneity:	Q=0.28 (df=1)	p=0.5960	I^2=0.0%		
Absent					
FIDELIO-DKD	114 / 1404	125 / 1400	78.7	0.91 [0.71,1.16]	
FIGARO-DKD	28 / 495	40 / 508	21.3	0.72 [0.45,1.15]	
Total	142 / 1899	165 / 1908		0.86 [0.70,1.07]	Z=-1.33, p=0.1838
Heterogeneity:	Q=0.77 (df=1)	p=0.3798	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.58 (df=1)	p=0.0323	I^2=78.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.144.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	128 / 1735	158 / 1700	72.3	0.79 [0.63,0.99]	
FIGARO-DKD	44 / 924	75 / 929	27.7	0.59 [0.41,0.85]	
Total	172 / 2659	233 / 2629		0.73 [0.60,0.88]	Z=-3.26, p=0.0011
Heterogeneity:	Q=1.88 (df=1)	p=0.1702	I^2=46.9%		
> 4.5					
FIDELIO-DKD	66 / 882	91 / 910	75.3	0.75 [0.55,1.01]	
FIGARO-DKD	22 / 433	31 / 426	24.7	0.70 [0.41,1.19]	
Total	88 / 1315	122 / 1336		0.74 [0.57,0.96]	Z=-2.29, p=0.0221
Heterogeneity:	Q=0.05 (df=1)	p=0.8239	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9613	I^2=0.0%		

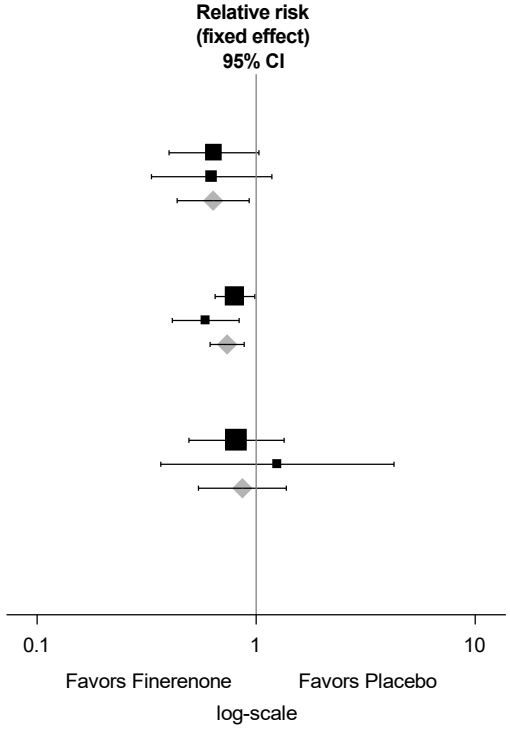


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.144.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

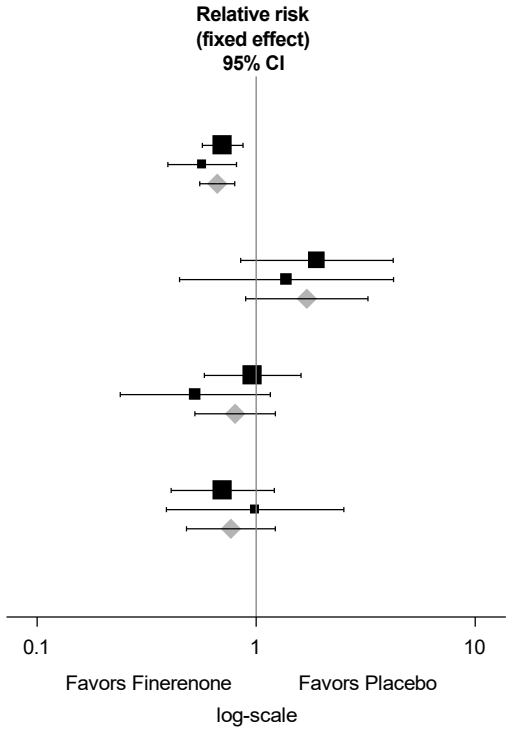
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	27 / 724	42 / 723	64.2	0.64 [0.40,1.03]	
FIGARO-DKD	15 / 494	24 / 495	35.8	0.63 [0.33,1.18]	
Total	42 / 1218	66 / 1218		0.64 [0.44,0.93]	Z=-2.34, p=0.0192
Heterogeneity:	Q=0.00 (df=1)	p=0.9510	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	144 / 1759	180 / 1760	73.9	0.80 [0.65,0.99]	
FIGARO-DKD	46 / 829	78 / 827	26.1	0.59 [0.41,0.84]	
Total	190 / 2588	258 / 2587		0.74 [0.62,0.88]	Z=-3.34, p=0.0008
Heterogeneity:	Q=2.18 (df=1)	p=0.1398	I^2=54.1%		
>= 160					
FIDELIO-DKD	23 / 133	27 / 127	85.7	0.81 [0.49,1.34]	
FIGARO-DKD	5 / 34	4 / 34	14.3	1.25 [0.37,4.26]	
Total	28 / 167	31 / 161		0.87 [0.55,1.37]	Z=-0.61, p=0.5388
Heterogeneity:	Q=0.40 (df=1)	p=0.5247	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.04 (df=2)	p=0.5960	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.144.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

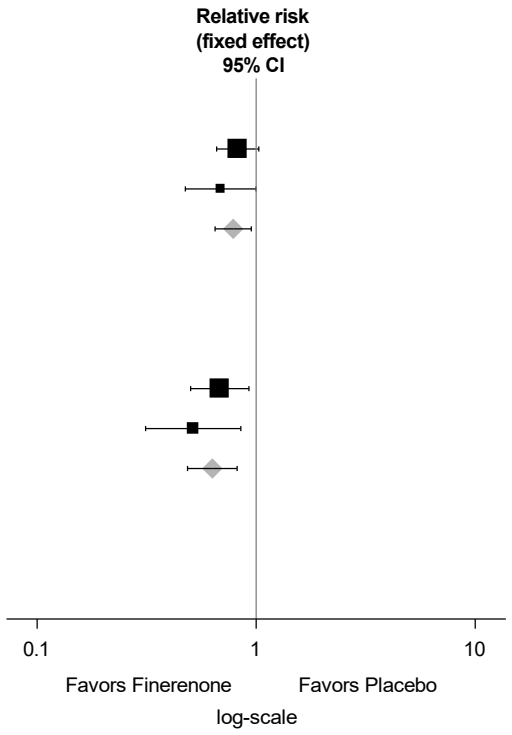
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	129 / 1634	186 / 1657	74.0	0.70 [0.57,0.87]	
FIGARO-DKD	44 / 1010	76 / 989	26.0	0.57 [0.40,0.81]	
Total	173 / 2644	262 / 2646		0.66 [0.55,0.80]	Z=-4.36, p=<.0001
Heterogeneity:	Q=1.02 (df=1)	p=0.3137	I^2=1.5%		
Black					
FIDELIO-DKD	17 / 129	8 / 115	66.3	1.89 [0.85,4.22]	
FIGARO-DKD	5 / 43	6 / 71	33.7	1.38 [0.45,4.24]	
Total	22 / 172	14 / 186		1.70 [0.90,3.24]	Z=1.62, p=0.1046
Heterogeneity:	Q=0.21 (df=1)	p=0.6501	I^2=0.0%		
Asian					
FIDELIO-DKD	28 / 678	29 / 677	70.7	0.96 [0.58,1.60]	
FIGARO-DKD	9 / 252	17 / 251	29.3	0.53 [0.24,1.16]	
Total	37 / 930	46 / 928		0.80 [0.53,1.22]	Z=-1.03, p=0.3053
Heterogeneity:	Q=1.59 (df=1)	p=0.2074	I^2=37.1%		
Others					
FIDELIO-DKD	20 / 176	26 / 161	74.7	0.70 [0.41,1.21]	
FIGARO-DKD	8 / 52	7 / 45	25.3	0.99 [0.39,2.51]	
Total	28 / 228	33 / 206		0.77 [0.48,1.22]	Z=-1.12, p=0.2647
Heterogeneity:	Q=0.38 (df=1)	p=0.5363	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.91 (df=3)	p=0.0478	I^2=62.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.144.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

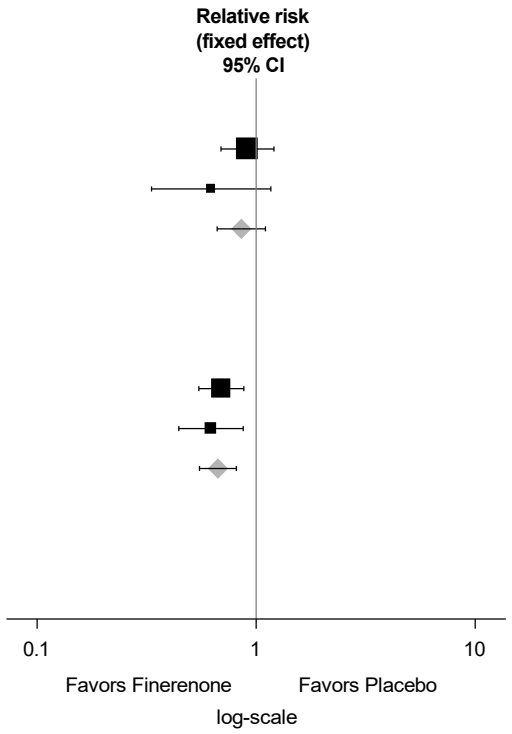
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	129 / 1797	163 / 1870	73.7	0.82 [0.66,1.03]	
FIGARO-DKD	44 / 917	65 / 933	26.3	0.69 [0.47,1.00]	
Total	173 / 2714	228 / 2803		0.79 [0.65,0.95]	Z=-2.49, p=0.0128
Heterogeneity:	Q=0.66 (df=1)	p=0.4181	I^2=0.0%		
Female					
FIDELIO-DKD	65 / 820	86 / 740	72.7	0.68 [0.50,0.93]	
FIGARO-DKD	22 / 440	41 / 423	27.3	0.52 [0.31,0.85]	
Total	87 / 1260	127 / 1163		0.63 [0.49,0.82]	Z=-3.47, p=0.0005
Heterogeneity:	Q=0.87 (df=1)	p=0.3508	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.77 (df=1)	p=0.1829	I^2=43.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.144.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

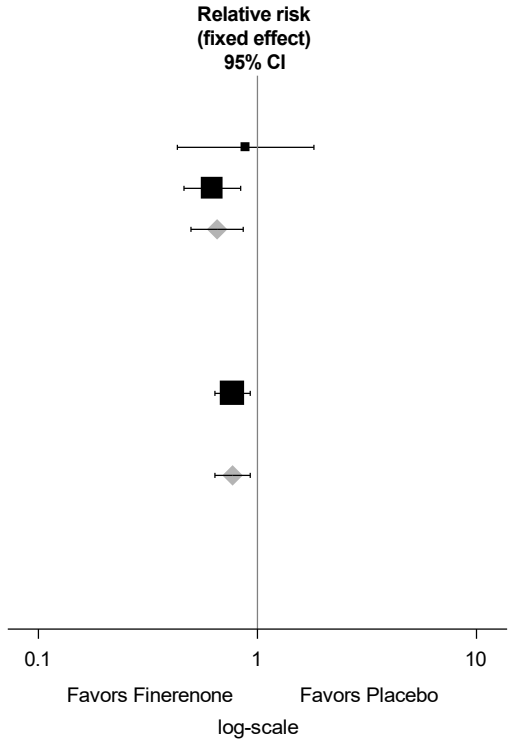
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	88 / 1103	94 / 1075	83.5	0.91 [0.69,1.21]	
FIGARO-DKD	15 / 336	24 / 335	16.5	0.62 [0.33,1.17]	
Total	103 / 1439	118 / 1410		0.86 [0.66,1.10]	Z=-1.21, p=0.2275
Heterogeneity:	Q=1.19 (df=1)	p=0.2760	I^2=15.7%		
>= 65					
FIDELIO-DKD	106 / 1514	155 / 1535	67.2	0.69 [0.55,0.88]	
FIGARO-DKD	51 / 1021	82 / 1021	32.8	0.62 [0.44,0.87]	
Total	157 / 2535	237 / 2556		0.67 [0.55,0.81]	Z=-4.06, p=<.0001
Heterogeneity:	Q=0.27 (df=1)	p=0.6061	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.28 (df=1)	p=0.1310	I^2=56.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.144.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

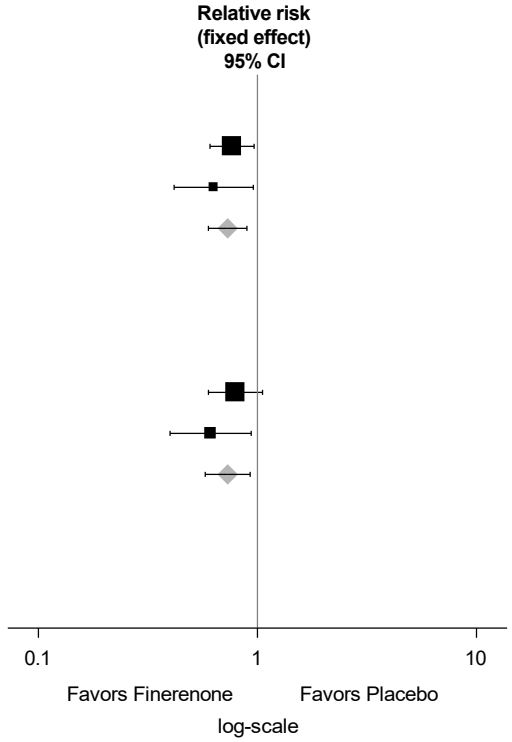
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	13 / 209	15 / 213	14.7	0.88 [0.43,1.81]	
FIGARO-DKD	66 / 1357	106 / 1356	85.3	0.62 [0.46,0.84]	
Total	79 / 1566	121 / 1569		0.65 [0.50,0.86]	Z=-3.03, p=0.0025
Heterogeneity:	Q=0.78 (df=1)	p=0.3769	I^2=0.0%		
Very High					
FIDELIO-DKD	181 / 2408	234 / 2397	100.0	0.77 [0.64,0.93]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	181 / 2408	234 / 2397		0.77 [0.64,0.93]	Z=-2.76, p=0.0058
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.93 (df=1)	p=0.3358	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.144.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

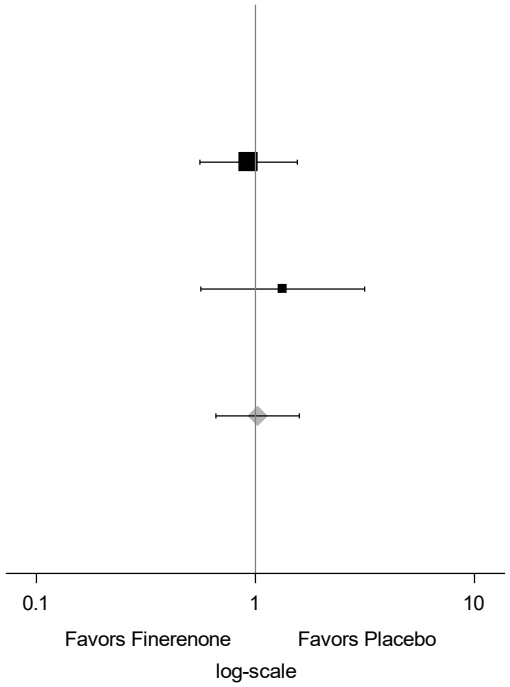
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	116 / 1556	150 / 1541	76.3	0.77 [0.61,0.97]	
FIGARO-DKD	34 / 637	53 / 627	23.7	0.63 [0.42,0.96]	
Total	150 / 2193	203 / 2168		0.73 [0.60,0.90]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.63 (df=1)	p=0.4272	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	78 / 1061	99 / 1069	69.2	0.79 [0.60,1.05]	
FIGARO-DKD	32 / 720	53 / 729	30.8	0.61 [0.40,0.94]	
Total	110 / 1781	152 / 1798		0.73 [0.58,0.93]	Z=-2.60, p=0.0094
Heterogeneity:	Q=1.00 (df=1)	p=0.3178	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9986	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.145: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypertensive crisis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

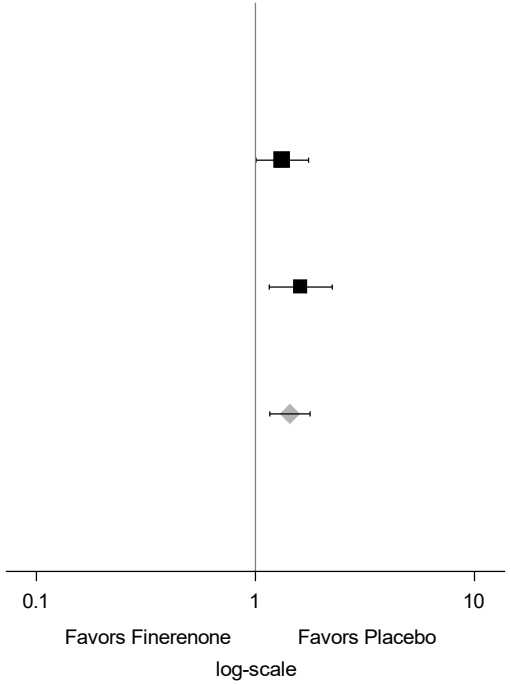
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	30 / 2610	73.9	0.93 [0.56,1.55]	
FIGARO-DKD	12 / 1357	9 / 1356	26.1	1.33 [0.56,3.15]	
Total	40 / 3974	39 / 3966		1.02 [0.66,1.59]	Z=0.10, p=0.9185
Heterogeneity:	Q=0.49 (df=1)	p=0.4829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.146: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

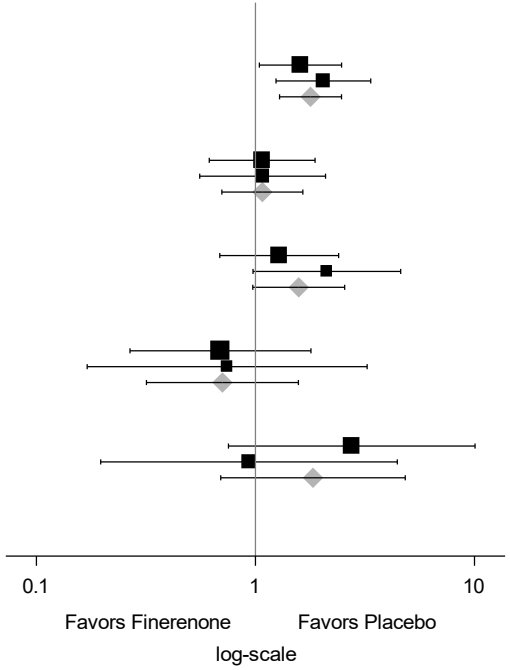
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2617	85 / 2610	59.0	1.33 [1.01,1.75]	
FIGARO-DKD	87 / 1357	54 / 1356	41.0	1.61 [1.16,2.24]	
Total	200 / 3974	139 / 3966		1.44 [1.16,1.78]	Z=3.36, p=0.0008
Heterogeneity:	Q=0.78 (df=1)	p=0.3775	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.146.1: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

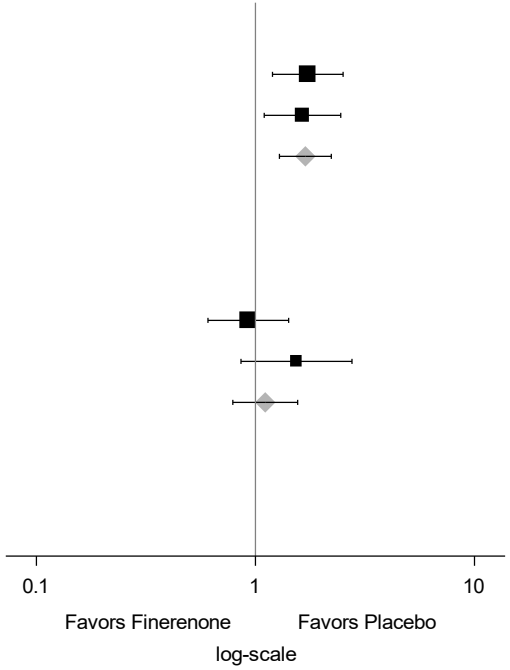
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	52 / 1075	32 / 1062	57.0	1.61 [1.04,2.47]	
FIGARO-DKD	45 / 638	22 / 637	43.0	2.04 [1.24,3.36]	
Total	97 / 1713	54 / 1699		1.78 [1.29,2.47]	Z=3.48, p=0.0005
Heterogeneity:	Q=0.51 (df=1)	p=0.4742	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 424	23 / 436	58.6	1.07 [0.62,1.87]	
FIGARO-DKD	17 / 267	16 / 271	41.4	1.08 [0.56,2.09]	
Total	41 / 691	39 / 707		1.08 [0.70,1.65]	Z=0.33, p=0.7383
Heterogeneity:	Q=0.00 (df=1)	p=0.9909	I^2=0.0%		
Asia					
FIDELIO-DKD	22 / 751	17 / 745	60.7	1.28 [0.69,2.40]	
FIGARO-DKD	19 / 289	9 / 290	39.3	2.12 [0.97,4.60]	
Total	41 / 1040	26 / 1035		1.58 [0.97,2.55]	Z=1.85, p=0.0649
Heterogeneity:	Q=0.97 (df=1)	p=0.3242	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 273	10 / 270	70.5	0.69 [0.27,1.79]	
FIGARO-DKD	3 / 102	4 / 101	29.5	0.74 [0.17,3.23]	
Total	10 / 375	14 / 371		0.71 [0.32,1.57]	Z=-0.85, p=0.3943
Heterogeneity:	Q=0.01 (df=1)	p=0.9374	I^2=0.0%		
Others					
FIDELIO-DKD	8 / 94	3 / 97	59.1	2.75 [0.75,10.06]	
FIGARO-DKD	3 / 61	3 / 57	40.9	0.93 [0.20,4.44]	
Total	11 / 155	6 / 154		1.83 [0.69,4.83]	Z=1.22, p=0.2215
Heterogeneity:	Q=1.09 (df=1)	p=0.2955	I^2=8.6%		
Subgroup Heterogeneity:	Q=6.89 (df=4)	p=0.1417	I^2=42.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.146.2: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

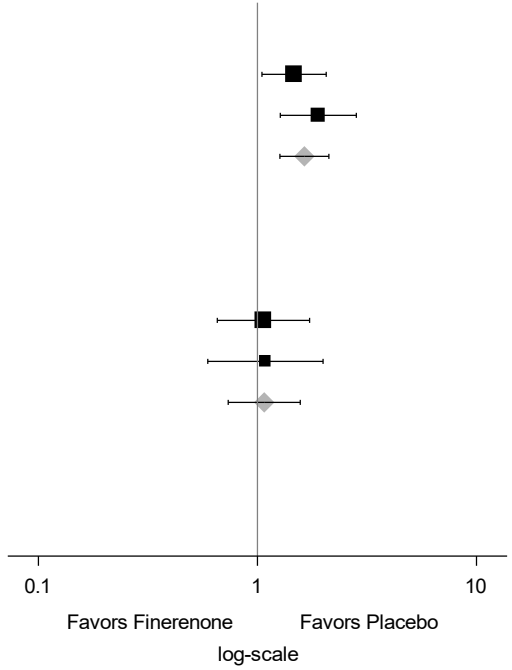
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	73 / 1213	42 / 1210	54.0	1.73 [1.20,2.51]	
FIGARO-DKD	60 / 862	36 / 848	46.0	1.64 [1.10,2.45]	
Total	133 / 2075	78 / 2058		1.69 [1.29,2.22]	Z=3.77, p=0.0002
Heterogeneity:	Q=0.04 (df=1)	p=0.8414	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 1404	43 / 1400	65.4	0.93 [0.61,1.42]	
FIGARO-DKD	27 / 495	18 / 508	34.6	1.54 [0.86,2.76]	
Total	67 / 1899	61 / 1908		1.11 [0.79,1.56]	Z=0.59, p=0.5539
Heterogeneity:	Q=1.89 (df=1)	p=0.1686	I^2=47.2%		
Subgroup Heterogeneity:	Q=3.59 (df=1)	p=0.0582	I^2=72.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.146.3: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

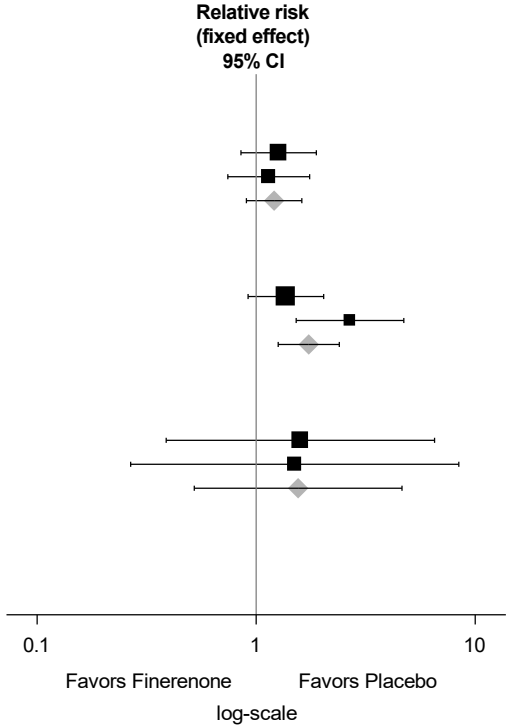
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	81 / 1735	54 / 1700	58.3	1.47 [1.05,2.06]	
FIGARO-DKD	66 / 924	35 / 929	41.7	1.90 [1.27,2.83]	
Total	147 / 2659	89 / 2629		1.64 [1.27,2.12]	Z=3.76, p=0.0002
Heterogeneity:	Q=0.91 (df=1)	p=0.3401	I^2=0.0%		
> 4.5					
FIDELIO-DKD	32 / 882	31 / 910	60.9	1.07 [0.66,1.73]	
FIGARO-DKD	21 / 433	19 / 426	39.1	1.09 [0.59,1.99]	
Total	53 / 1315	50 / 1336		1.07 [0.74,1.57]	Z=0.37, p=0.7128
Heterogeneity:	Q=0.00 (df=1)	p=0.9581	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.27 (df=1)	p=0.0707	I^2=69.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.146.4: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

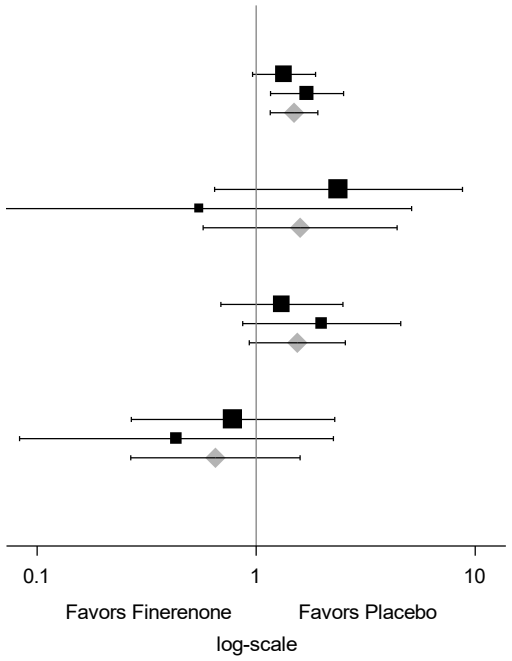
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	52 / 724	41 / 723	54.1	1.27 [0.85,1.88]	
FIGARO-DKD	41 / 494	36 / 495	45.9	1.14 [0.74,1.75]	
Total	93 / 1218	77 / 1218		1.21 [0.90,1.62]	Z=1.27, p=0.2044
Heterogeneity:	Q=0.12 (df=1)	p=0.7268	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	56 / 1759	41 / 1760	67.0	1.37 [0.92,2.03]	
FIGARO-DKD	43 / 829	16 / 827	33.0	2.68 [1.52,4.72]	
Total	99 / 2588	57 / 2587		1.74 [1.26,2.40]	Z=3.37, p=0.0007
Heterogeneity:	Q=3.66 (df=1)	p=0.0557	I^2=72.7%		
>= 160					
FIDELIO-DKD	5 / 133	3 / 127	59.9	1.59 [0.39,6.52]	
FIGARO-DKD	3 / 34	2 / 34	40.1	1.50 [0.27,8.42]	
Total	8 / 167	5 / 161		1.55 [0.52,4.63]	Z=0.79, p=0.4285
Heterogeneity:	Q=0.00 (df=1)	p=0.9585	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.73 (df=2)	p=0.2550	I^2=26.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.146.5: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

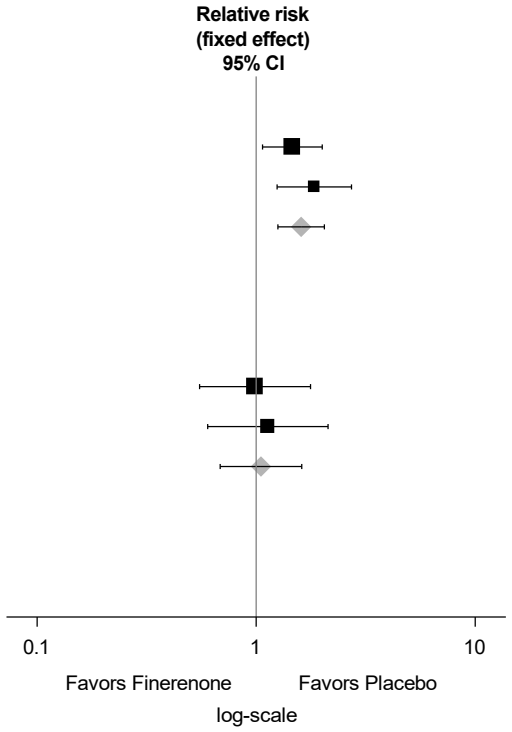
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	78 / 1634	59 / 1657	57.3	1.34 [0.96,1.87]	
FIGARO-DKD	68 / 1010	39 / 989	42.7	1.71 [1.16,2.51]	
Total	146 / 2644	98 / 2646		1.49 [1.16,1.91]	Z=3.12, p=0.0018
Heterogeneity:	Q=0.87 (df=1)	p=0.3498	I^2=0.0%		
Black					
FIDELIO-DKD	8 / 129	3 / 115	74.6	2.38 [0.65,8.75]	
FIGARO-DKD	1 / 43	3 / 71	25.4	0.55 [0.06,5.12]	
Total	9 / 172	6 / 186		1.59 [0.57,4.40]	Z=0.89, p=0.3745
Heterogeneity:	Q=1.23 (df=1)	p=0.2665	I^2=19.0%		
Asian					
FIDELIO-DKD	21 / 678	16 / 677	62.6	1.31 [0.69,2.49]	
FIGARO-DKD	16 / 252	8 / 251	37.4	1.99 [0.87,4.57]	
Total	37 / 930	24 / 928		1.54 [0.93,2.55]	Z=1.68, p=0.0933
Heterogeneity:	Q=0.61 (df=1)	p=0.4341	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 176	7 / 161	70.4	0.78 [0.27,2.28]	
FIGARO-DKD	2 / 52	4 / 45	29.6	0.43 [0.08,2.25]	
Total	8 / 228	11 / 206		0.65 [0.27,1.59]	Z=-0.94, p=0.3457
Heterogeneity:	Q=0.35 (df=1)	p=0.5532	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.22 (df=3)	p=0.3591	I^2=6.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.146.6: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

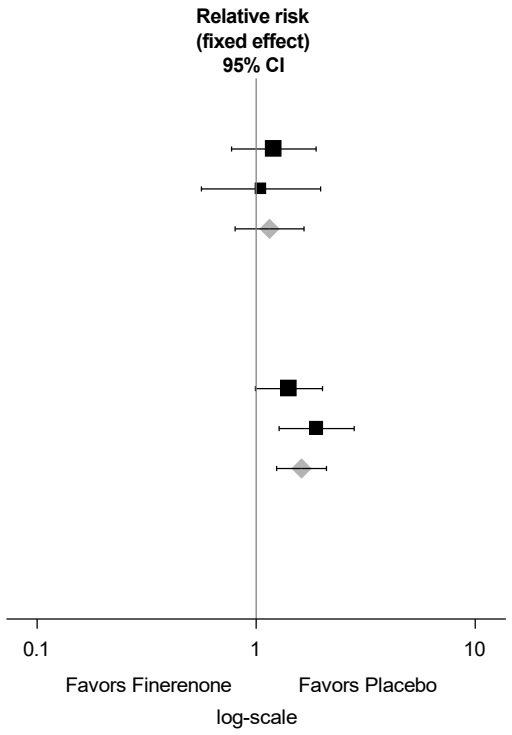
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	90 / 1797	64 / 1870	60.8	1.46 [1.07,2.00]	
FIGARO-DKD	67 / 917	37 / 933	39.2	1.84 [1.25,2.72]	
Total	157 / 2714	101 / 2803		1.60 [1.26,2.05]	Z=3.79, p=0.0001
Heterogeneity:	Q=0.81 (df=1)	p=0.3679	I^2=0.0%		
Female					
FIDELIO-DKD	23 / 820	21 / 740	54.1	0.99 [0.55,1.77]	
FIGARO-DKD	20 / 440	17 / 423	45.9	1.13 [0.60,2.13]	
Total	43 / 1260	38 / 1163		1.05 [0.68,1.61]	Z=0.23, p=0.8178
Heterogeneity:	Q=0.09 (df=1)	p=0.7588	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.81 (df=1)	p=0.0935	I^2=64.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.146.7: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

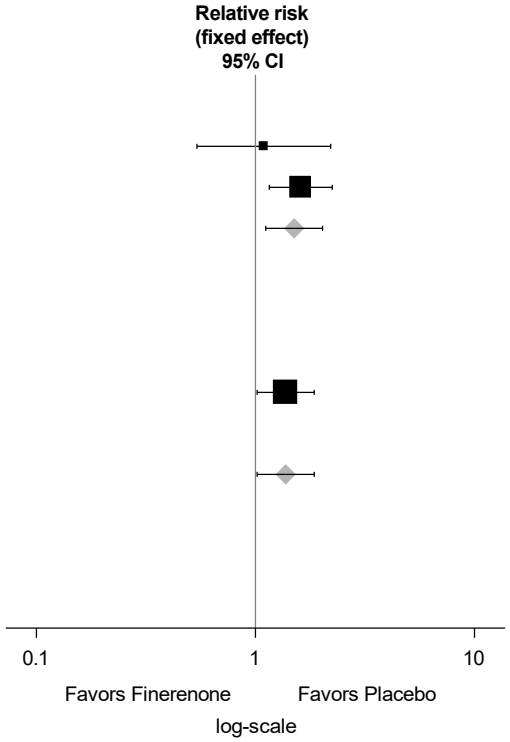
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	42 / 1103	34 / 1075	66.5	1.20 [0.77,1.88]	
FIGARO-DKD	19 / 336	18 / 335	33.5	1.05 [0.56,1.97]	
Total	61 / 1439	52 / 1410		1.15 [0.80,1.65]	Z=0.76, p=0.4463
Heterogeneity:	Q=0.12 (df=1)	p=0.7315	I^2=0.0%		
>= 65					
FIDELIO-DKD	71 / 1514	51 / 1535	55.6	1.41 [0.99,2.01]	
FIGARO-DKD	68 / 1021	36 / 1021	44.4	1.89 [1.27,2.80]	
Total	139 / 2535	87 / 2556		1.61 [1.24,2.09]	Z=3.56, p=0.0004
Heterogeneity:	Q=1.16 (df=1)	p=0.2805	I^2=14.1%		
Subgroup Heterogeneity:	Q=2.17 (df=1)	p=0.1407	I^2=53.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.146.8: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

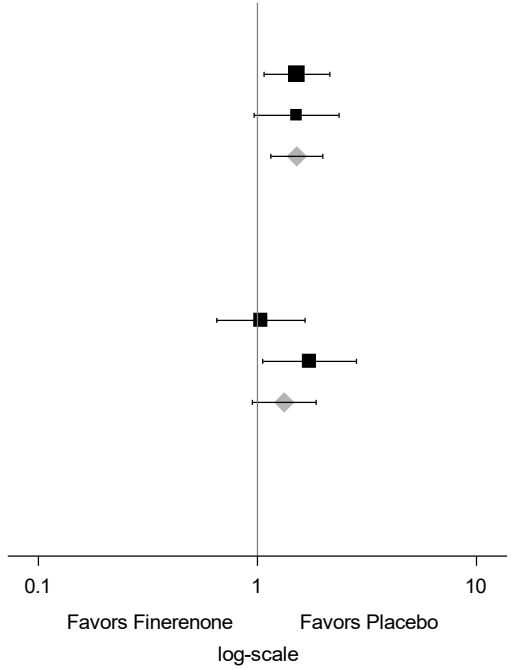
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	15 / 209	14 / 213	18.2	1.09 [0.54,2.21]	
FIGARO-DKD	87 / 1357	54 / 1356	81.8	1.61 [1.16,2.24]	
Total	102 / 1566	68 / 1569		1.50 [1.11,2.03]	Z=2.67, p=0.0075
Heterogeneity:	Q=0.96 (df=1)	p=0.3274	I^2=0.0%		
Very High					
FIDELIO-DKD	98 / 2408	71 / 2397	100.0	1.37 [1.02,1.86]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	98 / 2408	71 / 2397		1.37 [1.02,1.86]	Z=2.07, p=0.0380
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6790	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.146.9: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

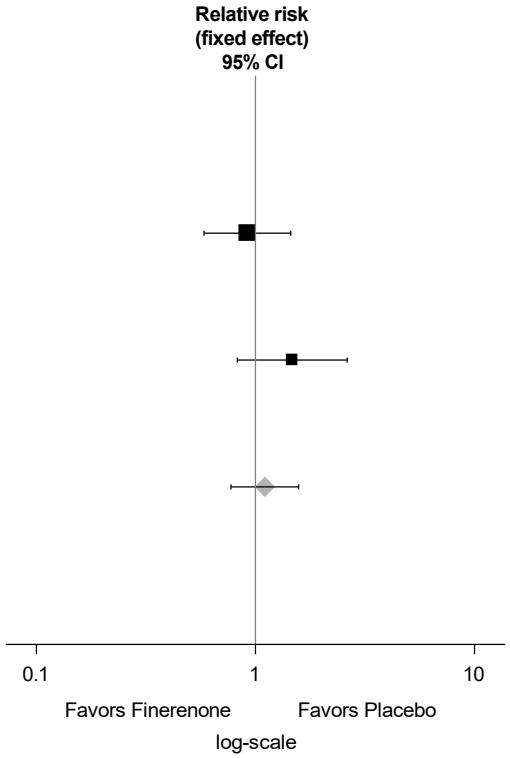
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	78 / 1556	51 / 1541	62.5	1.51 [1.07,2.14]	
FIGARO-DKD	46 / 637	30 / 627	37.5	1.51 [0.97,2.36]	
Total	124 / 2193	81 / 2168		1.51 [1.15,1.99]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.00 (df=1)	p=0.9901	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	34 / 1069	53.0	1.04 [0.65,1.65]	
FIGARO-DKD	41 / 720	24 / 729	47.0	1.73 [1.06,2.83]	
Total	76 / 1781	58 / 1798		1.33 [0.95,1.85]	Z=1.65, p=0.0994
Heterogeneity:	Q=2.19 (df=1)	p=0.1388	I^2=54.4%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5497	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.147: Forest Plot for Relative Risk of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

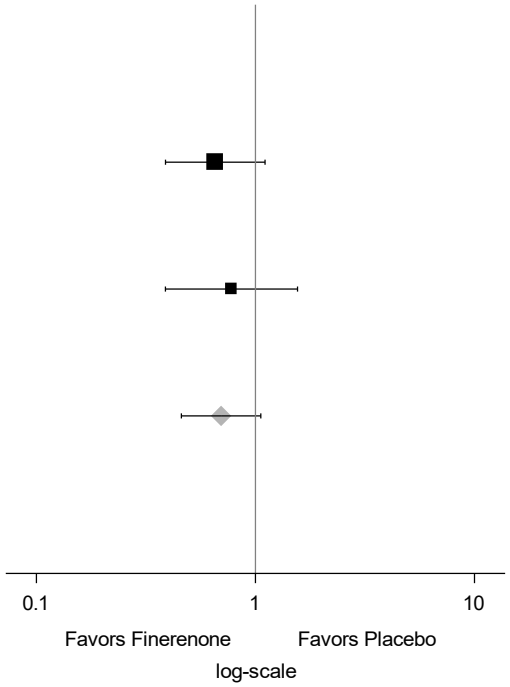
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	38 / 2610	61.6	0.92 [0.58,1.45]	
FIGARO-DKD	28 / 1357	19 / 1356	38.4	1.47 [0.83,2.62]	
Total	63 / 3974	57 / 3966		1.10 [0.77,1.57]	Z=0.54, p=0.5870
Heterogeneity:	Q=1.58 (df=1)	p=0.2088	I^2=36.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.148: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Blood and lymphatic system disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

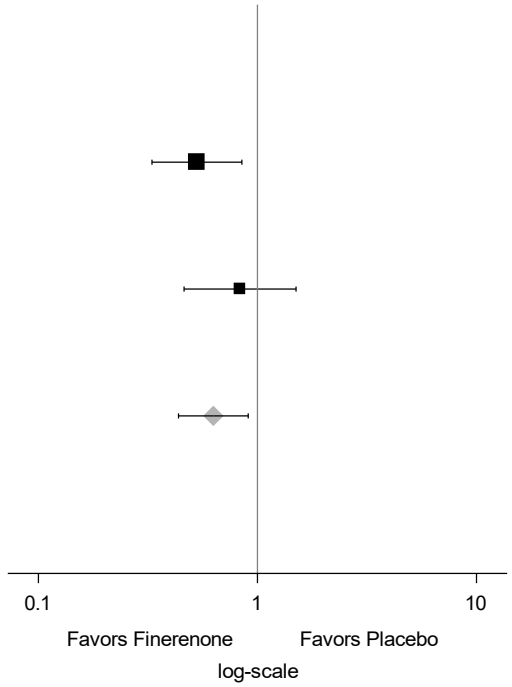
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	35 / 2610	63.8	0.66 [0.39,1.11]	
FIGARO-DKD	14 / 1357	18 / 1356	36.2	0.78 [0.39,1.56]	
Total	37 / 3974	53 / 3966		0.70 [0.46,1.06]	Z=-1.70, p=0.0899
Heterogeneity:	Q=0.15 (df=1)	p=0.7008	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.149: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

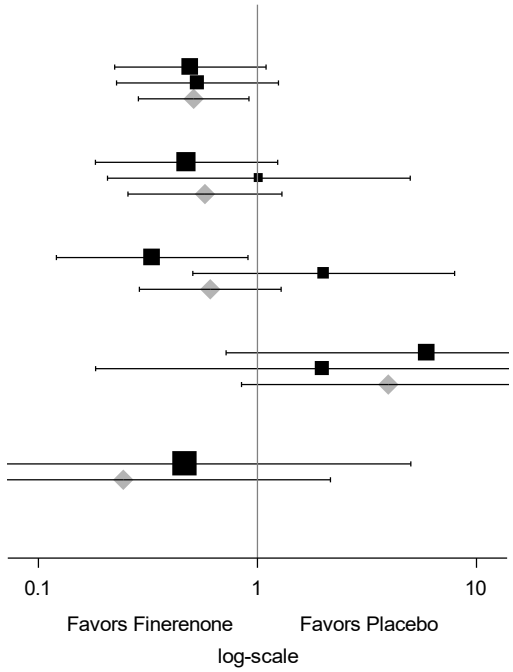
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	49 / 2610	60.8	0.53 [0.33,0.85]	
FIGARO-DKD	20 / 1357	24 / 1356	39.2	0.83 [0.46,1.50]	
Total	46 / 3974	73 / 3966		0.63 [0.44,0.91]	Z=-2.48, p=0.0131
Heterogeneity:	Q=1.39 (df=1)	p=0.2390	I^2=27.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.149.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

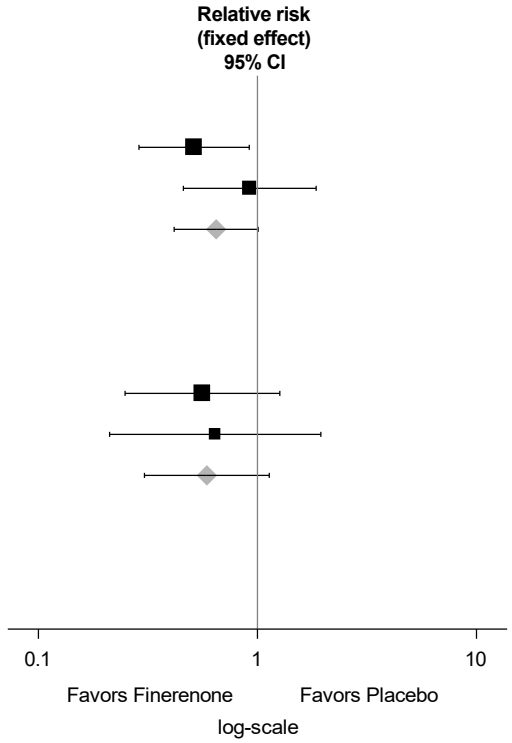
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	18 / 1062	53.4	0.49 [0.22,1.09]	
FIGARO-DKD	8 / 638	15 / 637	46.6	0.53 [0.23,1.25]	
Total	17 / 1713	33 / 1699		0.51 [0.29,0.91]	Z=-2.26, p=0.0237
Heterogeneity:	Q=0.02 (df=1)	p=0.8994	I^2=0.0%		
North America					
FIDELIO-DKD	6 / 424	13 / 436	73.4	0.47 [0.18,1.24]	
FIGARO-DKD	3 / 267	3 / 271	26.6	1.01 [0.21,4.98]	
Total	9 / 691	16 / 707		0.58 [0.26,1.29]	Z=-1.34, p=0.1812
Heterogeneity:	Q=0.64 (df=1)	p=0.4223	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 751	15 / 745	65.1	0.33 [0.12,0.91]	
FIGARO-DKD	6 / 289	3 / 290	34.9	2.01 [0.51,7.95]	
Total	11 / 1040	18 / 1035		0.61 [0.29,1.28]	Z=-1.31, p=0.1919
Heterogeneity:	Q=4.30 (df=1)	p=0.0382	I^2=76.7%		
Latin America					
FIDELIO-DKD	6 / 273	1 / 270	56.1	5.93 [0.72,48.96]	
FIGARO-DKD	2 / 102	1 / 101	43.9	1.98 [0.18,21.50]	
Total	8 / 375	2 / 371		3.96 [0.85,18.51]	Z=1.75, p=0.0806
Heterogeneity:	Q=0.47 (df=1)	p=0.4952	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,17E296]	
FIGARO-DKD	1 / 61	2 / 57	100.0	0.47 [0.04,5.01]	
Total	1 / 155	4 / 154		0.24 [0.03,2.15]	Z=-1.27, p=0.2043
Heterogeneity:	Q=0.29 (df=1)	p=0.5918	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.69 (df=4)	p=0.1530	I^2=40.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.149.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 1213	33 / 1210	59.2	0.51 [0.29,0.92]	
FIGARO-DKD	15 / 862	16 / 848	40.8	0.92 [0.46,1.85]	
Total	32 / 2075	49 / 2058		0.65 [0.42,1.01]	Z=-1.93, p=0.0538
Heterogeneity:	Q=1.60 (df=1)	p=0.2063	I^2=37.4%		
Absent					
FIDELIO-DKD	9 / 1404	16 / 1400	65.1	0.56 [0.25,1.27]	
FIGARO-DKD	5 / 495	8 / 508	34.9	0.64 [0.21,1.95]	
Total	14 / 1899	24 / 1908		0.59 [0.30,1.13]	Z=-1.59, p=0.1120
Heterogeneity:	Q=0.04 (df=1)	p=0.8485	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8086	I^2=0.0%		

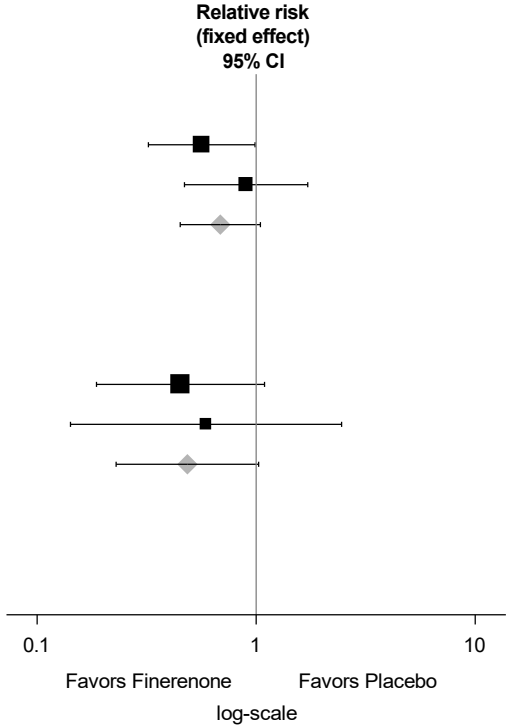


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.149.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

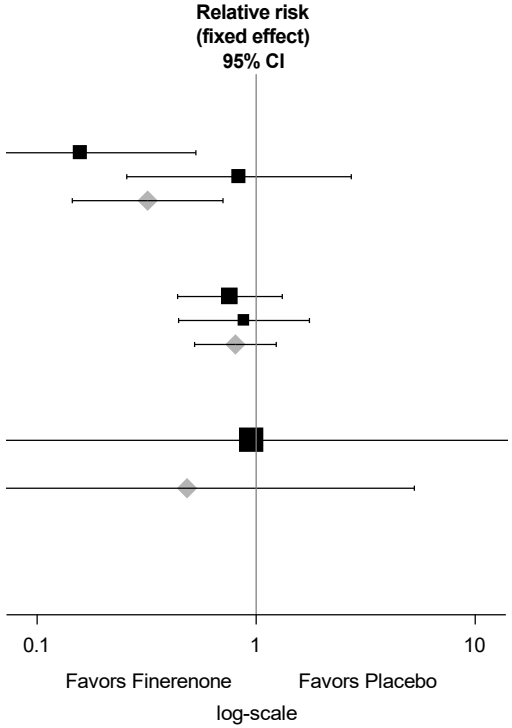
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 1735	33 / 1700	57.2	0.56 [0.32,0.99]	
FIGARO-DKD	17 / 924	19 / 929	42.8	0.90 [0.47,1.72]	
Total	36 / 2659	52 / 2629		0.69 [0.45,1.05]	Z=-1.75, p=0.0795
Heterogeneity:	Q=1.14 (df=1)	p=0.2857	I^2=12.3%		
> 4.5					
FIDELIO-DKD	7 / 882	16 / 910	72.2	0.45 [0.19,1.09]	
FIGARO-DKD	3 / 433	5 / 426	27.8	0.59 [0.14,2.45]	
Total	10 / 1315	21 / 1336		0.49 [0.23,1.03]	Z=-1.89, p=0.0585
Heterogeneity:	Q=0.10 (df=1)	p=0.7538	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.62 (df=1)	p=0.4300	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.149.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

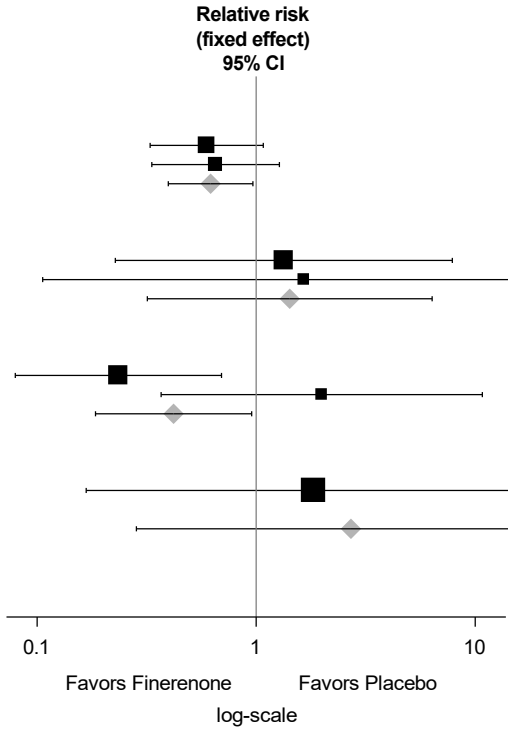
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 724	19 / 723	48.6	0.16 [0.05,0.53]	
FIGARO-DKD	5 / 494	6 / 495	51.4	0.84 [0.26,2.72]	
Total	8 / 1218	25 / 1218		0.32 [0.14,0.71]	Z=-2.82, p=0.0048
Heterogeneity:	Q=3.85 (df=1)	p=0.0499	I^2=74.0%		
130 - < 160					
FIDELIO-DKD	22 / 1759	29 / 1760	61.0	0.76 [0.44,1.32]	
FIGARO-DKD	15 / 829	17 / 827	39.0	0.88 [0.44,1.75]	
Total	37 / 2588	46 / 2587		0.80 [0.52,1.24]	Z=-1.00, p=0.3193
Heterogeneity:	Q=0.11 (df=1)	p=0.7417	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	1 / 127	100.0	0.95 [0.06,15.10]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,11E296]	
Total	1 / 167	2 / 161		0.48 [0.04,5.27]	Z=-0.60, p=0.5510
Heterogeneity:	Q=0.23 (df=1)	p=0.6289	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.09 (df=2)	p=0.1295	I^2=51.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.149.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

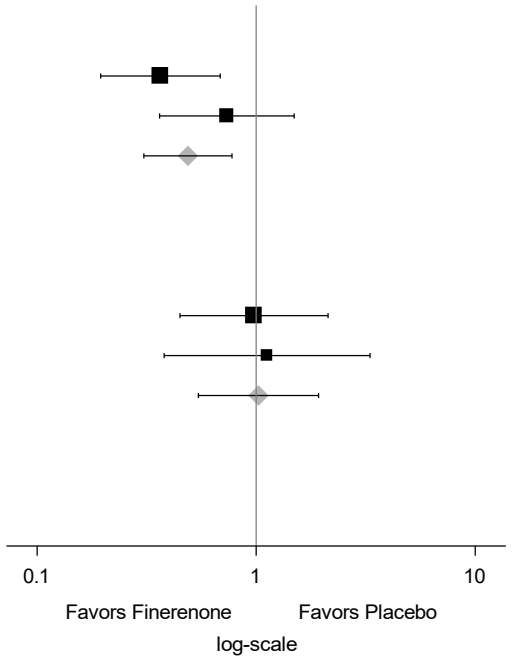
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 1634	29 / 1657	56.0	0.59 [0.33,1.08]	
FIGARO-DKD	14 / 1010	21 / 989	44.0	0.65 [0.33,1.28]	
Total	31 / 2644	50 / 2646		0.62 [0.40,0.97]	Z=-2.11, p=0.0347
Heterogeneity:	Q=0.04 (df=1)	p=0.8378	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 129	2 / 115	70.6	1.34 [0.23,7.86]	
FIGARO-DKD	1 / 43	1 / 71	29.4	1.65 [0.11,25.72]	
Total	4 / 172	3 / 186		1.42 [0.32,6.36]	Z=0.46, p=0.6442
Heterogeneity:	Q=0.02 (df=1)	p=0.8993	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 678	17 / 677	70.8	0.23 [0.08,0.69]	
FIGARO-DKD	4 / 252	2 / 251	29.2	1.99 [0.37,10.78]	
Total	8 / 930	19 / 928		0.42 [0.18,0.95]	Z=-2.07, p=0.0382
Heterogeneity:	Q=4.37 (df=1)	p=0.0366	I^2=77.1%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.83 [0.17,19.99]	
FIGARO-DKD	1 / 52	0 / 45	0.0	1E11 [1E11,1E11]	
Total	3 / 228	1 / 206		2.71 [0.28,25.83]	Z=0.87, p=0.3867
Heterogeneity:	Q=0.10 (df=1)	p=0.7479	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.69 (df=3)	p=0.2971	I^2=18.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.149.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

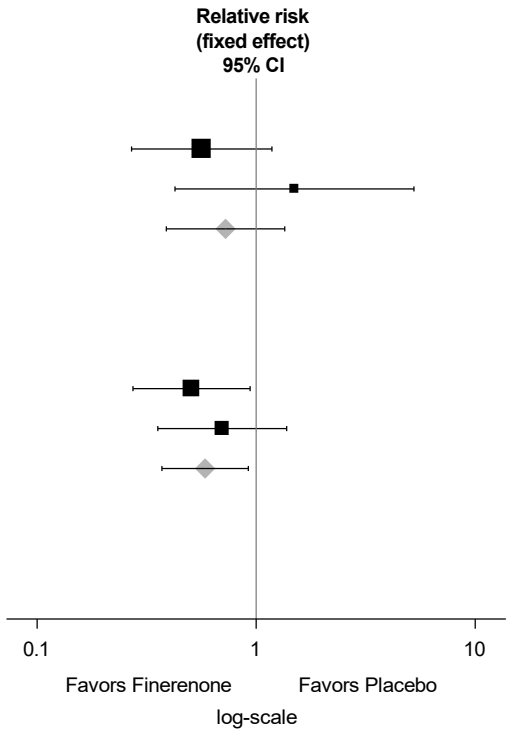
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	13 / 1797	37 / 1870	55.9	0.37 [0.20,0.69]	
FIGARO-DKD	13 / 917	18 / 933	44.1	0.73 [0.36,1.49]	
Total	26 / 2714	55 / 2803		0.49 [0.31,0.78]	Z=-3.03, p=0.0024
Heterogeneity:	Q=2.10 (df=1)	p=0.1477	I^2=52.3%		
Female					
FIDELIO-DKD	13 / 820	12 / 740	65.9	0.98 [0.45,2.13]	
FIGARO-DKD	7 / 440	6 / 423	34.1	1.12 [0.38,3.31]	
Total	20 / 1260	18 / 1163		1.02 [0.54,1.93]	Z=0.08, p=0.9398
Heterogeneity:	Q=0.04 (df=1)	p=0.8399	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.44 (df=1)	p=0.0635	I^2=71.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.149.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

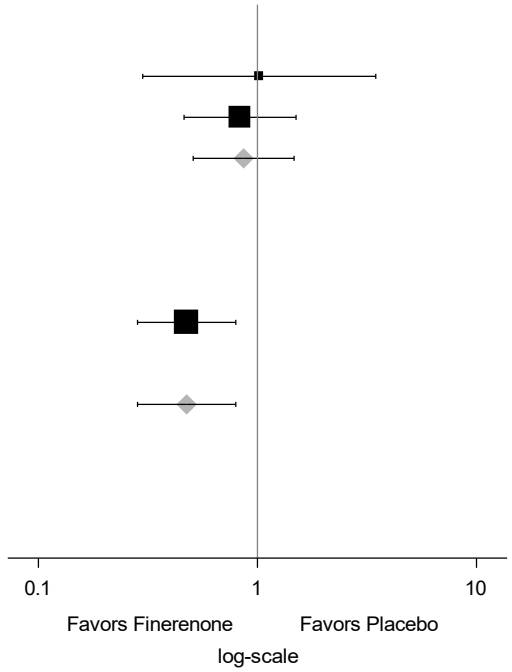
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1103	19 / 1075	74.3	0.56 [0.27,1.18]	
FIGARO-DKD	6 / 336	4 / 335	25.7	1.50 [0.43,5.25]	
Total	17 / 1439	23 / 1410		0.72 [0.39,1.35]	Z=-1.01, p=0.3105
Heterogeneity:	Q=1.72 (df=1)	p=0.1897	I^2=41.9%		
>= 65					
FIDELIO-DKD	15 / 1514	30 / 1535	54.8	0.51 [0.27,0.94]	
FIGARO-DKD	14 / 1021	20 / 1021	45.2	0.70 [0.36,1.38]	
Total	29 / 2535	50 / 2556		0.58 [0.37,0.92]	Z=-2.32, p=0.0205
Heterogeneity:	Q=0.48 (df=1)	p=0.4895	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5852	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.149.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

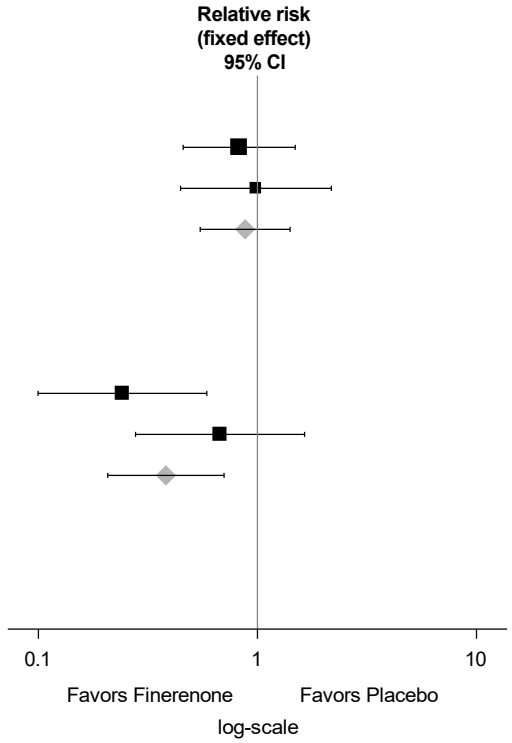
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	5 / 209	5 / 213	18.8	1.02 [0.30,3.47]	
FIGARO-DKD	20 / 1357	24 / 1356	81.2	0.83 [0.46,1.50]	
Total	25 / 1566	29 / 1569		0.86 [0.51,1.47]	Z=-0.54, p=0.5912
Heterogeneity:	Q=0.08 (df=1)	p=0.7708	I^2=0.0%		
Very High					
FIDELIO-DKD	21 / 2408	44 / 2397	100.0	0.48 [0.28,0.80]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	21 / 2408	44 / 2397		0.48 [0.28,0.80]	Z=-2.82, p=0.0048
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.51 (df=1)	p=0.1128	I^2=60.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.149.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

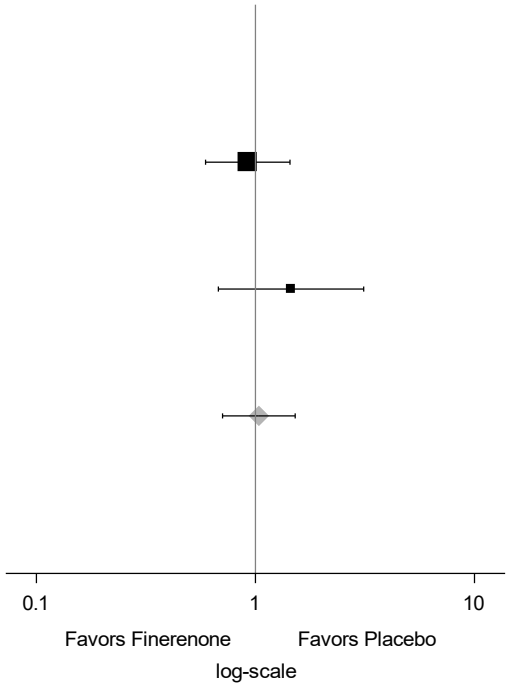
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	20 / 1556	24 / 1541	64.4	0.83 [0.46,1.49]	
FIGARO-DKD	12 / 637	12 / 627	35.6	0.98 [0.45,2.17]	
Total	32 / 2193	36 / 2168		0.88 [0.55,1.41]	Z=-0.54, p=0.5912
Heterogeneity:	Q=0.12 (df=1)	p=0.7266	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	6 / 1061	25 / 1069	50.1	0.24 [0.10,0.59]	
FIGARO-DKD	8 / 720	12 / 729	49.9	0.68 [0.28,1.64]	
Total	14 / 1781	37 / 1798		0.38 [0.21,0.70]	Z=-3.09, p=0.0020
Heterogeneity:	Q=2.60 (df=1)	p=0.1070	I^2=61.5%		
Subgroup Heterogeneity:	Q=4.47 (df=1)	p=0.0346	I^2=77.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.150: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

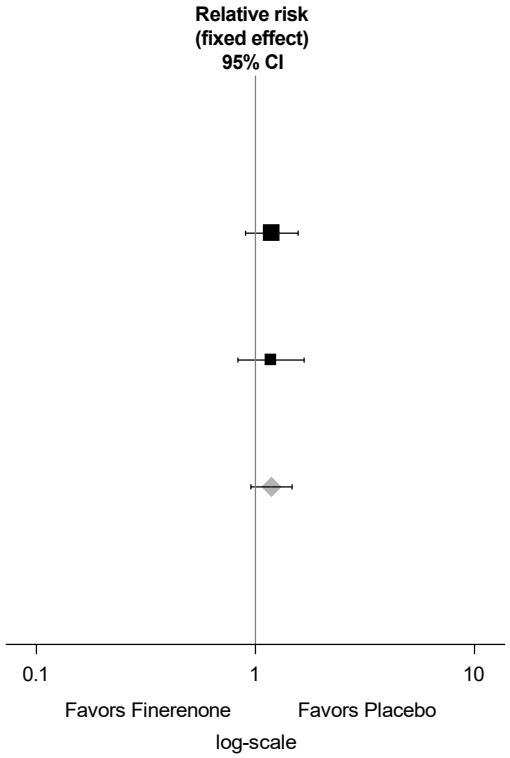
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	40 / 2610	74.8	0.92 [0.59,1.44]	
FIGARO-DKD	16 / 1357	11 / 1356	25.2	1.45 [0.68,3.12]	
Total	53 / 3974	51 / 3966		1.04 [0.71,1.52]	Z=0.18, p=0.8539
Heterogeneity:	Q=1.02 (df=1)	p=0.3132	I^2=1.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.151: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

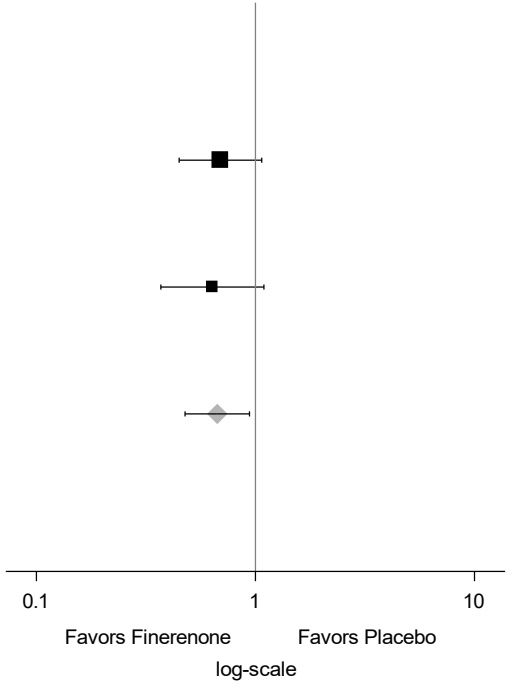
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	106 / 2617	89 / 2610	61.3	1.19 [0.90,1.57]	
FIGARO-DKD	66 / 1357	56 / 1356	38.7	1.18 [0.83,1.67]	
Total	172 / 3974	145 / 3966		1.18 [0.95,1.47]	Z=1.53, p=0.1265
Heterogeneity:	Q=0.00 (df=1)	p=0.9699	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.152: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

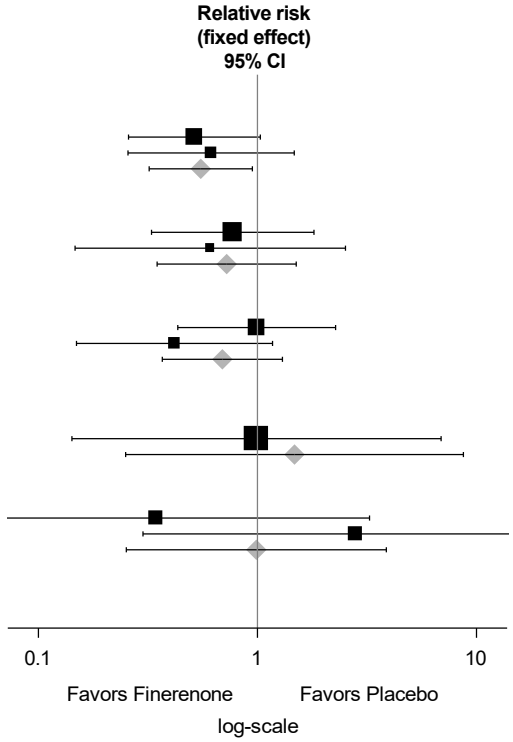
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2617	49 / 2610	60.9	0.69 [0.45,1.07]	
FIGARO-DKD	21 / 1357	33 / 1356	39.1	0.64 [0.37,1.09]	
Total	55 / 3974	82 / 3966		0.67 [0.48,0.94]	Z=-2.32, p=0.0202
Heterogeneity:	Q=0.06 (df=1)	p=0.8113	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.152.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

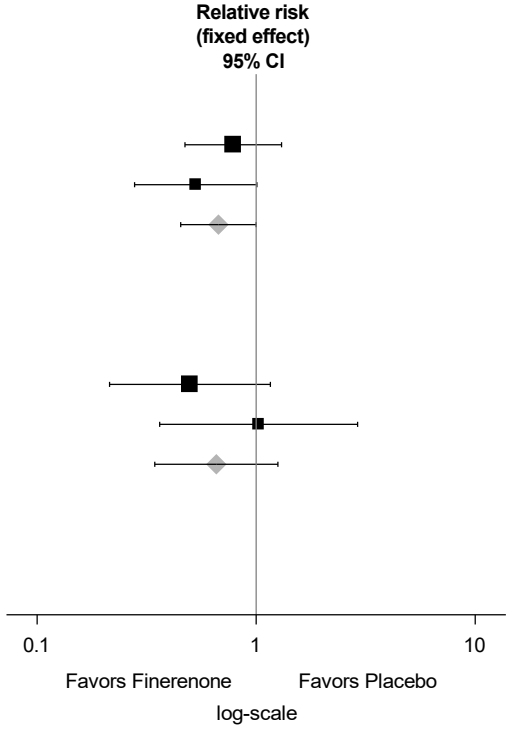
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 1075	23 / 1062	61.4	0.52 [0.26,1.03]	
FIGARO-DKD	8 / 638	13 / 637	38.6	0.61 [0.26,1.47]	
Total	20 / 1713	36 / 1699		0.55 [0.32,0.95]	Z=-2.15, p=0.0313
Heterogeneity:	Q=0.10 (df=1)	p=0.7575	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 424	12 / 436	73.5	0.77 [0.33,1.81]	
FIGARO-DKD	3 / 267	5 / 271	26.5	0.61 [0.15,2.52]	
Total	12 / 691	17 / 707		0.72 [0.35,1.50]	Z=-0.87, p=0.3857
Heterogeneity:	Q=0.08 (df=1)	p=0.7801	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 751	11 / 745	60.7	0.99 [0.43,2.27]	
FIGARO-DKD	5 / 289	12 / 290	39.3	0.42 [0.15,1.17]	
Total	16 / 1040	23 / 1035		0.69 [0.37,1.30]	Z=-1.15, p=0.2522
Heterogeneity:	Q=1.64 (df=1)	p=0.2000	I^2=39.1%		
Latin America					
FIDELIO-DKD	1 / 273	0 / 270	0.0	141E9 [141E9,141E9]	
FIGARO-DKD	2 / 102	2 / 101	100.0	0.99 [0.14,6.89]	
Total	3 / 375	2 / 371		1.48 [0.25,8.71]	Z=0.43, p=0.6671
Heterogeneity:	Q=0.16 (df=1)	p=0.6866	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	49.8	0.34 [0.04,3.25]	
FIGARO-DKD	3 / 61	1 / 57	50.2	2.80 [0.30,26.18]	
Total	4 / 155	4 / 154		0.99 [0.25,3.88]	Z=-0.02, p=0.9864
Heterogeneity:	Q=1.69 (df=1)	p=0.1942	I^2=40.7%		
Subgroup Heterogeneity:	Q=1.62 (df=4)	p=0.8048	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.152.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

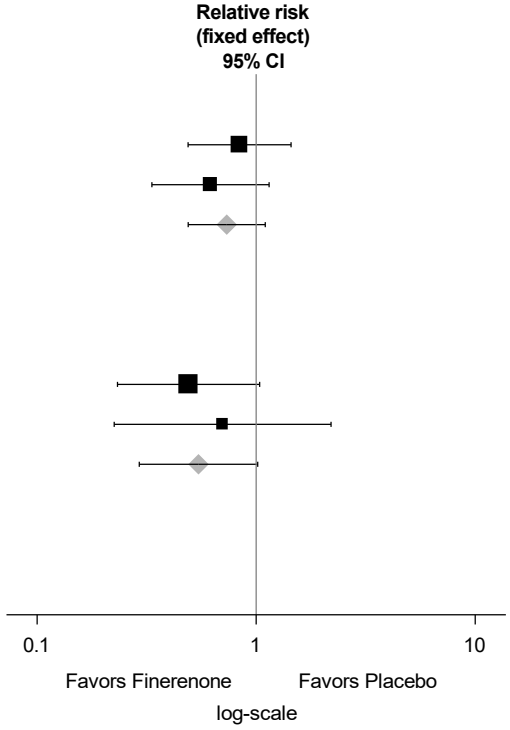
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 1213	33 / 1210	61.6	0.79 [0.47,1.31]	
FIGARO-DKD	14 / 862	26 / 848	38.4	0.53 [0.28,1.01]	
Total	40 / 2075	59 / 2058		0.67 [0.45,1.00]	Z=-1.96, p=0.0501
Heterogeneity:	Q=0.89 (df=1)	p=0.3451	I^2=0.0%		
Absent					
FIDELIO-DKD	8 / 1404	16 / 1400	60.2	0.50 [0.21,1.16]	
FIGARO-DKD	7 / 495	7 / 508	39.8	1.03 [0.36,2.90]	
Total	15 / 1899	23 / 1908		0.66 [0.34,1.26]	Z=-1.27, p=0.2047
Heterogeneity:	Q=1.11 (df=1)	p=0.2910	I^2=10.3%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9543	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.152.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

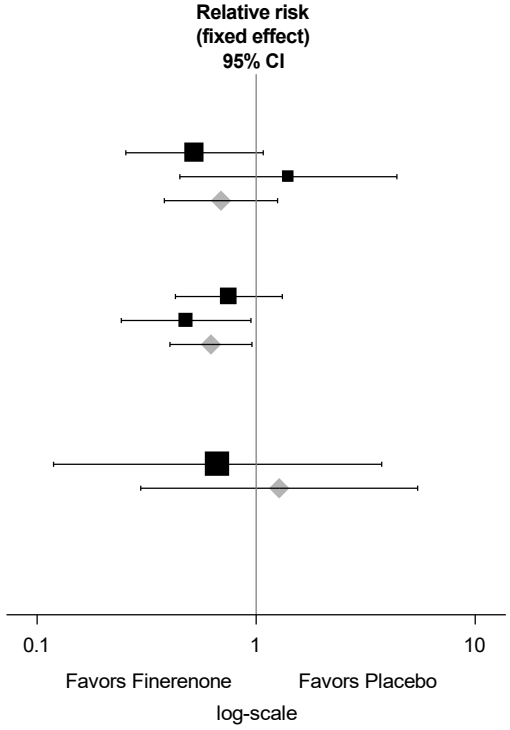
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	24 / 1735	28 / 1700	56.5	0.84 [0.49,1.44]	
FIGARO-DKD	16 / 924	26 / 929	43.5	0.62 [0.33,1.15]	
Total	40 / 2659	54 / 2629		0.73 [0.49,1.10]	Z=-1.50, p=0.1343
Heterogeneity:	Q=0.53 (df=1)	p=0.4651	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 882	21 / 910	69.9	0.49 [0.23,1.04]	
FIGARO-DKD	5 / 433	7 / 426	30.1	0.70 [0.22,2.20]	
Total	15 / 1315	28 / 1336		0.55 [0.29,1.02]	Z=-1.91, p=0.0562
Heterogeneity:	Q=0.27 (df=1)	p=0.6067	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4333	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.152.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

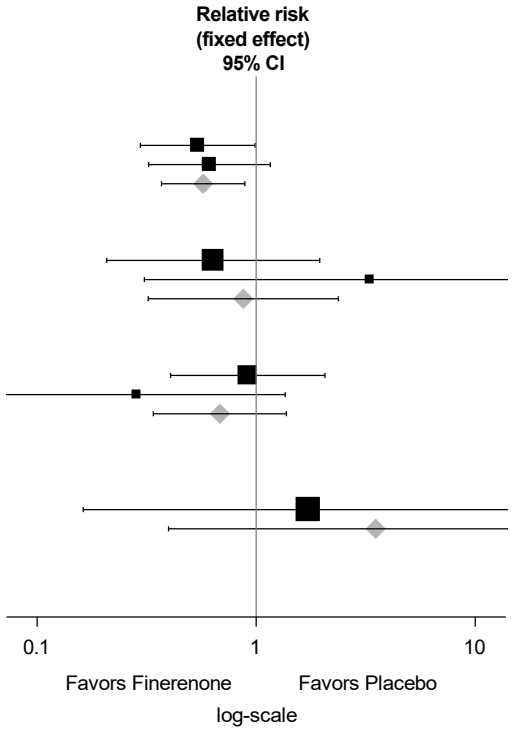
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	11 / 724	21 / 723	71.4	0.52 [0.25,1.08]	
FIGARO-DKD	7 / 494	5 / 495	28.6	1.40 [0.45,4.39]	
Total	18 / 1218	26 / 1218		0.69 [0.38,1.25]	Z=-1.22, p=0.2230
Heterogeneity:	Q=2.05 (df=1)	p=0.1521	I^2=51.2%		
130 - < 160					
FIDELIO-DKD	21 / 1759	28 / 1760	59.5	0.75 [0.43,1.32]	
FIGARO-DKD	12 / 829	25 / 827	40.5	0.48 [0.24,0.95]	
Total	33 / 2588	53 / 2587		0.62 [0.40,0.96]	Z=-2.16, p=0.0306
Heterogeneity:	Q=0.99 (df=1)	p=0.3186	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 133	0 / 127	0.0	213E9 [213E9,213E9]	
FIGARO-DKD	2 / 34	3 / 34	100.0	0.67 [0.12,3.74]	
Total	4 / 167	3 / 161		1.27 [0.30,5.46]	Z=0.33, p=0.7445
Heterogeneity:	Q=0.54 (df=1)	p=0.4619	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.87 (df=2)	p=0.6459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.152.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

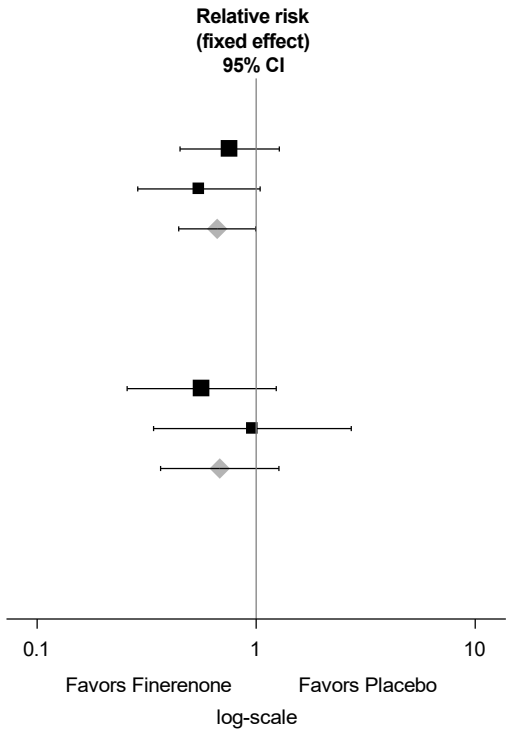
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	16 / 1634	30 / 1657	52.9	0.54 [0.30,0.99]	
FIGARO-DKD	15 / 1010	24 / 989	47.1	0.61 [0.32,1.16]	
Total	31 / 2644	54 / 2646		0.57 [0.37,0.89]	Z=-2.49, p=0.0127
Heterogeneity:	Q=0.08 (df=1)	p=0.7827	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	7 / 115	81.8	0.64 [0.21,1.95]	
FIGARO-DKD	2 / 43	1 / 71	18.2	3.30 [0.31,35.34]	
Total	7 / 172	8 / 186		0.87 [0.32,2.37]	Z=-0.27, p=0.7906
Heterogeneity:	Q=1.52 (df=1)	p=0.2183	I^2=34.0%		
Asian					
FIDELIO-DKD	11 / 678	12 / 677	78.8	0.92 [0.41,2.06]	
FIGARO-DKD	2 / 252	7 / 251	21.2	0.28 [0.06,1.36]	
Total	13 / 930	19 / 928		0.68 [0.34,1.37]	Z=-1.07, p=0.2847
Heterogeneity:	Q=1.71 (df=1)	p=0.1912	I^2=41.5%		
Others					
FIDELIO-DKD	2 / 176	0 / 161	0.0	161E9 [161E9,161E9]	
FIGARO-DKD	2 / 52	1 / 45	100.0	1.73 [0.16,18.46]	
Total	4 / 228	1 / 206		3.51 [0.40,30.97]	Z=1.13, p=0.2582
Heterogeneity:	Q=0.34 (df=1)	p=0.5580	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.97 (df=3)	p=0.3956	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.152.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

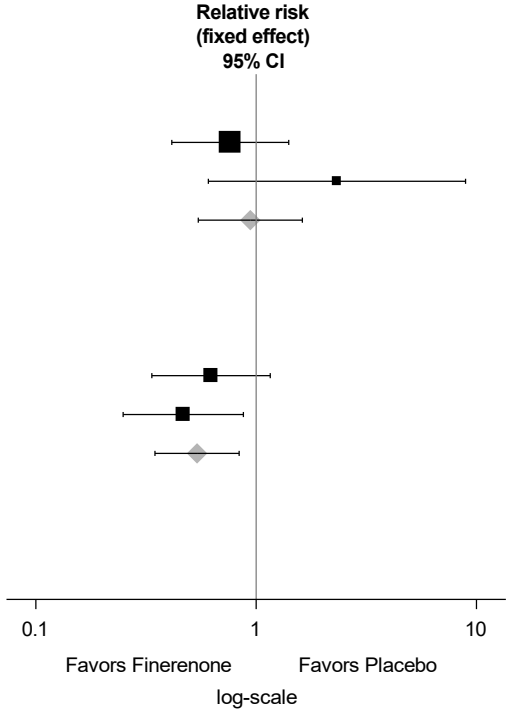
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 1797	33 / 1870	60.3	0.76 [0.45,1.28]	
FIGARO-DKD	14 / 917	26 / 933	39.7	0.55 [0.29,1.04]	
Total	38 / 2714	59 / 2803		0.66 [0.44,0.99]	Z=-1.99, p=0.0468
Heterogeneity:	Q=0.58 (df=1)	p=0.4445	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	16 / 740	63.7	0.56 [0.26,1.24]	
FIGARO-DKD	7 / 440	7 / 423	36.3	0.96 [0.34,2.72]	
Total	17 / 1260	23 / 1163		0.68 [0.37,1.27]	Z=-1.21, p=0.2275
Heterogeneity:	Q=0.64 (df=1)	p=0.4219	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9432	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.152.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

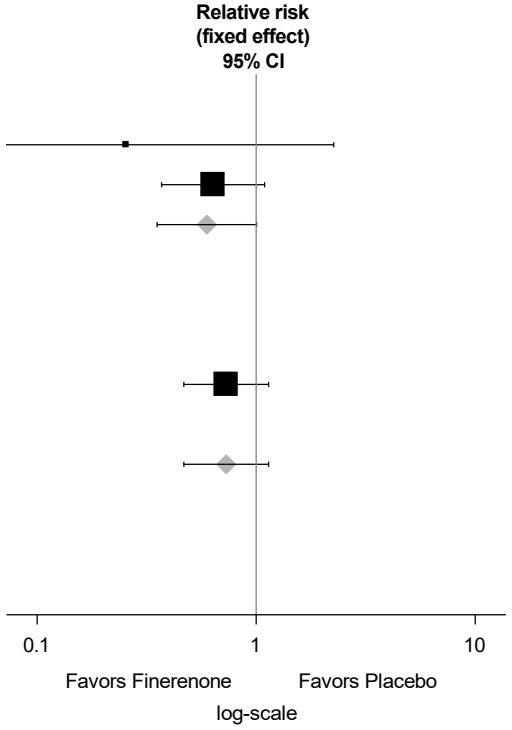
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 1103	23 / 1075	82.9	0.76 [0.41,1.41]	
FIGARO-DKD	7 / 336	3 / 335	17.1	2.33 [0.61,8.92]	
Total	25 / 1439	26 / 1410		0.94 [0.55,1.62]	Z=-0.22, p=0.8256
Heterogeneity:	Q=2.20 (df=1)	p=0.1384	I^2=54.5%		
>= 65					
FIDELIO-DKD	16 / 1514	26 / 1535	50.8	0.62 [0.34,1.16]	
FIGARO-DKD	14 / 1021	30 / 1021	49.2	0.47 [0.25,0.87]	
Total	30 / 2535	56 / 2556		0.54 [0.35,0.84]	Z=-2.75, p=0.0059
Heterogeneity:	Q=0.42 (df=1)	p=0.5185	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1188	I^2=58.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.152.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

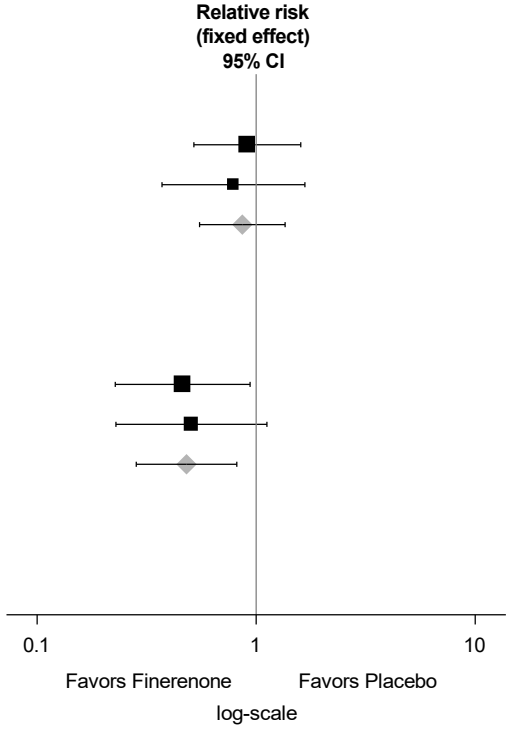
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	4 / 213	5.8	0.25 [0.03,2.26]	
FIGARO-DKD	21 / 1357	33 / 1356	94.2	0.64 [0.37,1.09]	
Total	22 / 1566	37 / 1569		0.60 [0.35,1.00]	Z=-1.94, p=0.0520
Heterogeneity:	Q=0.64 (df=1)	p=0.4246	I^2=0.0%		
Very High					
FIDELIO-DKD	33 / 2408	45 / 2397	100.0	0.73 [0.47,1.14]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	33 / 2408	45 / 2397		0.73 [0.47,1.14]	Z=-1.38, p=0.1663
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5611	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.152.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

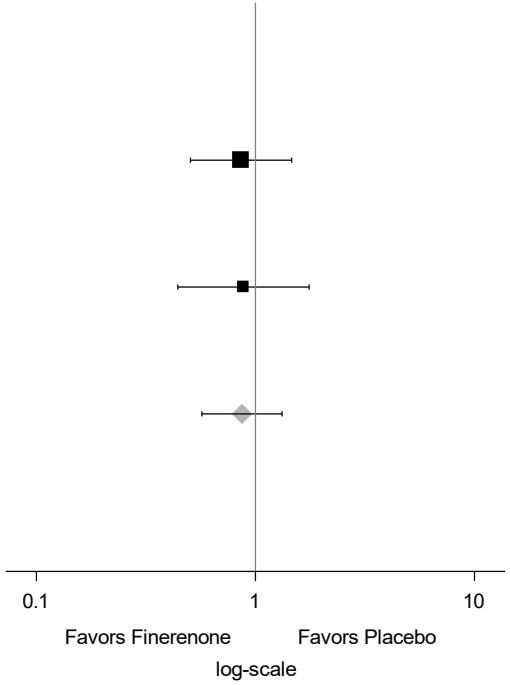
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	23 / 1556	25 / 1541	64.1	0.91 [0.52,1.60]	
FIGARO-DKD	12 / 637	15 / 627	35.9	0.79 [0.37,1.67]	
Total	35 / 2193	40 / 2168		0.86 [0.55,1.36]	Z=-0.63, p=0.5256
Heterogeneity:	Q=0.09 (df=1)	p=0.7605	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	24 / 1069	55.6	0.46 [0.23,0.94]	
FIGARO-DKD	9 / 720	18 / 729	44.4	0.51 [0.23,1.12]	
Total	20 / 1781	42 / 1798		0.48 [0.28,0.82]	Z=-2.72, p=0.0066
Heterogeneity:	Q=0.03 (df=1)	p=0.8655	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=1)	p=0.0975	I^2=63.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.153: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

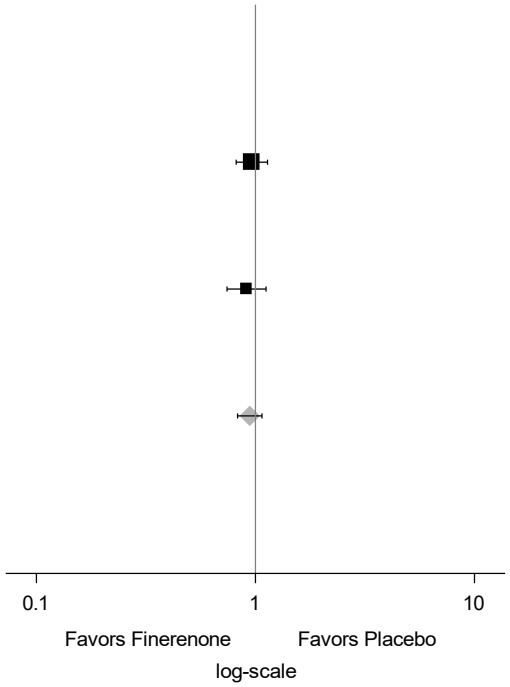
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	29 / 2610	62.7	0.86 [0.50,1.46]	
FIGARO-DKD	15 / 1357	17 / 1356	37.3	0.88 [0.44,1.76]	
Total	40 / 3974	46 / 3966		0.87 [0.57,1.32]	Z=-0.66, p=0.5099
Heterogeneity:	Q=0.00 (df=1)	p=0.9548	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.154: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

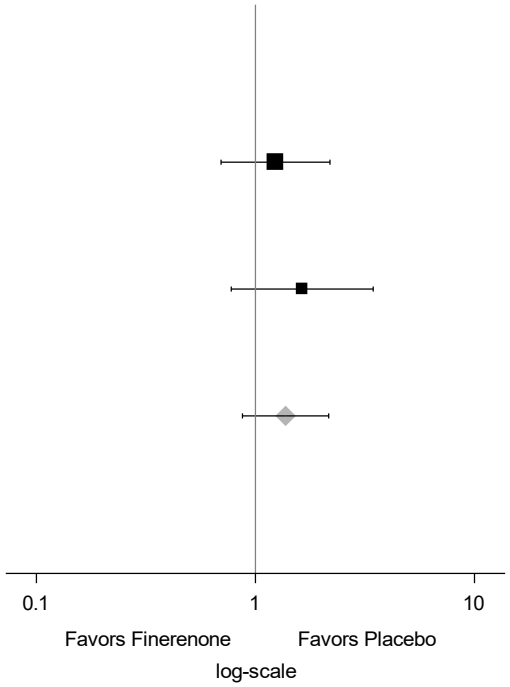
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	251 / 2617	260 / 2610	60.8	0.96 [0.82,1.14]	
FIGARO-DKD	154 / 1357	169 / 1356	39.2	0.91 [0.74,1.12]	
Total	405 / 3974	429 / 3966		0.94 [0.83,1.07]	Z=-0.91, p=0.3612
Heterogeneity:	Q=0.17 (df=1)	p=0.6776	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.155: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

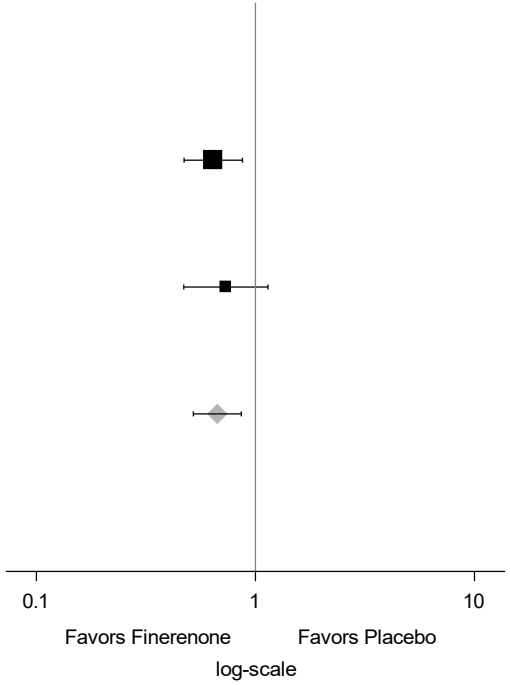
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	21 / 2610	63.0	1.23 [0.70,2.19]	
FIGARO-DKD	18 / 1357	11 / 1356	37.0	1.64 [0.78,3.45]	
Total	44 / 3974	32 / 3966		1.37 [0.87,2.16]	Z=1.37, p=0.1709
Heterogeneity:	Q=0.34 (df=1)	p=0.5584	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.156: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

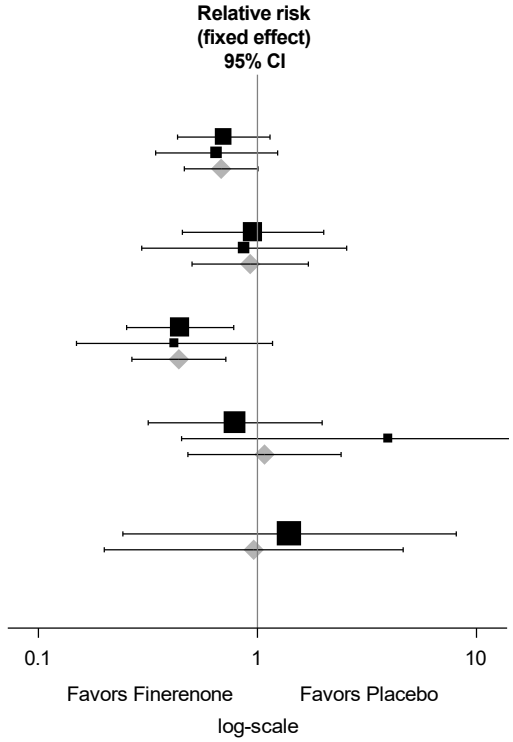
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 2617	101 / 2610	67.6	0.64 [0.47,0.87]	
FIGARO-DKD	33 / 1357	45 / 1356	32.4	0.73 [0.47,1.14]	
Total	98 / 3974	146 / 3966		0.67 [0.52,0.86]	Z=-3.12, p=0.0018
Heterogeneity:	Q=0.23 (df=1)	p=0.6298	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.156.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

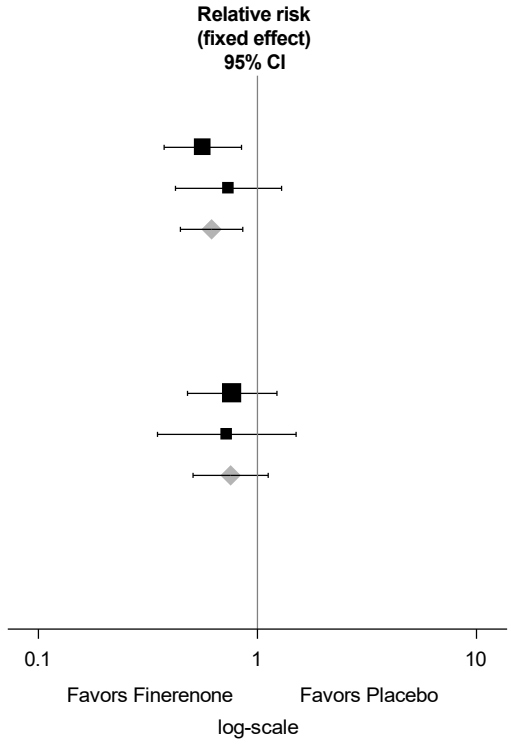
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 1075	38 / 1062	63.5	0.70 [0.43,1.14]	
FIGARO-DKD	15 / 638	23 / 637	36.5	0.65 [0.34,1.24]	
Total	42 / 1713	61 / 1699		0.68 [0.46,1.01]	Z=-1.93, p=0.0535
Heterogeneity:	Q=0.03 (df=1)	p=0.8548	I^2=0.0%		
North America					
FIDELIO-DKD	13 / 424	14 / 436	67.8	0.95 [0.45,2.01]	
FIGARO-DKD	6 / 267	7 / 271	32.2	0.87 [0.30,2.55]	
Total	19 / 691	21 / 707		0.93 [0.50,1.71]	Z=-0.24, p=0.8069
Heterogeneity:	Q=0.02 (df=1)	p=0.8891	I^2=0.0%		
Asia					
FIDELIO-DKD	17 / 751	38 / 745	77.0	0.44 [0.25,0.78]	
FIGARO-DKD	5 / 289	12 / 290	23.0	0.42 [0.15,1.17]	
Total	22 / 1040	50 / 1035		0.44 [0.27,0.72]	Z=-3.28, p=0.0010
Heterogeneity:	Q=0.01 (df=1)	p=0.9207	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 273	10 / 270	85.0	0.79 [0.32,1.97]	
FIGARO-DKD	4 / 102	1 / 101	15.0	3.96 [0.45,34.83]	
Total	12 / 375	11 / 371		1.08 [0.48,2.41]	Z=0.18, p=0.8569
Heterogeneity:	Q=1.82 (df=1)	p=0.1779	I^2=44.9%		
Others					
FIDELIO-DKD	0 / 94	1 / 97	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	3 / 61	2 / 57	100.0	1.40 [0.24,8.09]	
Total	3 / 155	3 / 154		0.96 [0.20,4.63]	Z=-0.05, p=0.9609
Heterogeneity:	Q=0.18 (df=1)	p=0.6733	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.48 (df=4)	p=0.2418	I^2=27.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.156.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

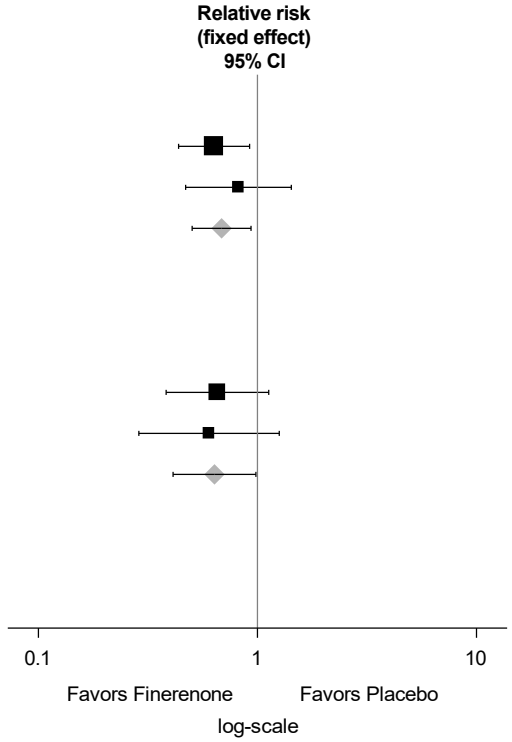
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	35 / 1213	62 / 1210	65.3	0.56 [0.37,0.85]	
FIGARO-DKD	21 / 862	28 / 848	34.7	0.74 [0.42,1.29]	
Total	56 / 2075	90 / 2058		0.62 [0.44,0.86]	Z=-2.88, p=0.0039
Heterogeneity:	Q=0.59 (df=1)	p=0.4429	I^2=0.0%		
Absent					
FIDELIO-DKD	30 / 1404	39 / 1400	70.6	0.77 [0.48,1.23]	
FIGARO-DKD	12 / 495	17 / 508	29.4	0.72 [0.35,1.50]	
Total	42 / 1899	56 / 1908		0.75 [0.51,1.12]	Z=-1.40, p=0.1616
Heterogeneity:	Q=0.02 (df=1)	p=0.8972	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.58 (df=1)	p=0.4446	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.156.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

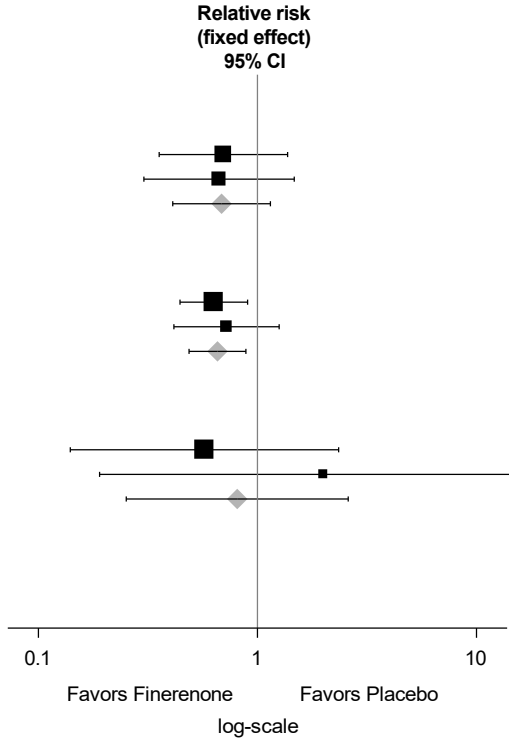
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	44 / 1735	68 / 1700	68.9	0.63 [0.44,0.92]	
FIGARO-DKD	22 / 924	27 / 929	31.1	0.82 [0.47,1.43]	
Total	66 / 2659	95 / 2629		0.69 [0.50,0.93]	Z=-2.39, p=0.0169
Heterogeneity:	Q=0.56 (df=1)	p=0.4529	I^2=0.0%		
> 4.5					
FIDELIO-DKD	21 / 882	33 / 910	65.2	0.66 [0.38,1.13]	
FIGARO-DKD	11 / 433	18 / 426	34.8	0.60 [0.29,1.26]	
Total	32 / 1315	51 / 1336		0.64 [0.41,0.98]	Z=-2.03, p=0.0421
Heterogeneity:	Q=0.04 (df=1)	p=0.8503	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7846	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.156.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

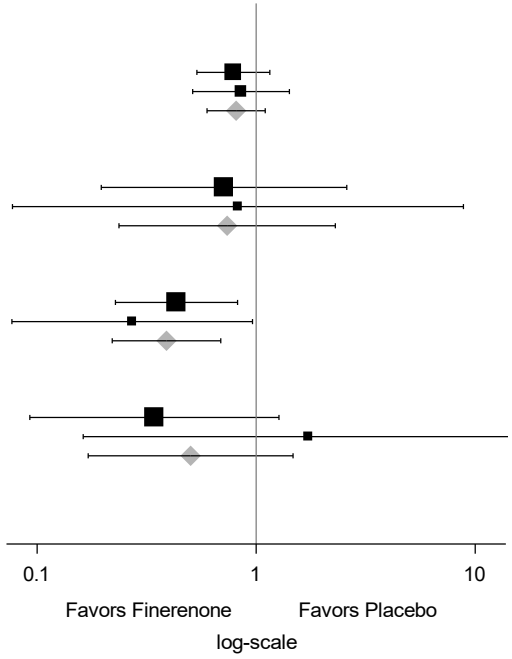
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 724	20 / 723	57.8	0.70 [0.36,1.37]	
FIGARO-DKD	10 / 494	15 / 495	42.2	0.67 [0.30,1.47]	
Total	24 / 1218	35 / 1218		0.69 [0.41,1.15]	Z=-1.44, p=0.1497
Heterogeneity:	Q=0.01 (df=1)	p=0.9318	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	48 / 1759	76 / 1760	70.8	0.63 [0.44,0.90]	
FIGARO-DKD	21 / 829	29 / 827	29.2	0.72 [0.42,1.26]	
Total	69 / 2588	105 / 2587		0.66 [0.49,0.89]	Z=-2.76, p=0.0058
Heterogeneity:	Q=0.16 (df=1)	p=0.6901	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 133	5 / 127	73.6	0.57 [0.14,2.35]	
FIGARO-DKD	2 / 34	1 / 34	26.4	2.00 [0.19,21.03]	
Total	5 / 167	6 / 161		0.81 [0.25,2.60]	Z=-0.36, p=0.7209
Heterogeneity:	Q=0.80 (df=1)	p=0.3716	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=2)	p=0.9397	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.156.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

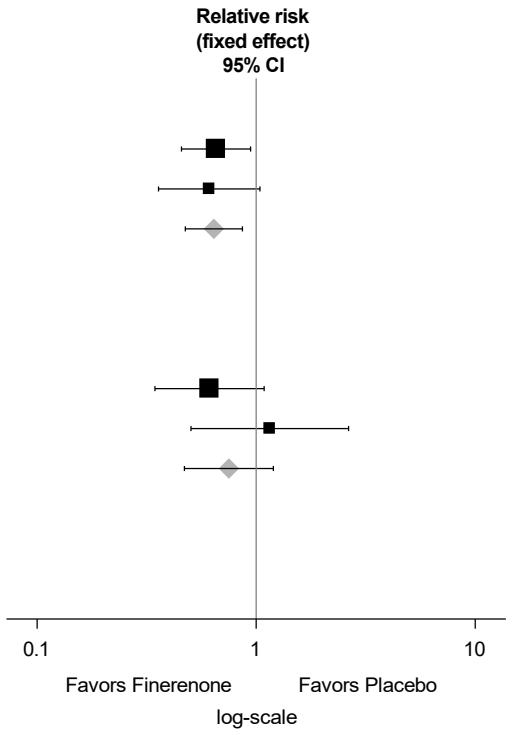
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 1634	58 / 1657	63.8	0.79 [0.54,1.15]	
FIGARO-DKD	27 / 1010	31 / 989	36.2	0.85 [0.51,1.42]	
Total	72 / 2644	89 / 2646		0.81 [0.60,1.10]	Z=-1.35, p=0.1772
Heterogeneity:	Q=0.06 (df=1)	p=0.8040	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 129	5 / 115	77.1	0.71 [0.20,2.59]	
FIGARO-DKD	1 / 43	2 / 71	22.9	0.83 [0.08,8.84]	
Total	5 / 172	7 / 186		0.74 [0.24,2.30]	Z=-0.53, p=0.5990
Heterogeneity:	Q=0.01 (df=1)	p=0.9154	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 678	30 / 677	79.5	0.43 [0.23,0.82]	
FIGARO-DKD	3 / 252	11 / 251	20.5	0.27 [0.08,0.96]	
Total	16 / 930	41 / 928		0.39 [0.22,0.69]	Z=-3.24, p=0.0012
Heterogeneity:	Q=0.42 (df=1)	p=0.5194	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 176	8 / 161	76.6	0.34 [0.09,1.27]	
FIGARO-DKD	2 / 52	1 / 45	23.4	1.73 [0.16,18.46]	
Total	5 / 228	9 / 206		0.50 [0.17,1.47]	Z=-1.25, p=0.2097
Heterogeneity:	Q=1.38 (df=1)	p=0.2409	I^2=27.3%		
Subgroup Heterogeneity:	Q=5.24 (df=3)	p=0.1547	I^2=42.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.156.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

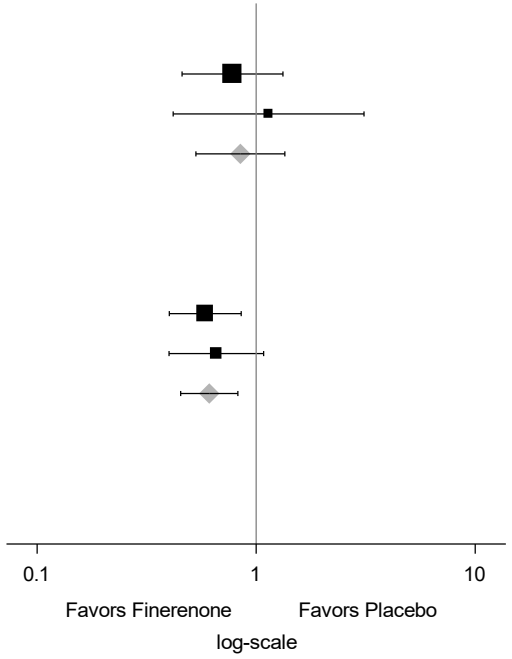
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	46 / 1797	73 / 1870	68.3	0.66 [0.46,0.94]	
FIGARO-DKD	21 / 917	35 / 933	31.7	0.61 [0.36,1.04]	
Total	67 / 2714	108 / 2803		0.64 [0.47,0.87]	Z=-2.90, p=0.0037
Heterogeneity:	Q=0.05 (df=1)	p=0.8280	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 820	28 / 740	67.6	0.61 [0.34,1.09]	
FIGARO-DKD	12 / 440	10 / 423	32.4	1.15 [0.50,2.64]	
Total	31 / 1260	38 / 1163		0.75 [0.47,1.20]	Z=-1.20, p=0.2293
Heterogeneity:	Q=1.52 (df=1)	p=0.2181	I^2=34.1%		
Subgroup Heterogeneity:	Q=0.31 (df=1)	p=0.5774	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.156.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

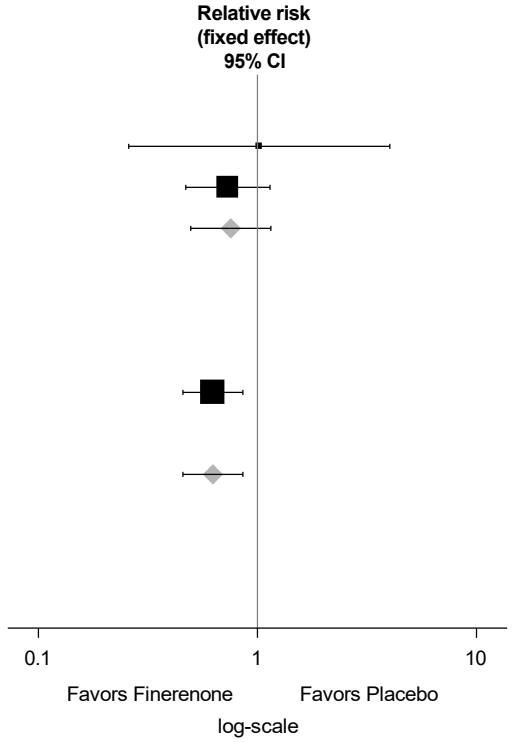
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	24 / 1103	30 / 1075	78.2	0.78 [0.46,1.32]	
FIGARO-DKD	8 / 336	7 / 335	21.8	1.14 [0.42,3.11]	
Total	32 / 1439	37 / 1410		0.85 [0.53,1.35]	Z=-0.70, p=0.4861
Heterogeneity:	Q=0.43 (df=1)	p=0.5122	I^2=0.0%		
>= 65					
FIDELIO-DKD	41 / 1514	71 / 1535	63.4	0.59 [0.40,0.85]	
FIGARO-DKD	25 / 1021	38 / 1021	36.6	0.66 [0.40,1.08]	
Total	66 / 2535	109 / 2556		0.61 [0.45,0.83]	Z=-3.21, p=0.0013
Heterogeneity:	Q=0.13 (df=1)	p=0.7143	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.33 (df=1)	p=0.2490	I^2=24.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.156.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

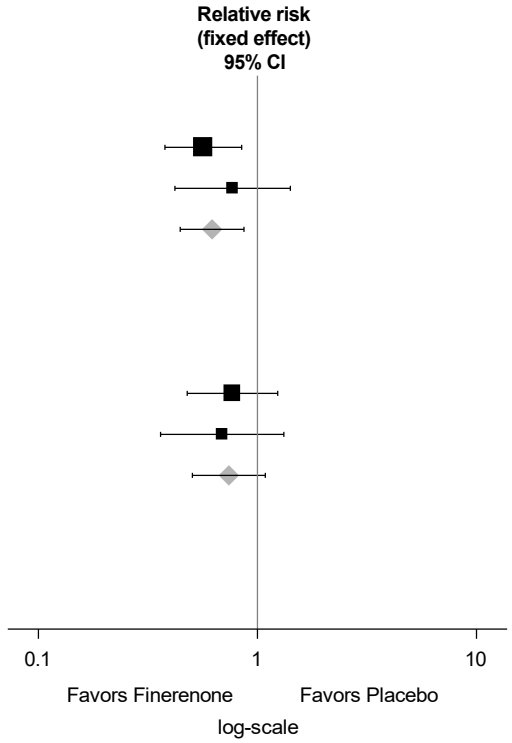
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	4 / 213	9.4	1.02 [0.26,4.02]	
FIGARO-DKD	33 / 1357	45 / 1356	90.6	0.73 [0.47,1.14]	
Total	37 / 1566	49 / 1569		0.76 [0.50,1.15]	Z=-1.30, p=0.1923
Heterogeneity:	Q=0.20 (df=1)	p=0.6540	I^2=0.0%		
Very High					
FIDELIO-DKD	61 / 2408	97 / 2397	100.0	0.63 [0.46,0.86]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	61 / 2408	97 / 2397		0.63 [0.46,0.86]	Z=-2.91, p=0.0036
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.49 (df=1)	p=0.4828	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.156.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

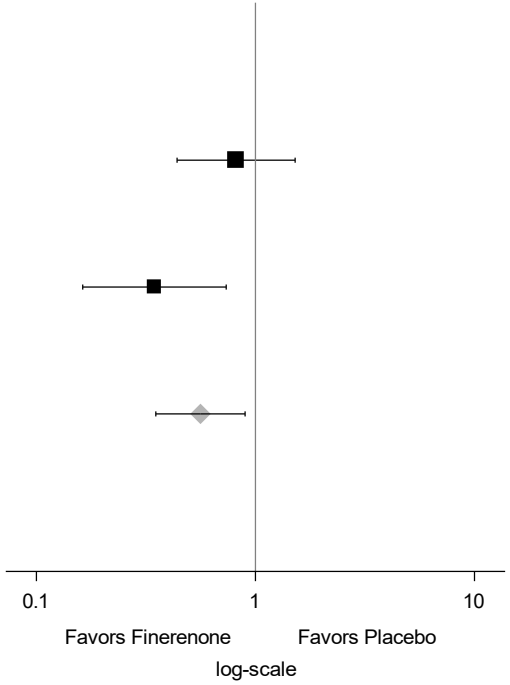
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	36 / 1556	63 / 1541	69.4	0.57 [0.38,0.85]	
FIGARO-DKD	18 / 637	23 / 627	30.6	0.77 [0.42,1.41]	
Total	54 / 2193	86 / 2168		0.62 [0.44,0.87]	Z=-2.79, p=0.0053
Heterogeneity:	Q=0.69 (df=1)	p=0.4068	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	38 / 1069	65.0	0.77 [0.48,1.24]	
FIGARO-DKD	15 / 720	22 / 729	35.0	0.69 [0.36,1.32]	
Total	44 / 1781	60 / 1798		0.74 [0.50,1.09]	Z=-1.54, p=0.1242
Heterogeneity:	Q=0.07 (df=1)	p=0.7927	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4980	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

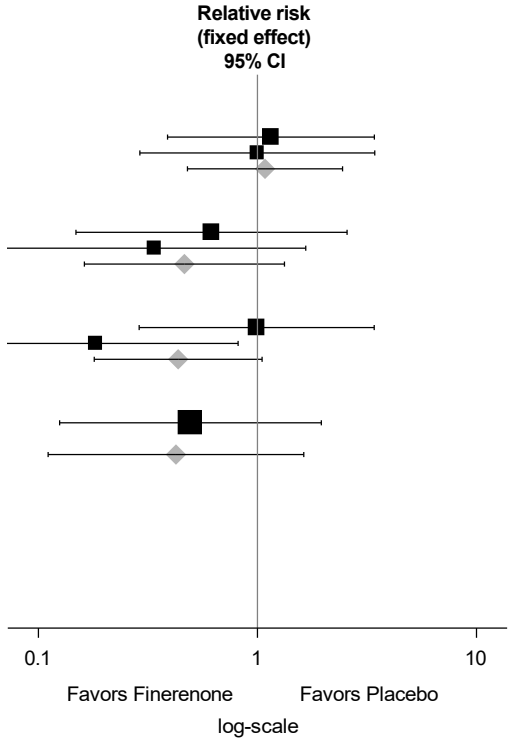
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	22 / 2610	59.6	0.82 [0.44,1.52]	
FIGARO-DKD	9 / 1357	26 / 1356	40.4	0.35 [0.16,0.74]	
Total	27 / 3974	48 / 3966		0.56 [0.35,0.90]	Z=-2.41, p=0.0158
Heterogeneity:	Q=2.98 (df=1)	p=0.0843	I^2=66.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.157.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

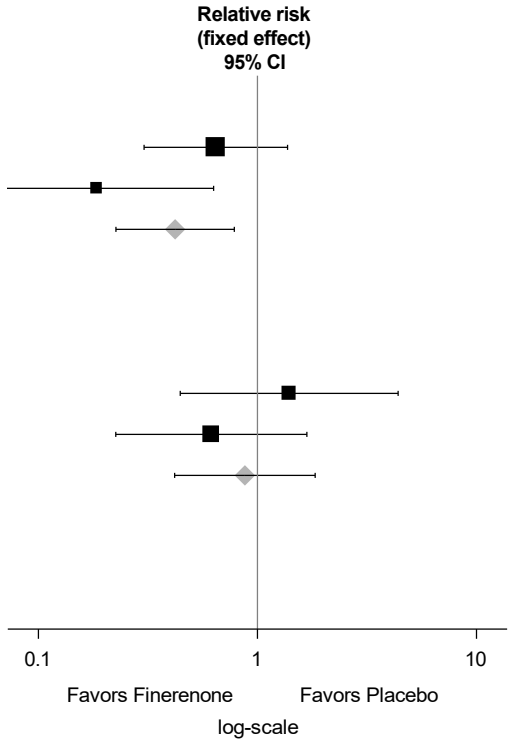
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	7 / 1075	6 / 1062	56.3	1.15 [0.39,3.42]	
FIGARO-DKD	5 / 638	5 / 637	43.7	1.00 [0.29,3.43]	
Total	12 / 1713	11 / 1699		1.08 [0.48,2.45]	Z=0.19, p=0.8486
Heterogeneity:	Q=0.03 (df=1)	p=0.8642	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	5 / 436	55.5	0.62 [0.15,2.57]	
FIGARO-DKD	2 / 267	6 / 271	44.5	0.34 [0.07,1.66]	
Total	5 / 691	11 / 707		0.46 [0.16,1.33]	Z=-1.43, p=0.1524
Heterogeneity:	Q=0.30 (df=1)	p=0.5808	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 751	5 / 745	59.5	0.99 [0.29,3.41]	
FIGARO-DKD	2 / 289	11 / 290	40.5	0.18 [0.04,0.82]	
Total	7 / 1040	16 / 1035		0.43 [0.18,1.05]	Z=-1.85, p=0.0640
Heterogeneity:	Q=3.00 (df=1)	p=0.0830	I^2=66.7%		
Latin America					
FIDELIO-DKD	3 / 273	6 / 270	100.0	0.49 [0.12,1.96]	
FIGARO-DKD	0 / 102	1 / 101	0.0	0.00 [0.00,12E296]	
Total	3 / 375	7 / 371		0.42 [0.11,1.63]	Z=-1.25, p=0.2114
Heterogeneity:	Q=0.05 (df=1)	p=0.8279	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	0 / 97	0.0	-	
FIGARO-DKD	0 / 61	3 / 57	0.0	0.00 [0.00,66E295]	
Total	0 / 155	3 / 154		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.01 (df=4)	p=0.5563	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

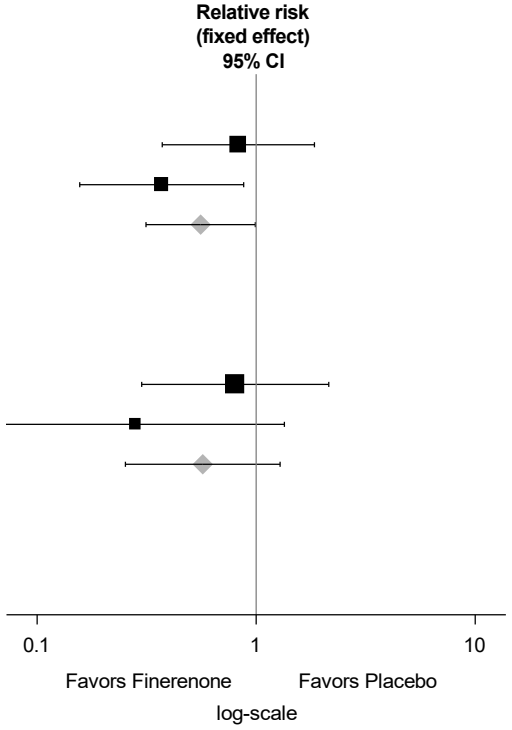
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	11 / 1213	17 / 1210	72.7	0.65 [0.30,1.37]	
FIGARO-DKD	3 / 862	16 / 848	27.3	0.18 [0.05,0.63]	
Total	14 / 2075	33 / 2058		0.42 [0.23,0.78]	Z=-2.73, p=0.0064
Heterogeneity:	Q=2.96 (df=1)	p=0.0851	I^2=66.3%		
Absent					
FIDELIO-DKD	7 / 1404	5 / 1400	43.5	1.40 [0.44,4.39]	
FIGARO-DKD	6 / 495	10 / 508	56.5	0.62 [0.23,1.68]	
Total	13 / 1899	15 / 1908		0.88 [0.42,1.83]	Z=-0.35, p=0.7265
Heterogeneity:	Q=1.11 (df=1)	p=0.2923	I^2=9.8%		
Subgroup Heterogeneity:	Q=2.22 (df=1)	p=0.1365	I^2=54.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

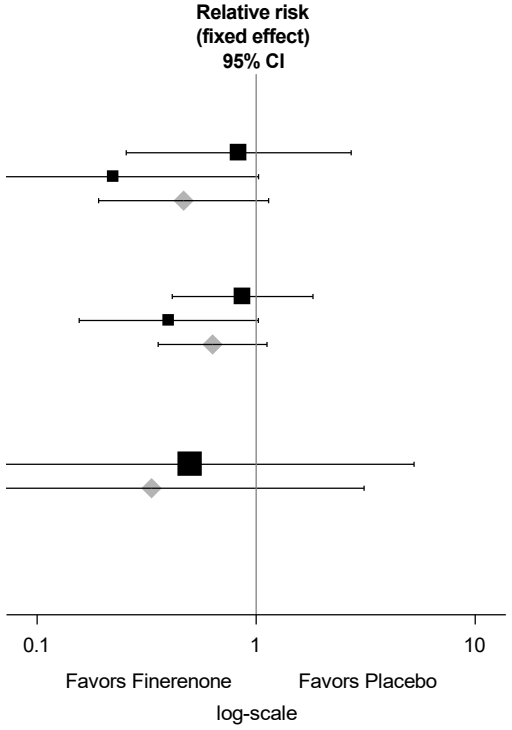
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	11 / 1735	13 / 1700	53.7	0.83 [0.37,1.85]	
FIGARO-DKD	7 / 924	19 / 929	46.3	0.37 [0.16,0.88]	
Total	18 / 2659	32 / 2629		0.56 [0.31,0.99]	Z=-1.99, p=0.0465
Heterogeneity:	Q=1.81 (df=1)	p=0.1786	I^2=44.7%		
> 4.5					
FIDELIO-DKD	7 / 882	9 / 910	71.7	0.80 [0.30,2.15]	
FIGARO-DKD	2 / 433	7 / 426	28.3	0.28 [0.06,1.35]	
Total	9 / 1315	16 / 1336		0.57 [0.25,1.29]	Z=-1.35, p=0.1758
Heterogeneity:	Q=1.25 (df=1)	p=0.2640	I^2=19.8%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9655	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

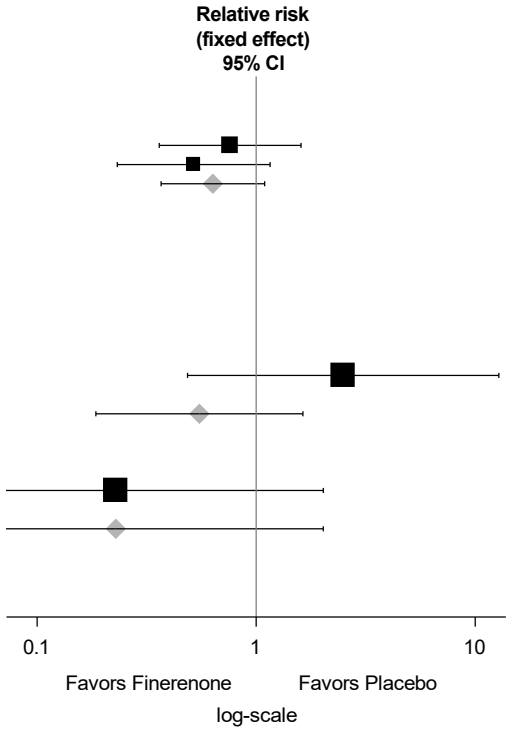
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	6 / 723	62.5	0.83 [0.26,2.71]	
FIGARO-DKD	2 / 494	9 / 495	37.5	0.22 [0.05,1.03]	
Total	7 / 1218	15 / 1218		0.47 [0.19,1.14]	Z=-1.67, p=0.0943
Heterogeneity:	Q=1.82 (df=1)	p=0.1771	I^2=45.1%		
130 - < 160					
FIDELIO-DKD	13 / 1759	15 / 1760	61.8	0.87 [0.41,1.82]	
FIGARO-DKD	6 / 829	15 / 827	38.2	0.40 [0.16,1.02]	
Total	19 / 2588	30 / 2587		0.63 [0.36,1.12]	Z=-1.57, p=0.1163
Heterogeneity:	Q=1.62 (df=1)	p=0.2034	I^2=38.2%		
>= 160					
FIDELIO-DKD	0 / 133	1 / 127	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	1 / 34	2 / 34	100.0	0.50 [0.05,5.26]	
Total	1 / 167	3 / 161		0.33 [0.04,3.11]	Z=-0.96, p=0.3347
Heterogeneity:	Q=0.11 (df=1)	p=0.7347	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=2)	p=0.7629	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

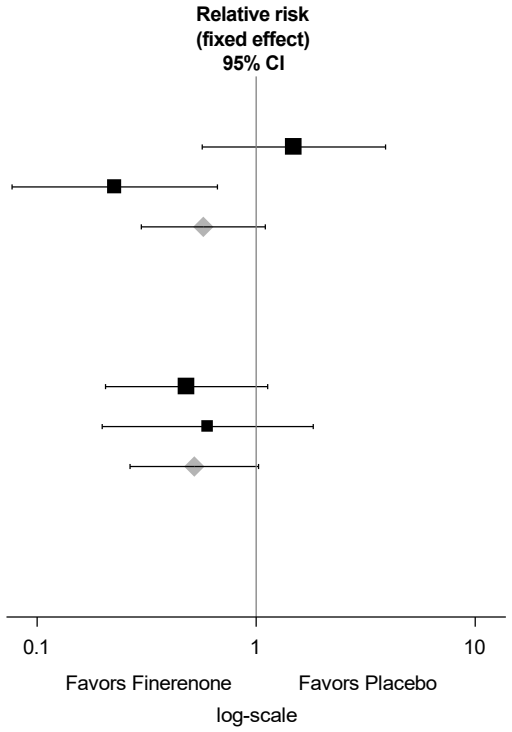
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	12 / 1634	16 / 1657	53.7	0.76 [0.36,1.60]	
FIGARO-DKD	9 / 1010	17 / 989	46.3	0.52 [0.23,1.16]	
Total	21 / 2644	33 / 2646		0.63 [0.37,1.09]	Z=-1.64, p=0.1011
Heterogeneity:	Q=0.47 (df=1)	p=0.4929	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	0 / 115	0.0	-	
FIGARO-DKD	0 / 43	2 / 71	0.0	0.00 [0.00,12E296]	
Total	0 / 172	2 / 186		0.00 [0.00,0.00]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	5 / 678	2 / 677	100.0	2.50 [0.49,12.82]	
FIGARO-DKD	0 / 252	7 / 251	0.0	0.00 [0.00,12E296]	
Total	5 / 930	9 / 928		0.55 [0.19,1.63]	Z=-1.07, p=0.2825
Heterogeneity:	Q=3.28 (df=1)	p=0.0702	I^2=69.5%		
Others					
FIDELIO-DKD	1 / 176	4 / 161	100.0	0.23 [0.03,2.02]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	1 / 228	4 / 206		0.23 [0.03,2.02]	Z=-1.33, p=0.1849
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=3)	p=0.8474	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.157.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

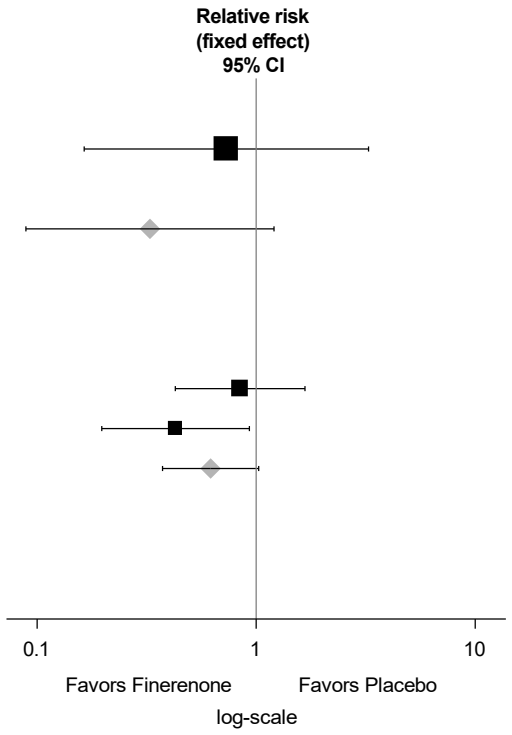
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	10 / 1797	7 / 1870	55.7	1.49 [0.57,3.90]	
FIGARO-DKD	4 / 917	18 / 933	44.3	0.23 [0.08,0.67]	
Total	14 / 2714	25 / 2803		0.57 [0.30,1.10]	Z=-1.67, p=0.0946
Heterogeneity:	Q=6.61 (df=1)	p=0.0102	I^2=84.9%		
Female					
FIDELIO-DKD	8 / 820	15 / 740	62.9	0.48 [0.21,1.13]	
FIGARO-DKD	5 / 440	8 / 423	37.1	0.60 [0.20,1.82]	
Total	13 / 1260	23 / 1163		0.52 [0.27,1.03]	Z=-1.89, p=0.0591
Heterogeneity:	Q=0.10 (df=1)	p=0.7559	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8431	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.157.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

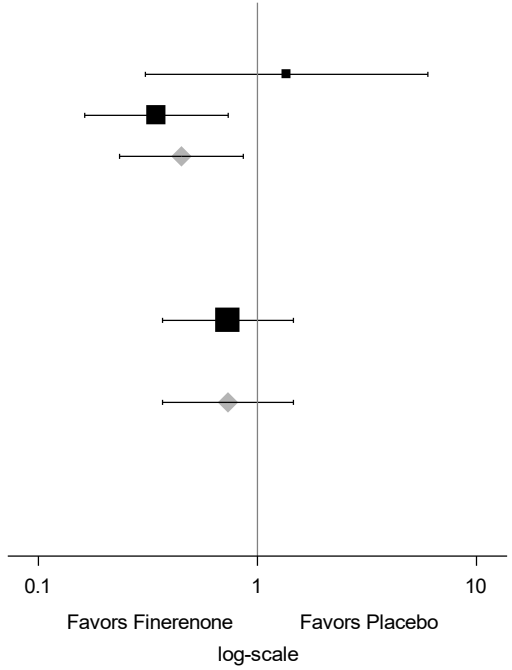
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 1103	4 / 1075	100.0	0.73 [0.16,3.26]	
FIGARO-DKD	0 / 336	5 / 335	0.0	0.00 [0.00,85E295]	
Total	3 / 1439	9 / 1410		0.33 [0.09,1.21]	Z=-1.68, p=0.0933
Heterogeneity:	Q=1.11 (df=1)	p=0.2922	I^2=9.9%		
>= 65					
FIDELIO-DKD	15 / 1514	18 / 1535	56.5	0.84 [0.43,1.67]	
FIGARO-DKD	9 / 1021	21 / 1021	43.5	0.43 [0.20,0.93]	
Total	24 / 2535	39 / 2556		0.62 [0.37,1.03]	Z=-1.86, p=0.0633
Heterogeneity:	Q=1.66 (df=1)	p=0.1973	I^2=39.8%		
Subgroup Heterogeneity:	Q=0.80 (df=1)	p=0.3716	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.157.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	3 / 213	20.5	1.36 [0.31,6.00]	
FIGARO-DKD	9 / 1357	26 / 1356	79.5	0.35 [0.16,0.74]	
Total	13 / 1566	29 / 1569		0.45 [0.23,0.86]	Z=-2.41, p=0.0160
Heterogeneity:	Q=2.60 (df=1)	p=0.1071	I^2=61.5%		
Very High					
FIDELIO-DKD	14 / 2408	19 / 2397	100.0	0.73 [0.37,1.46]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	14 / 2408	19 / 2397		0.73 [0.37,1.46]	Z=-0.88, p=0.3772
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.03 (df=1)	p=0.3112	I^2=2.5%		

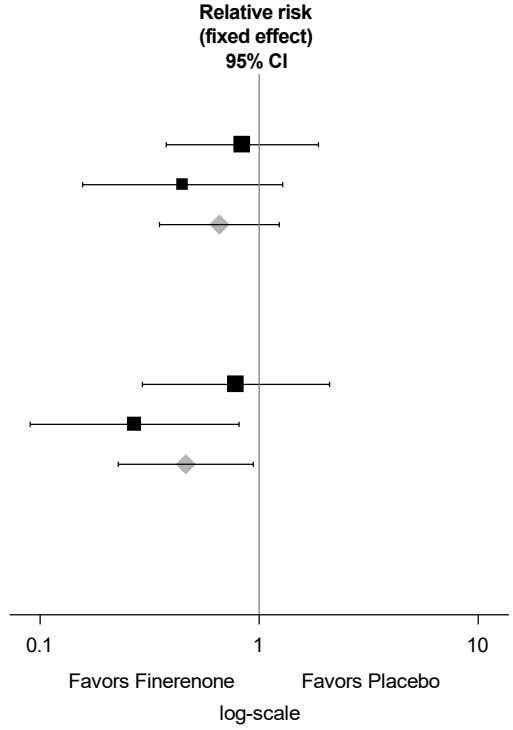


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.157.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Urinary tract infection (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

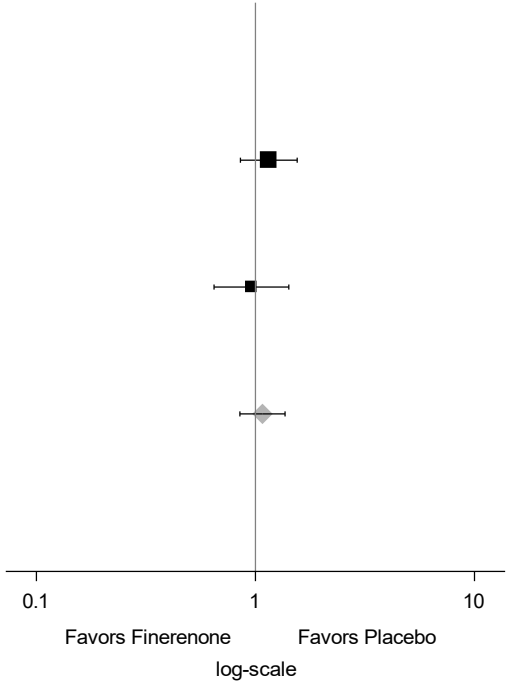
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	11 / 1556	13 / 1541	63.3	0.84 [0.38,1.86]	
FIGARO-DKD	5 / 637	11 / 627	36.7	0.45 [0.16,1.28]	
Total	16 / 2193	24 / 2168		0.66 [0.35,1.24]	Z=-1.30, p=0.1929
Heterogeneity:	Q=0.87 (df=1)	p=0.3515	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	7 / 1061	9 / 1069	55.5	0.78 [0.29,2.10]	
FIGARO-DKD	4 / 720	15 / 729	44.5	0.27 [0.09,0.81]	
Total	11 / 1781	24 / 1798		0.46 [0.23,0.94]	Z=-2.13, p=0.0333
Heterogeneity:	Q=2.03 (df=1)	p=0.1546	I^2=50.6%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4662	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.158: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

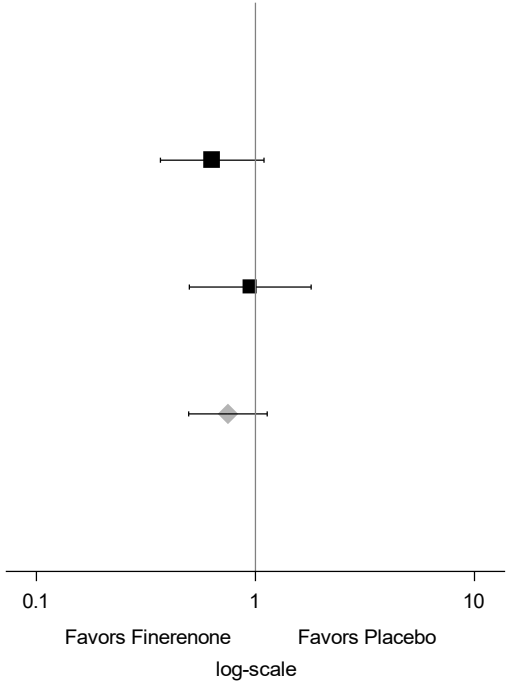
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	90 / 2617	78 / 2610	63.4	1.15 [0.85,1.55]	
FIGARO-DKD	47 / 1357	49 / 1356	36.6	0.96 [0.65,1.42]	
Total	137 / 3974	127 / 3966		1.08 [0.85,1.36]	Z=0.61, p=0.5430
Heterogeneity:	Q=0.53 (df=1)	p=0.4677	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.159: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

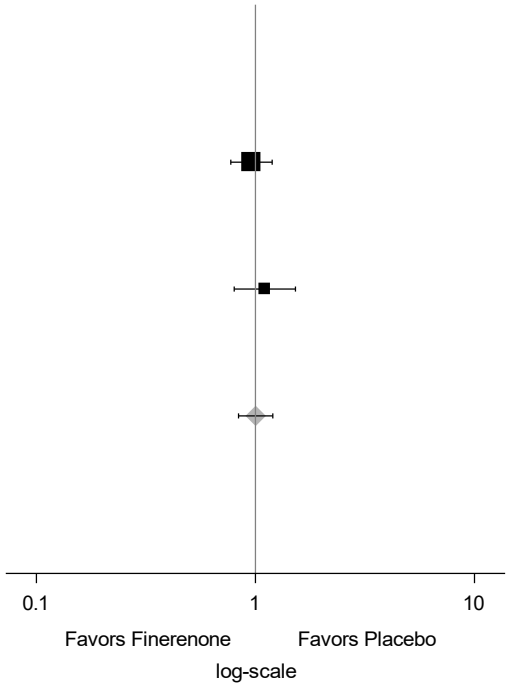
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2617	33 / 2610	58.0	0.63 [0.37,1.09]	
FIGARO-DKD	18 / 1357	19 / 1356	42.0	0.95 [0.50,1.80]	
Total	39 / 3974	52 / 3966		0.75 [0.50,1.13]	Z=-1.37, p=0.1696
Heterogeneity:	Q=0.87 (df=1)	p=0.3510	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.160: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

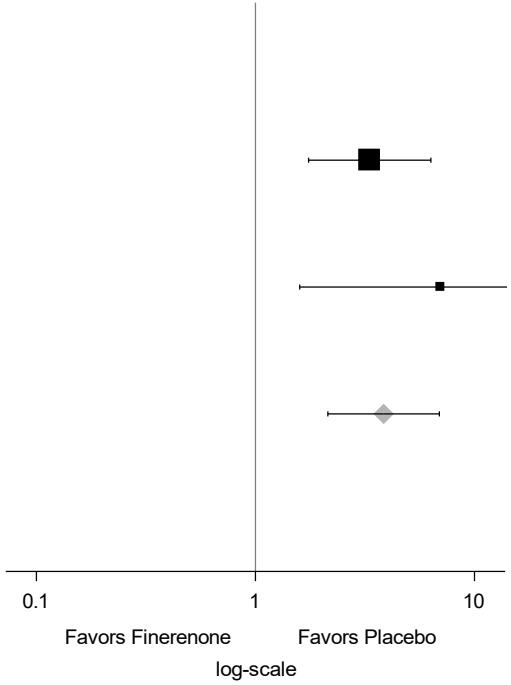
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	150 / 2617	156 / 2610	68.7	0.96 [0.77,1.19]	
FIGARO-DKD	74 / 1357	67 / 1356	31.3	1.10 [0.80,1.52]	
Total	224 / 3974	223 / 3966		1.00 [0.84,1.20]	Z=0.02, p=0.9809
Heterogeneity:	Q=0.50 (df=1)	p=0.4783	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.161: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

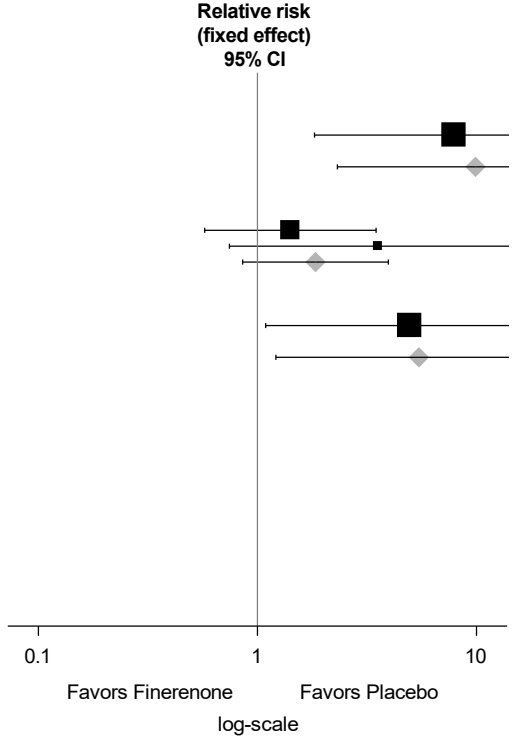
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2617	12 / 2610	84.1	3.32 [1.75,6.32]	
FIGARO-DKD	14 / 1357	2 / 1356	15.9	6.99 [1.59,30.72]	
Total	54 / 3974	14 / 3966		3.85 [2.14,6.91]	Z=4.51, p=<.0001
Heterogeneity:	Q=0.83 (df=1)	p=0.3636	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.161.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

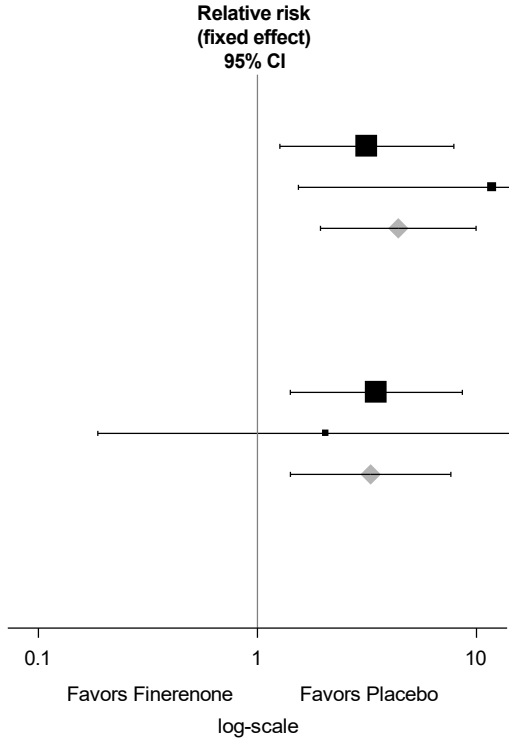
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	2 / 1062	100.0	7.90 [1.82,34.29]	
FIGARO-DKD	4 / 638	0 / 637	0.0	888E8 [888E8,888E8]	
Total	20 / 1713	2 / 1699		9.89 [2.32,42.26]	Z=3.09, p=0.0020
Heterogeneity:	Q=0.09 (df=1)	p=0.7641	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 424	8 / 436	75.0	1.41 [0.57,3.48]	
FIGARO-DKD	7 / 267	2 / 271	25.0	3.55 [0.74,16.95]	
Total	18 / 691	10 / 707		1.84 [0.86,3.96]	Z=1.56, p=0.1181
Heterogeneity:	Q=1.01 (df=1)	p=0.3149	I^2=1.0%		
Asia					
FIDELIO-DKD	10 / 751	2 / 745	100.0	4.96 [1.09,22.56]	
FIGARO-DKD	1 / 289	0 / 290	0.0	133E9 [133E9,133E9]	
Total	11 / 1040	2 / 1035		5.46 [1.21,24.56]	Z=2.21, p=0.0269
Heterogeneity:	Q=0.02 (df=1)	p=0.9013	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	0 / 270	0.0	104E9 [104E9,104E9]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	2 / 375	0 / 371		2.33E7 [2.33E7,2.33E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	0 / 97	0.0	151E9 [151E9,151E9]	
FIGARO-DKD	2 / 61	0 / 57	0.0	171E9 [171E9,171E9]	
Total	3 / 155	0 / 154		945E8 [945E8,945E8]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.77 (df=4)	p=0.3123	I^2=16.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.161.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

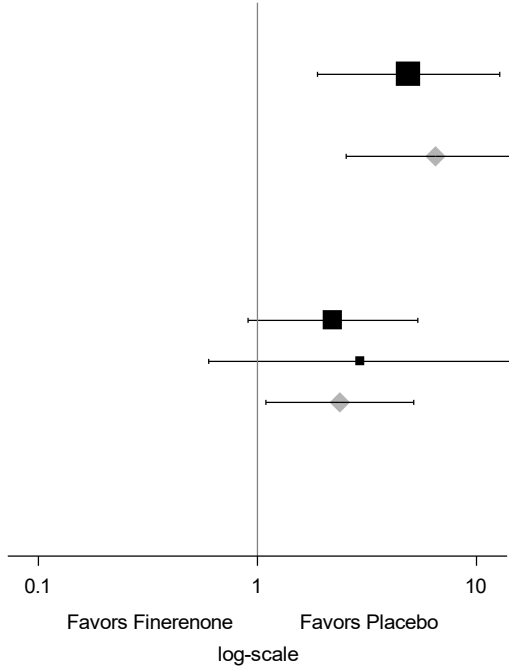
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 1213	6 / 1210	83.2	3.16 [1.27,7.88]	
FIGARO-DKD	12 / 862	1 / 848	16.8	11.81 [1.54,90.59]	
Total	31 / 2075	7 / 2058		4.39 [1.94,9.96]	Z=3.55, p=0.0004
Heterogeneity:	Q=1.40 (df=1)	p=0.2360	I^2=28.8%		
Absent					
FIDELIO-DKD	21 / 1404	6 / 1400	87.5	3.49 [1.41,8.62]	
FIGARO-DKD	2 / 495	1 / 508	12.5	2.05 [0.19,22.56]	
Total	23 / 1899	7 / 1908		3.29 [1.41,7.64]	Z=2.77, p=0.0057
Heterogeneity:	Q=0.17 (df=1)	p=0.6845	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6278	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.161.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1735	5 / 1700	100.0	4.90 [1.88,12.77]	
FIGARO-DKD	8 / 924	0 / 929	0.0	123E9 [123E9,123E9]	
Total	33 / 2659	5 / 2629		6.50 [2.54,16.62]	Z=3.91, p=<.0001
Heterogeneity:	Q=0.33 (df=1)	p=0.5631	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 882	7 / 910	76.2	2.21 [0.91,5.40]	
FIGARO-DKD	6 / 433	2 / 426	23.8	2.95 [0.60,14.54]	
Total	21 / 1315	9 / 1336		2.38 [1.09,5.17]	Z=2.18, p=0.0290
Heterogeneity:	Q=0.10 (df=1)	p=0.7566	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.62 (df=1)	p=0.1058	I^2=61.8%		

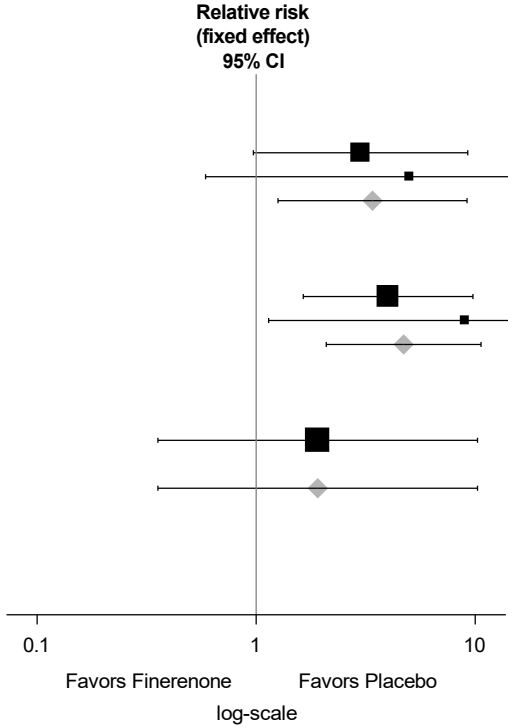


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.161.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

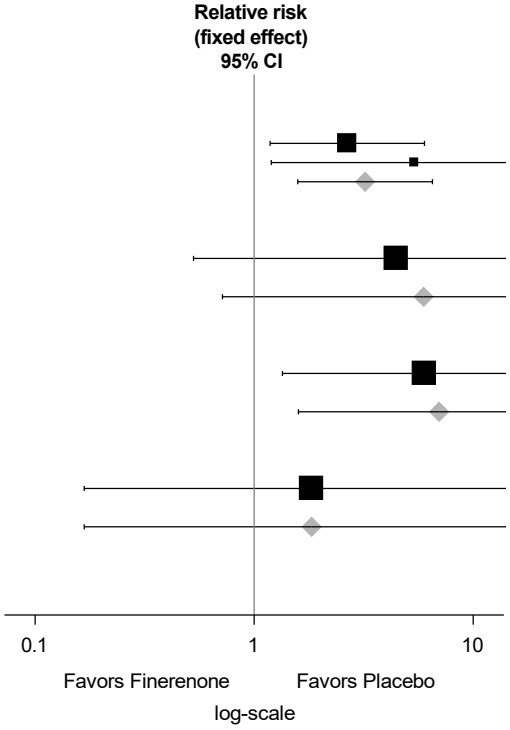
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	4 / 723	78.3	3.00 [0.97,9.25]	
FIGARO-DKD	5 / 494	1 / 495	21.7	5.01 [0.59,42.73]	
Total	17 / 1218	5 / 1218		3.40 [1.26,9.18]	Z=2.41, p=0.0159
Heterogeneity:	Q=0.17 (df=1)	p=0.6766	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	24 / 1759	6 / 1760	84.3	4.00 [1.64,9.77]	
FIGARO-DKD	9 / 829	1 / 827	15.7	8.98 [1.14,70.71]	
Total	33 / 2588	7 / 2587		4.71 [2.09,10.63]	Z=3.73, p=0.0002
Heterogeneity:	Q=0.50 (df=1)	p=0.4779	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	2 / 127	100.0	1.91 [0.36,10.25]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	4 / 167	2 / 161		1.91 [0.36,10.25]	Z=0.75, p=0.4503
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.96 (df=2)	p=0.6186	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.161.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

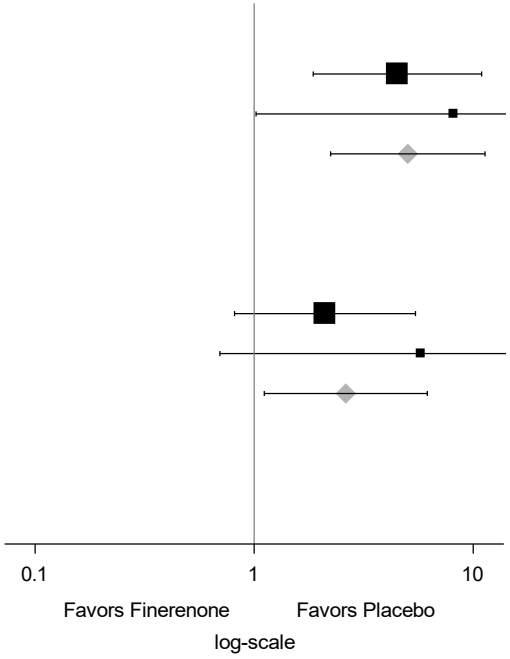
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1634	8 / 1657	77.5	2.66 [1.18,5.99]	
FIGARO-DKD	11 / 1010	2 / 989	22.5	5.39 [1.20,24.24]	
Total	32 / 2644	10 / 2646		3.21 [1.58,6.51]	Z=3.23, p=0.0012
Heterogeneity:	Q=0.66 (df=1)	p=0.4169	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	1 / 115	100.0	4.46 [0.53,37.59]	
FIGARO-DKD	1 / 43	0 / 71	0.0	329E9 [329E9,329E9]	
Total	6 / 172	1 / 186		5.94 [0.72,49.18]	Z=1.65, p=0.0988
Heterogeneity:	Q=0.07 (df=1)	p=0.7923	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 678	2 / 677	100.0	5.99 [1.35,26.67]	
FIGARO-DKD	2 / 252	0 / 251	0.0	112E9 [112E9,112E9]	
Total	14 / 930	2 / 928		6.98 [1.59,30.64]	Z=2.58, p=0.0100
Heterogeneity:	Q=0.04 (df=1)	p=0.8404	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.83 [0.17,19.99]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	2 / 228	1 / 206		1.83 [0.17,19.99]	Z=0.50, p=0.6205
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.39 (df=3)	p=0.7080	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.161.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

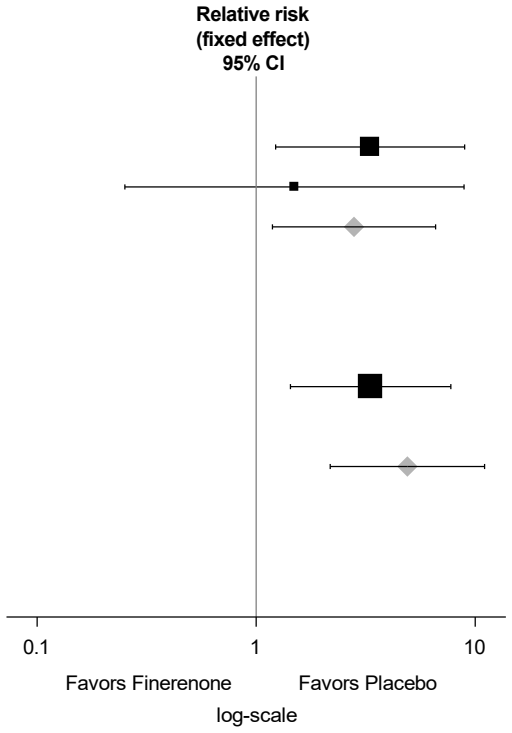
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 1797	6 / 1870	84.6	4.51 [1.86,10.93]	
FIGARO-DKD	8 / 917	1 / 933	15.4	8.14 [1.02,64.95]	
Total	34 / 2714	7 / 2803		5.03 [2.23,11.32]	Z=3.90, p=<.0001
Heterogeneity:	Q=0.26 (df=1)	p=0.6069	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 820	6 / 740	83.1	2.11 [0.81,5.45]	
FIGARO-DKD	6 / 440	1 / 423	16.9	5.77 [0.70,47.71]	
Total	20 / 1260	7 / 1163		2.62 [1.11,6.17]	Z=2.20, p=0.0276
Heterogeneity:	Q=0.74 (df=1)	p=0.3901	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.17 (df=1)	p=0.2790	I^2=14.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.161.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

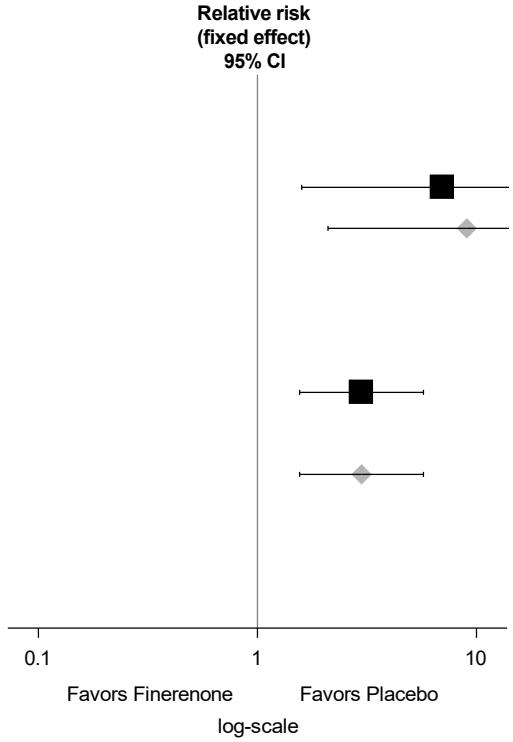
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	17 / 1103	5 / 1075	76.3	3.31 [1.23,8.95]	
FIGARO-DKD	3 / 336	2 / 335	23.7	1.50 [0.25,8.89]	
Total	20 / 1439	7 / 1410		2.80 [1.19,6.59]	Z=2.35, p=0.0187
Heterogeneity:	Q=0.59 (df=1)	p=0.4441	I^2=0.0%		
>= 65					
FIDELIO-DKD	23 / 1514	7 / 1535	100.0	3.33 [1.43,7.74]	
FIGARO-DKD	11 / 1021	0 / 1021	0.0	153E9 [153E9,153E9]	
Total	34 / 2535	7 / 2556		4.90 [2.18,11.04]	Z=3.84, p=0.0001
Heterogeneity:	Q=0.81 (df=1)	p=0.3691	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.87 (df=1)	p=0.3516	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.161.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

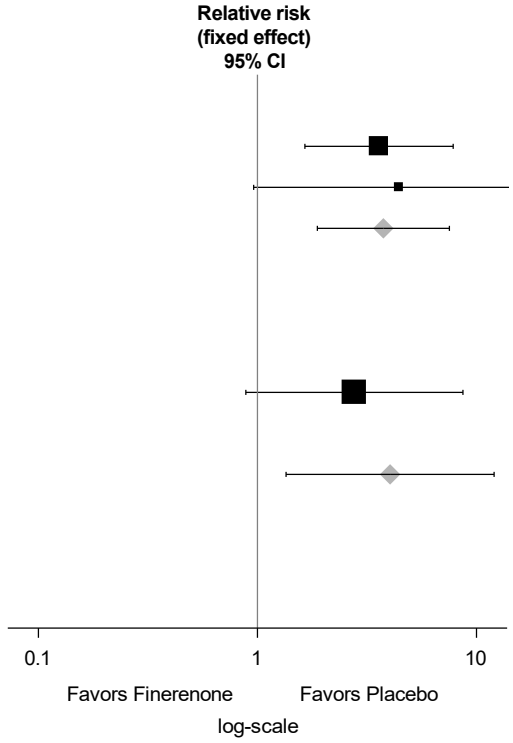
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	0 / 213	0.0	996E8 [996E8,996E8]	
FIGARO-DKD	14 / 1357	2 / 1356	100.0	6.99 [1.59,30.72]	
Total	18 / 1566	2 / 1569		9.03 [2.10,38.86]	Z=2.96, p=0.0031
Heterogeneity:	Q=0.11 (df=1)	p=0.7350	I^2=0.0%		
Very High					
FIDELIO-DKD	36 / 2408	12 / 2397	100.0	2.99 [1.56,5.73]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	36 / 2408	12 / 2397		2.99 [1.56,5.73]	Z=3.29, p=0.0010
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.84 (df=1)	p=0.1746	I^2=45.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.161.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

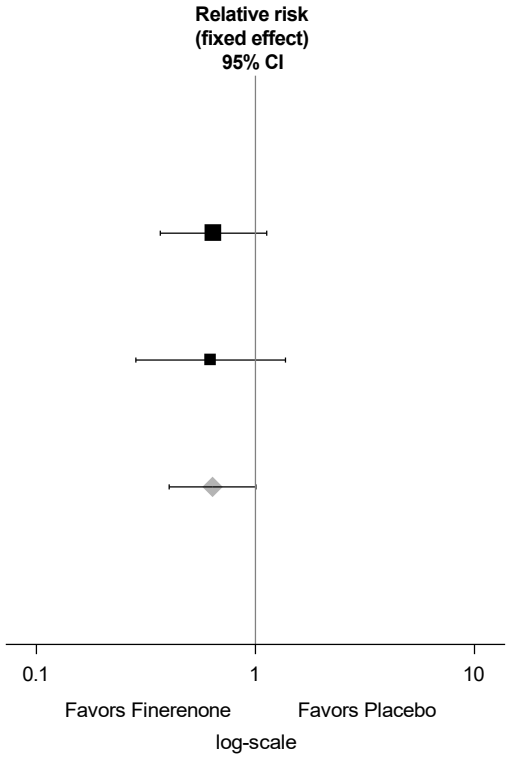
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	29 / 1556	8 / 1541	79.4	3.59 [1.65,7.83]	
FIGARO-DKD	9 / 637	2 / 627	20.6	4.43 [0.96,20.42]	
Total	38 / 2193	10 / 2168		3.76 [1.88,7.52]	Z=3.74, p=0.0002
Heterogeneity:	Q=0.06 (df=1)	p=0.8103	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	4 / 1069	100.0	2.77 [0.89,8.67]	
FIGARO-DKD	5 / 720	0 / 729	0.0	984E8 [984E8,984E8]	
Total	16 / 1781	4 / 1798		4.03 [1.35,12.03]	Z=2.50, p=0.0124
Heterogeneity:	Q=0.42 (df=1)	p=0.5193	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9151	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.162: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

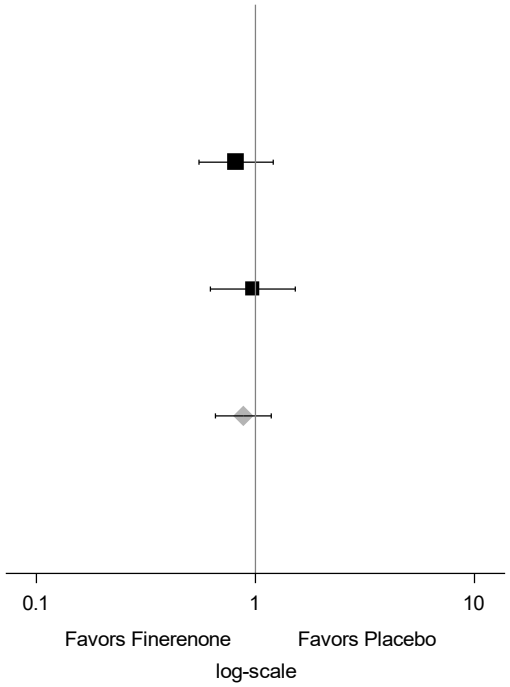
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	31 / 2610	66.4	0.64 [0.37,1.13]	
FIGARO-DKD	10 / 1357	16 / 1356	33.6	0.62 [0.28,1.37]	
Total	30 / 3974	47 / 3966		0.64 [0.40,1.00]	Z=-1.94, p=0.0525
Heterogeneity:	Q=0.00 (df=1)	p=0.9517	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.163: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

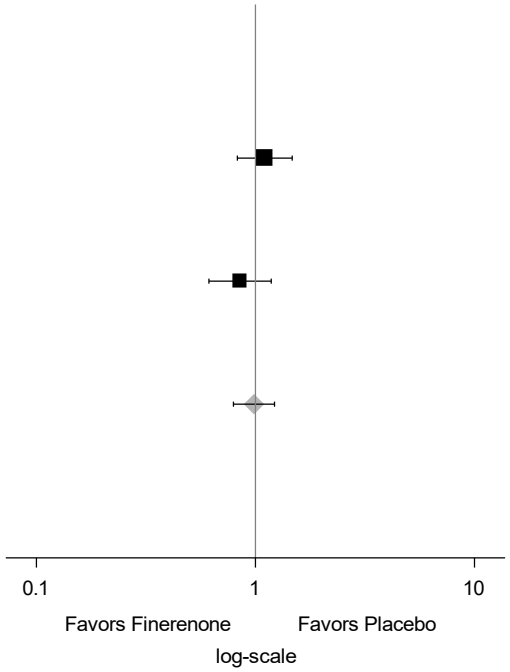
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	55 / 2610	56.7	0.82 [0.55,1.21]	
FIGARO-DKD	37 / 1357	38 / 1356	43.3	0.97 [0.62,1.52]	
Total	82 / 3974	93 / 3966		0.88 [0.66,1.18]	Z=-0.85, p=0.3951
Heterogeneity:	Q=0.34 (df=1)	p=0.5608	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.164: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

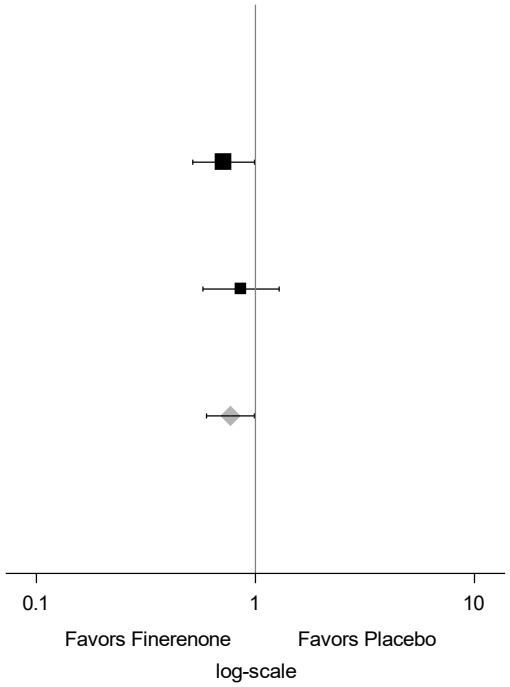
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2617	85 / 2610	56.3	1.10 [0.83,1.47]	
FIGARO-DKD	63 / 1357	74 / 1356	43.7	0.85 [0.61,1.18]	
Total	157 / 3974	159 / 3966		0.98 [0.79,1.22]	Z=-0.14, p=0.8876
Heterogeneity:	Q=1.36 (df=1)	p=0.2435	I^2=26.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.165: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

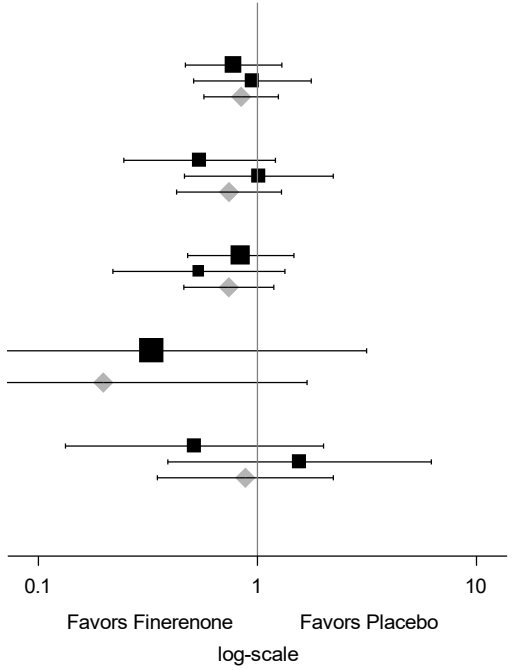
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	85 / 2610	60.4	0.72 [0.52,0.99]	
FIGARO-DKD	43 / 1357	50 / 1356	39.6	0.86 [0.58,1.28]	
Total	104 / 3974	135 / 3966		0.77 [0.60,0.99]	Z=-2.04, p=0.0411
Heterogeneity:	Q=0.48 (df=1)	p=0.4868	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.165.1: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Region - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

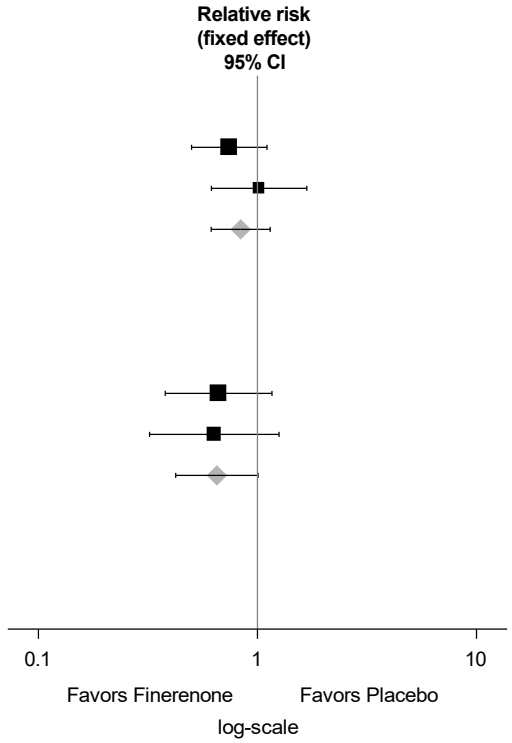
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 1075	33 / 1062	59.8	0.78 [0.47,1.29]	
FIGARO-DKD	19 / 638	20 / 637	40.2	0.95 [0.51,1.76]	
Total	45 / 1713	53 / 1699		0.84 [0.57,1.25]	Z=-0.86, p=0.3908
Heterogeneity:	Q=0.23 (df=1)	p=0.6279	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 424	17 / 436	49.1	0.54 [0.25,1.21]	
FIGARO-DKD	12 / 267	12 / 271	50.9	1.01 [0.46,2.22]	
Total	21 / 691	29 / 707		0.74 [0.43,1.29]	Z=-1.06, p=0.2880
Heterogeneity:	Q=1.20 (df=1)	p=0.2740	I^2=16.4%		
Asia					
FIDELIO-DKD	22 / 751	26 / 745	72.4	0.84 [0.48,1.47]	
FIGARO-DKD	7 / 289	13 / 290	27.6	0.54 [0.22,1.33]	
Total	29 / 1040	39 / 1035		0.74 [0.46,1.19]	Z=-1.25, p=0.2119
Heterogeneity:	Q=0.66 (df=1)	p=0.4165	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 273	3 / 270	100.0	0.33 [0.03,3.15]	
FIGARO-DKD	0 / 102	2 / 101	0.0	0.00 [0.00,17E296]	
Total	1 / 375	5 / 371		0.20 [0.02,1.68]	Z=-1.48, p=0.1381
Heterogeneity:	Q=0.20 (df=1)	p=0.6572	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 94	6 / 97	51.0	0.52 [0.13,2.00]	
FIGARO-DKD	5 / 61	3 / 57	49.0	1.56 [0.39,6.22]	
Total	8 / 155	9 / 154		0.88 [0.35,2.22]	Z=-0.27, p=0.7875
Heterogeneity:	Q=1.25 (df=1)	p=0.2640	I^2=19.8%		
Subgroup Heterogeneity:	Q=1.87 (df=4)	p=0.7597	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.165.2: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by History of CVD - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

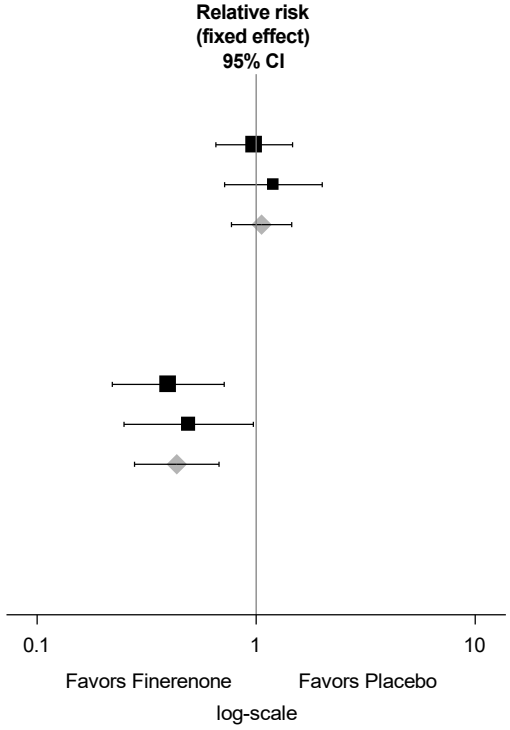
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	41 / 1213	55 / 1210	61.5	0.74 [0.50,1.11]	
FIGARO-DKD	30 / 862	29 / 848	38.5	1.02 [0.62,1.68]	
Total	71 / 2075	84 / 2058		0.84 [0.61,1.14]	Z=-1.11, p=0.2650
Heterogeneity:	Q=0.93 (df=1)	p=0.3361	I^2=0.0%		
Absent					
FIDELIO-DKD	20 / 1404	30 / 1400	59.5	0.66 [0.38,1.16]	
FIGARO-DKD	13 / 495	21 / 508	40.5	0.64 [0.32,1.25]	
Total	33 / 1899	51 / 1908		0.65 [0.42,1.01]	Z=-1.93, p=0.0533
Heterogeneity:	Q=0.01 (df=1)	p=0.9198	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.85 (df=1)	p=0.3565	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.165.3: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

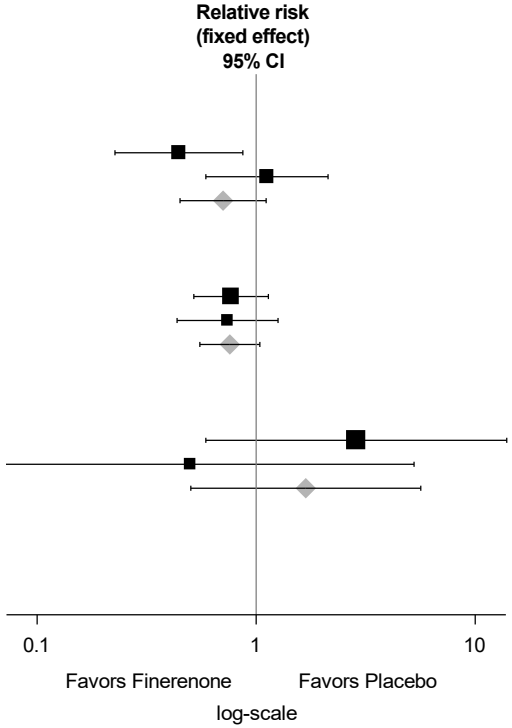
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 1735	46 / 1700	61.8	0.98 [0.65,1.47]	
FIGARO-DKD	31 / 924	26 / 929	38.2	1.20 [0.72,2.00]	
Total	77 / 2659	72 / 2629		1.06 [0.77,1.45]	Z=0.35, p=0.7252
Heterogeneity:	Q=0.37 (df=1)	p=0.5447	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 882	39 / 910	57.2	0.40 [0.22,0.71]	
FIGARO-DKD	12 / 433	24 / 426	42.8	0.49 [0.25,0.97]	
Total	27 / 1315	63 / 1336		0.43 [0.28,0.68]	Z=-3.68, p=0.0002
Heterogeneity:	Q=0.22 (df=1)	p=0.6395	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.26 (df=1)	p=0.0014	I^2=90.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.165.4: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

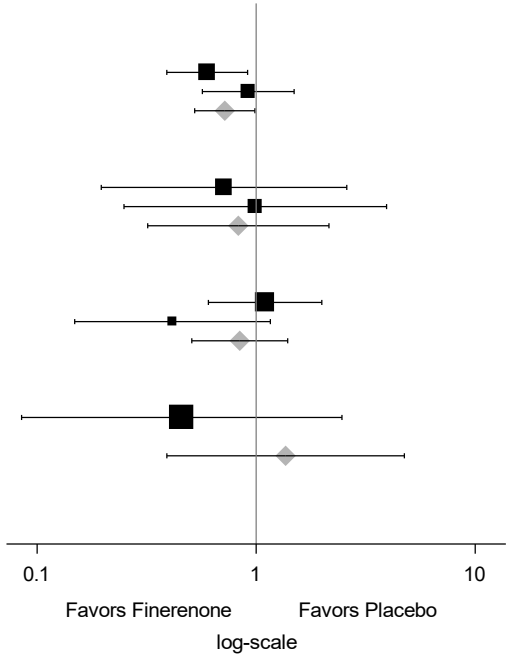
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	27 / 723	47.7	0.44 [0.23,0.87]	
FIGARO-DKD	19 / 494	17 / 495	52.3	1.12 [0.59,2.13]	
Total	31 / 1218	44 / 1218		0.71 [0.45,1.11]	Z=-1.51, p=0.1320
Heterogeneity:	Q=3.81 (df=1)	p=0.0508	I^2=73.8%		
130 - < 160					
FIDELIO-DKD	43 / 1759	56 / 1760	64.7	0.77 [0.52,1.14]	
FIGARO-DKD	23 / 829	31 / 827	35.3	0.74 [0.44,1.26]	
Total	66 / 2588	87 / 2587		0.76 [0.55,1.04]	Z=-1.72, p=0.0853
Heterogeneity:	Q=0.01 (df=1)	p=0.9117	I^2=0.0%		
>= 160					
FIDELIO-DKD	6 / 133	2 / 127	68.9	2.86 [0.59,13.93]	
FIGARO-DKD	1 / 34	2 / 34	31.1	0.50 [0.05,5.26]	
Total	7 / 167	4 / 161		1.68 [0.50,5.64]	Z=0.85, p=0.3977
Heterogeneity:	Q=1.46 (df=1)	p=0.2275	I^2=31.3%		
Subgroup Heterogeneity:	Q=1.76 (df=2)	p=0.4146	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.165.5: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Race - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

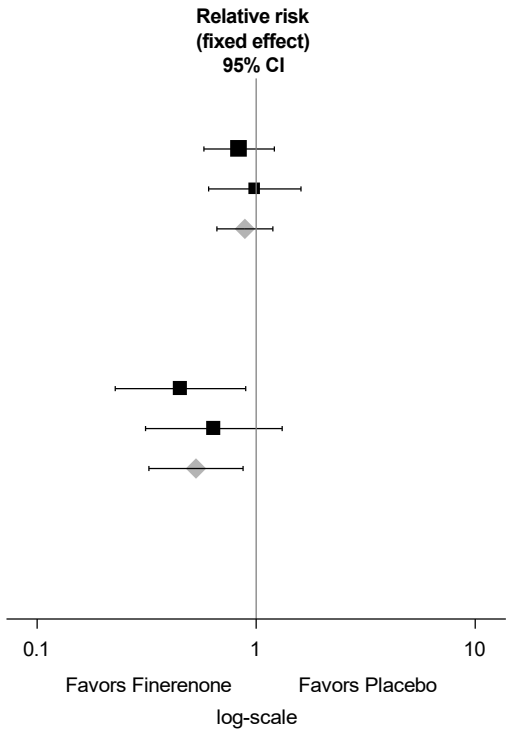
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	33 / 1634	56 / 1657	56.3	0.60 [0.39,0.91]	
FIGARO-DKD	31 / 1010	33 / 989	43.7	0.92 [0.57,1.49]	
Total	64 / 2644	89 / 2646		0.72 [0.52,0.99]	Z=-2.04, p=0.0411
Heterogeneity:	Q=1.73 (df=1)	p=0.1883	I^2=42.2%		
Black					
FIDELIO-DKD	4 / 129	5 / 115	53.4	0.71 [0.20,2.59]	
FIGARO-DKD	3 / 43	5 / 71	46.6	0.99 [0.25,3.94]	
Total	7 / 172	10 / 186		0.83 [0.32,2.15]	Z=-0.39, p=0.6995
Heterogeneity:	Q=0.12 (df=1)	p=0.7331	I^2=0.0%		
Asian					
FIDELIO-DKD	22 / 678	20 / 677	74.9	1.10 [0.61,1.99]	
FIGARO-DKD	5 / 252	12 / 251	25.1	0.42 [0.15,1.16]	
Total	27 / 930	32 / 928		0.84 [0.51,1.39]	Z=-0.67, p=0.5020
Heterogeneity:	Q=2.58 (df=1)	p=0.1081	I^2=61.3%		
Others					
FIDELIO-DKD	2 / 176	4 / 161	100.0	0.46 [0.08,2.46]	
FIGARO-DKD	4 / 52	0 / 45	0.0	147E9 [147E9,147E9]	
Total	6 / 228	4 / 206		1.36 [0.39,4.75]	Z=0.49, p=0.6271
Heterogeneity:	Q=1.61 (df=1)	p=0.2039	I^2=38.1%		
Subgroup Heterogeneity:	Q=1.12 (df=3)	p=0.7718	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.165.6: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Sex - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

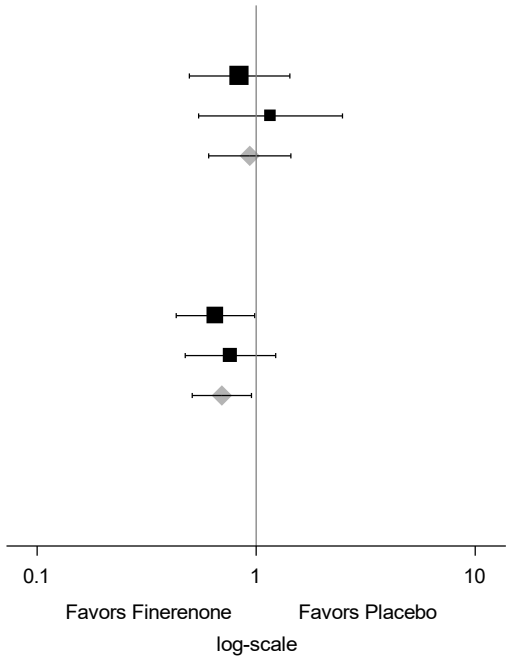
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	49 / 1797	61 / 1870	63.2	0.84 [0.58,1.21]	
FIGARO-DKD	31 / 917	32 / 933	36.8	0.99 [0.61,1.60]	
Total	80 / 2714	93 / 2803		0.89 [0.66,1.19]	Z=-0.79, p=0.4286
Heterogeneity:	Q=0.28 (df=1)	p=0.5969	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 820	24 / 740	52.3	0.45 [0.23,0.90]	
FIGARO-DKD	12 / 440	18 / 423	47.7	0.64 [0.31,1.31]	
Total	24 / 1260	42 / 1163		0.53 [0.32,0.87]	Z=-2.51, p=0.0122
Heterogeneity:	Q=0.48 (df=1)	p=0.4884	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.06 (df=1)	p=0.0802	I^2=67.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.165.7: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Age Group (years) - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

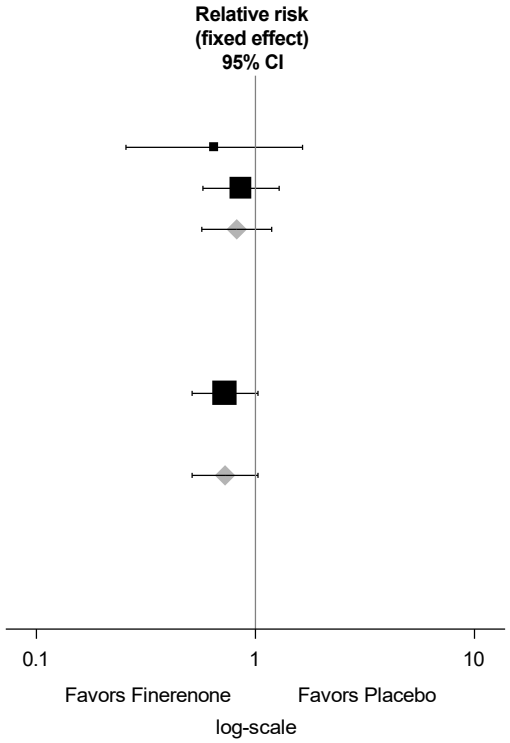
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	25 / 1103	29 / 1075	67.2	0.84 [0.50,1.42]	
FIGARO-DKD	14 / 336	12 / 335	32.8	1.16 [0.55,2.48]	
Total	39 / 1439	41 / 1410		0.93 [0.61,1.44]	Z=-0.31, p=0.7600
Heterogeneity:	Q=0.48 (df=1)	p=0.4894	I^2=0.0%		
>= 65					
FIDELIO-DKD	36 / 1514	56 / 1535	57.0	0.65 [0.43,0.98]	
FIGARO-DKD	29 / 1021	38 / 1021	43.0	0.76 [0.47,1.23]	
Total	65 / 2535	94 / 2556		0.70 [0.51,0.95]	Z=-2.27, p=0.0231
Heterogeneity:	Q=0.24 (df=1)	p=0.6233	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.17 (df=1)	p=0.2799	I^2=14.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.165.8: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

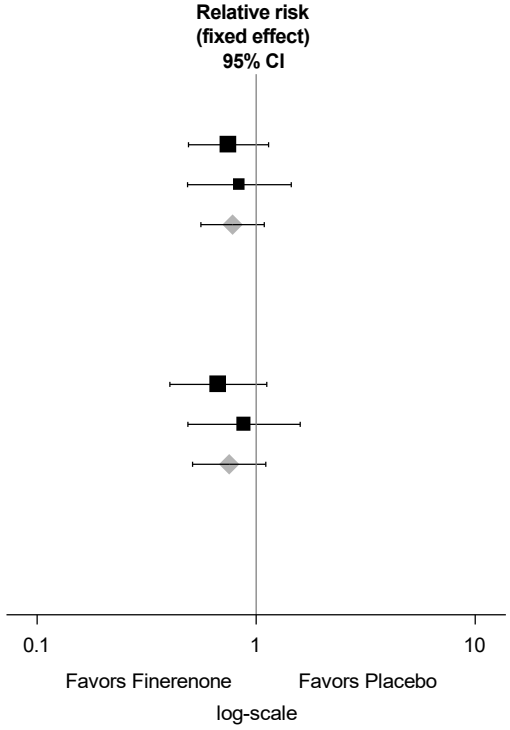
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	11 / 213	15.7	0.65 [0.26,1.64]	
FIGARO-DKD	43 / 1357	50 / 1356	84.3	0.86 [0.58,1.28]	
Total	50 / 1566	61 / 1569		0.82 [0.57,1.19]	Z=-1.05, p=0.2938
Heterogeneity:	Q=0.30 (df=1)	p=0.5853	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 2408	74 / 2397	100.0	0.73 [0.51,1.03]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	54 / 2408	74 / 2397		0.73 [0.51,1.03]	Z=-1.81, p=0.0703
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.23 (df=1)	p=0.6331	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.165.9: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

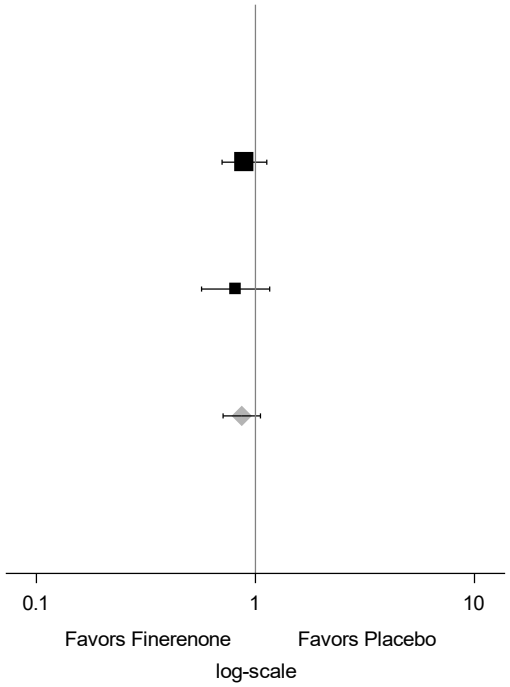
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	37 / 1556	49 / 1541	62.6	0.75 [0.49,1.14]	
FIGARO-DKD	23 / 637	27 / 627	37.4	0.84 [0.49,1.45]	
Total	60 / 2193	76 / 2168		0.78 [0.56,1.09]	Z=-1.46, p=0.1445
Heterogeneity:	Q=0.11 (df=1)	p=0.7447	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	24 / 1061	36 / 1069	57.3	0.67 [0.40,1.12]	
FIGARO-DKD	20 / 720	23 / 729	42.7	0.88 [0.49,1.59]	
Total	44 / 1781	59 / 1798		0.75 [0.51,1.11]	Z=-1.44, p=0.1485
Heterogeneity:	Q=0.46 (df=1)	p=0.4964	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8907	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.166: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

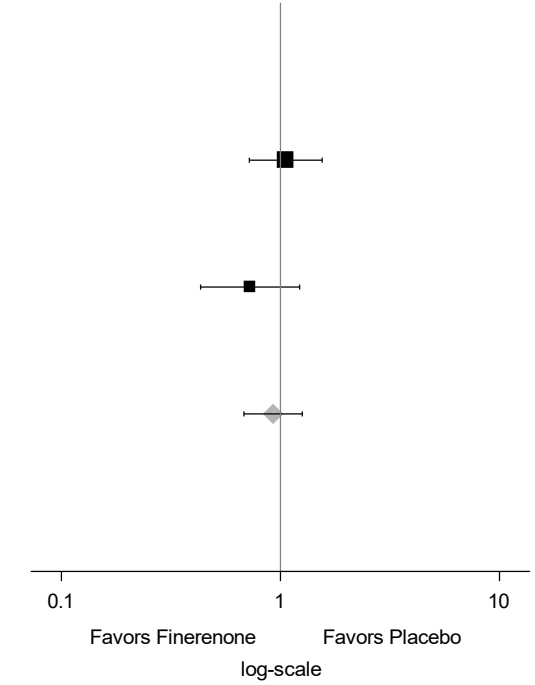
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	125 / 2617	140 / 2610	69.9	0.89 [0.70,1.13]	
FIGARO-DKD	52 / 1357	64 / 1356	30.1	0.81 [0.57,1.16]	
Total	177 / 3974	204 / 3966		0.87 [0.71,1.05]	Z=-1.44, p=0.1511
Heterogeneity:	Q=0.18 (df=1)	p=0.6725	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.167: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

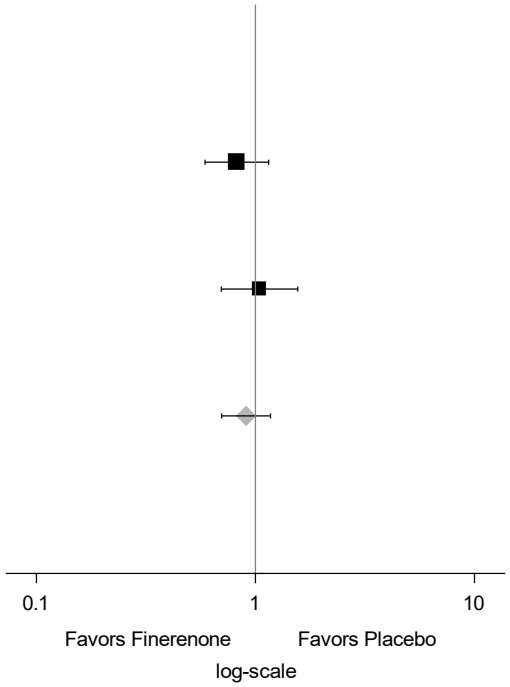
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2617	50 / 2610	64.9	1.06 [0.72,1.55]	
FIGARO-DKD	24 / 1357	33 / 1356	35.1	0.73 [0.43,1.22]	
Total	77 / 3974	83 / 3966		0.93 [0.68,1.26]	Z=-0.49, p=0.6224
Heterogeneity:	Q=1.29 (df=1)	p=0.2554	I^2=22.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.168: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

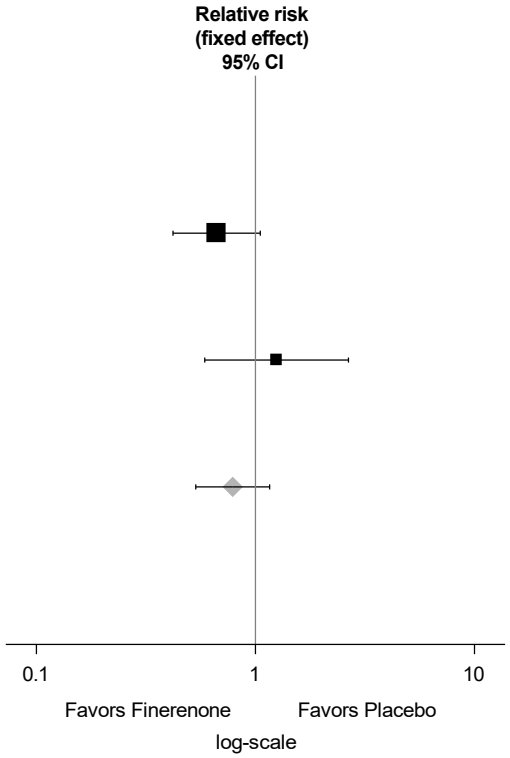
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	74 / 2610	59.1	0.82 [0.59,1.15]	
FIGARO-DKD	47 / 1357	45 / 1356	40.9	1.04 [0.70,1.56]	
Total	108 / 3974	119 / 3966		0.91 [0.70,1.17]	Z=-0.75, p=0.4524
Heterogeneity:	Q=0.80 (df=1)	p=0.3711	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.169: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

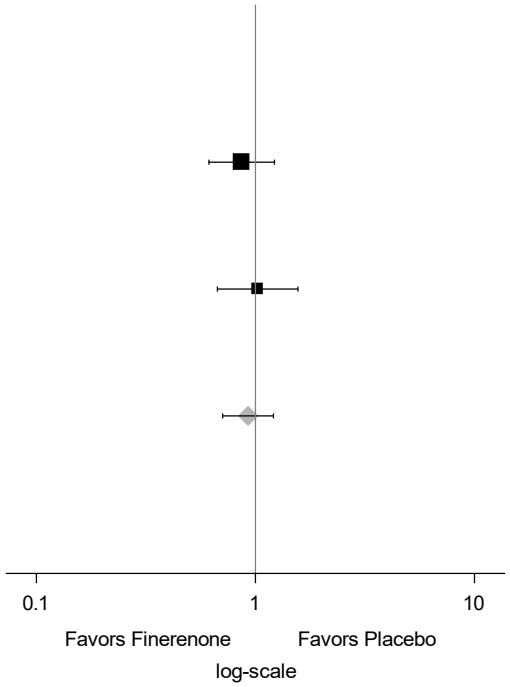
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	45 / 2610	73.1	0.66 [0.42,1.05]	
FIGARO-DKD	15 / 1357	12 / 1356	26.9	1.25 [0.59,2.66]	
Total	45 / 3974	57 / 3966		0.79 [0.53,1.16]	Z=-1.21, p=0.2275
Heterogeneity:	Q=1.96 (df=1)	p=0.1620	I^2=48.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.170: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

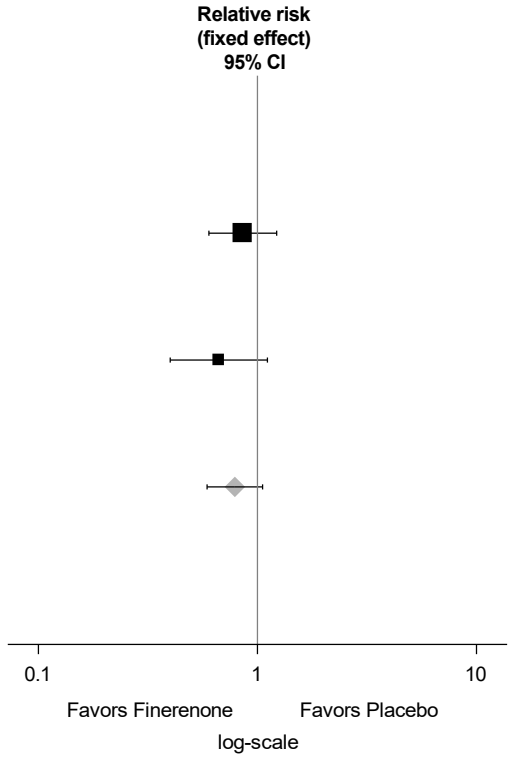
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	59 / 2617	68 / 2610	60.2	0.87 [0.61,1.22]	
FIGARO-DKD	42 / 1357	41 / 1356	39.8	1.02 [0.67,1.56]	
Total	101 / 3974	109 / 3966		0.93 [0.71,1.21]	Z=-0.57, p=0.5676
Heterogeneity:	Q=0.36 (df=1)	p=0.5465	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.171: Forest Plot for Relative Risk of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

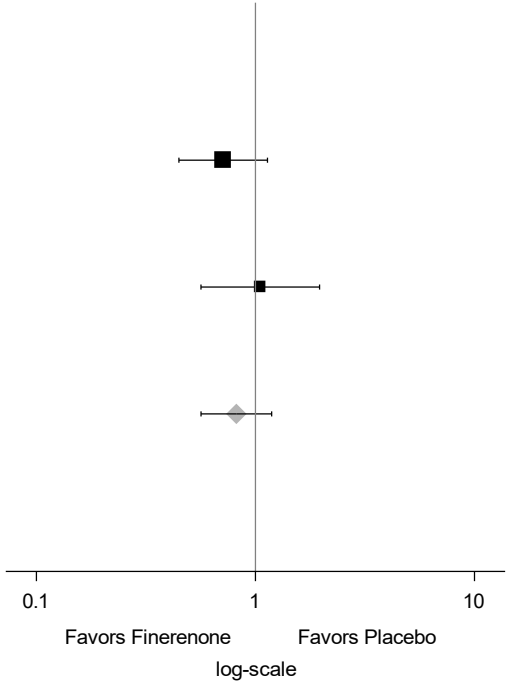
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	55 / 2617	64 / 2610	67.3	0.86 [0.60,1.22]	
FIGARO-DKD	24 / 1357	36 / 1356	32.7	0.67 [0.40,1.11]	
Total	79 / 3974	100 / 3966		0.79 [0.59,1.06]	Z=-1.60, p=0.1102
Heterogeneity:	Q=0.63 (df=1)	p=0.4279	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.172: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

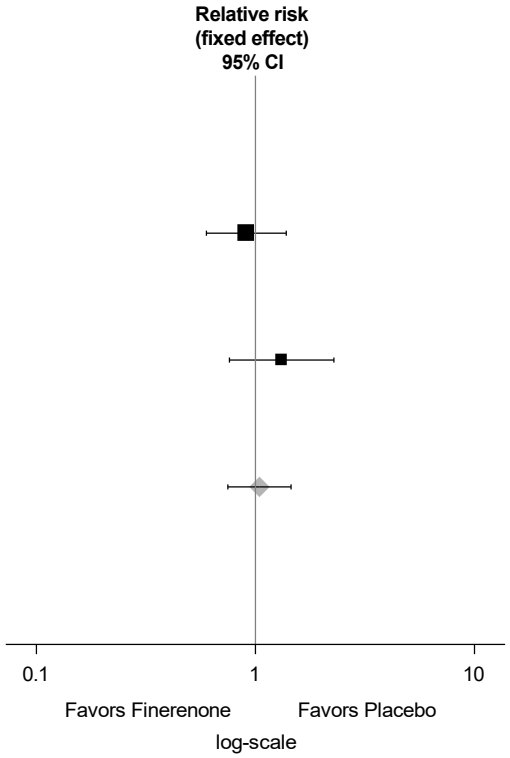
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	42 / 2610	64.2	0.71 [0.45,1.13]	
FIGARO-DKD	20 / 1357	19 / 1356	35.8	1.05 [0.56,1.96]	
Total	50 / 3974	61 / 3966		0.82 [0.56,1.19]	Z=-1.06, p=0.2892
Heterogeneity:	Q=0.96 (df=1)	p=0.3262	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.173: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

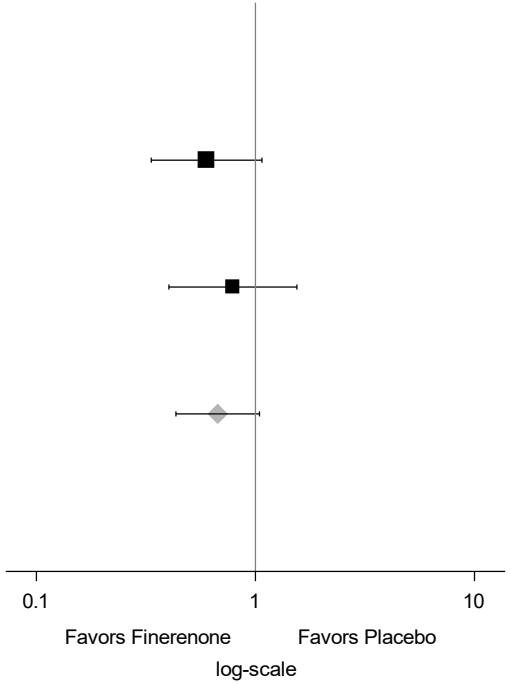
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2617	45 / 2610	63.1	0.91 [0.60,1.38]	
FIGARO-DKD	29 / 1357	22 / 1356	36.9	1.32 [0.76,2.28]	
Total	70 / 3974	67 / 3966		1.04 [0.75,1.45]	Z=0.25, p=0.8040
Heterogeneity:	Q=1.11 (df=1)	p=0.2923	I^2=9.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.174: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

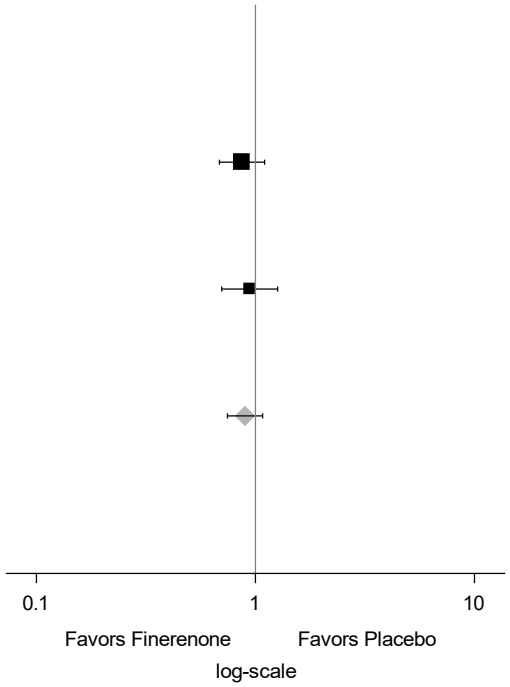
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	30 / 2610	57.2	0.60 [0.33,1.07]	
FIGARO-DKD	15 / 1357	19 / 1356	42.8	0.79 [0.40,1.55]	
Total	33 / 3974	49 / 3966		0.67 [0.43,1.04]	Z=-1.77, p=0.0764
Heterogeneity:	Q=0.37 (df=1)	p=0.5425	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.175: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

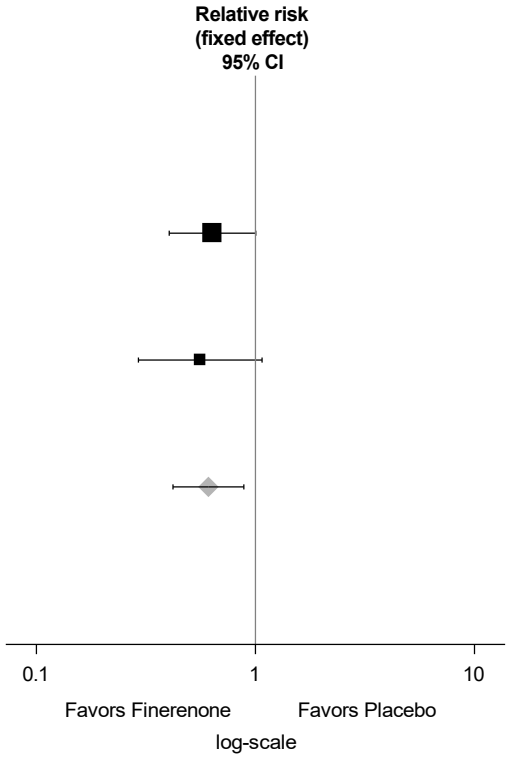
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	121 / 2617	139 / 2610	60.5	0.87 [0.68,1.10]	
FIGARO-DKD	81 / 1357	86 / 1356	39.5	0.94 [0.70,1.26]	
Total	202 / 3974	225 / 3966		0.90 [0.75,1.08]	Z=-1.16, p=0.2453
Heterogeneity:	Q=0.18 (df=1)	p=0.6755	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.176: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

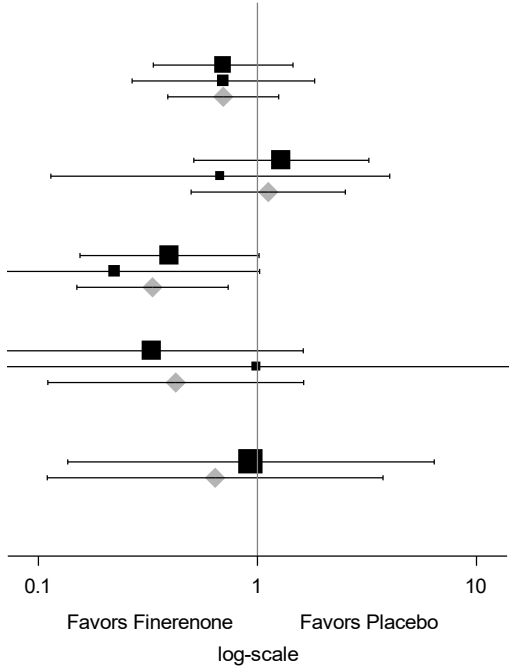
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	47 / 2610	67.1	0.64 [0.40,1.00]	
FIGARO-DKD	14 / 1357	25 / 1356	32.9	0.56 [0.29,1.07]	
Total	44 / 3974	72 / 3966		0.61 [0.42,0.89]	Z=-2.60, p=0.0093
Heterogeneity:	Q=0.10 (df=1)	p=0.7501	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.176.1: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

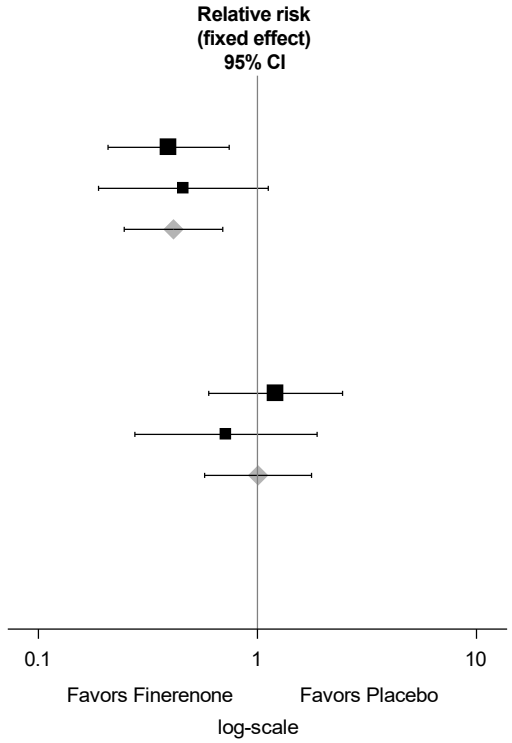
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 1075	17 / 1062	63.1	0.70 [0.33,1.45]	
FIGARO-DKD	7 / 638	10 / 637	36.9	0.70 [0.27,1.82]	
Total	19 / 1713	27 / 1699		0.70 [0.39,1.25]	Z=-1.21, p=0.2267
Heterogeneity:	Q=0.00 (df=1)	p=0.9971	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 424	8 / 436	78.9	1.29 [0.51,3.23]	
FIGARO-DKD	2 / 267	3 / 271	21.1	0.68 [0.11,4.02]	
Total	12 / 691	11 / 707		1.12 [0.50,2.52]	Z=0.27, p=0.7840
Heterogeneity:	Q=0.39 (df=1)	p=0.5304	I^2=0.0%		
Asia					
FIDELIO-DKD	6 / 751	15 / 745	72.4	0.40 [0.15,1.02]	
FIGARO-DKD	2 / 289	9 / 290	27.6	0.22 [0.05,1.02]	
Total	8 / 1040	24 / 1035		0.33 [0.15,0.74]	Z=-2.72, p=0.0066
Heterogeneity:	Q=0.40 (df=1)	p=0.5270	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	6 / 270	75.0	0.33 [0.07,1.62]	
FIGARO-DKD	1 / 102	1 / 101	25.0	0.99 [0.06,15.62]	
Total	3 / 375	7 / 371		0.42 [0.11,1.63]	Z=-1.25, p=0.2106
Heterogeneity:	Q=0.46 (df=1)	p=0.4979	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	1 / 97	0.0	0.00 [0.00,12E296]	
FIGARO-DKD	2 / 61	2 / 57	100.0	0.93 [0.14,6.41]	
Total	2 / 155	3 / 154		0.64 [0.11,3.74]	Z=-0.49, p=0.6214
Heterogeneity:	Q=0.15 (df=1)	p=0.7014	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.88 (df=4)	p=0.2995	I^2=18.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.176.2: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

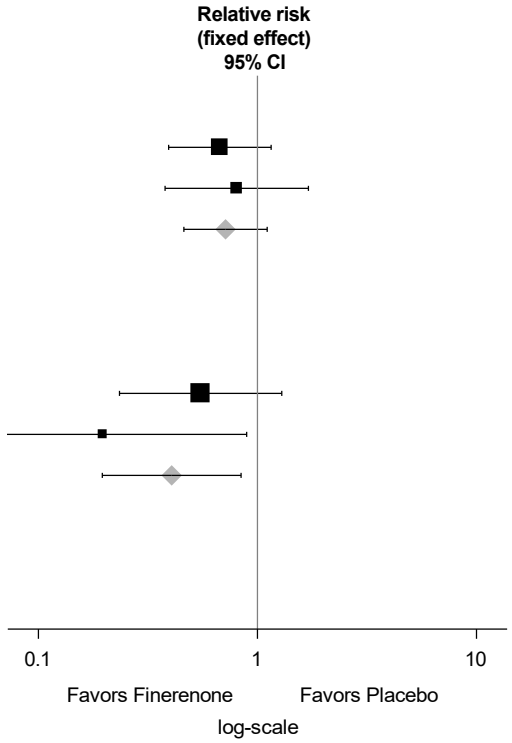
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1213	33 / 1210	66.2	0.39 [0.21,0.74]	
FIGARO-DKD	7 / 862	15 / 848	33.8	0.46 [0.19,1.12]	
Total	20 / 2075	48 / 2058		0.41 [0.25,0.69]	Z=-3.34, p=0.0008
Heterogeneity:	Q=0.08 (df=1)	p=0.7809	I^2=0.0%		
Absent					
FIDELIO-DKD	17 / 1404	14 / 1400	65.0	1.21 [0.60,2.45]	
FIGARO-DKD	7 / 495	10 / 508	35.0	0.72 [0.28,1.87]	
Total	24 / 1899	24 / 1908		1.01 [0.57,1.77]	Z=0.02, p=0.9816
Heterogeneity:	Q=0.74 (df=1)	p=0.3893	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.20 (df=1)	p=0.0226	I^2=80.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.176.3: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 1735	32 / 1700	66.2	0.67 [0.39,1.15]	
FIGARO-DKD	12 / 924	15 / 929	33.8	0.80 [0.38,1.71]	
Total	34 / 2659	47 / 2629		0.71 [0.46,1.11]	Z=-1.50, p=0.1331
Heterogeneity:	Q=0.14 (df=1)	p=0.7075	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	15 / 910	75.9	0.55 [0.23,1.29]	
FIGARO-DKD	2 / 433	10 / 426	24.1	0.20 [0.04,0.89]	
Total	10 / 1315	25 / 1336		0.41 [0.20,0.84]	Z=-2.42, p=0.0154
Heterogeneity:	Q=1.37 (df=1)	p=0.2419	I^2=27.0%		
Subgroup Heterogeneity:	Q=1.70 (df=1)	p=0.1922	I^2=41.2%		

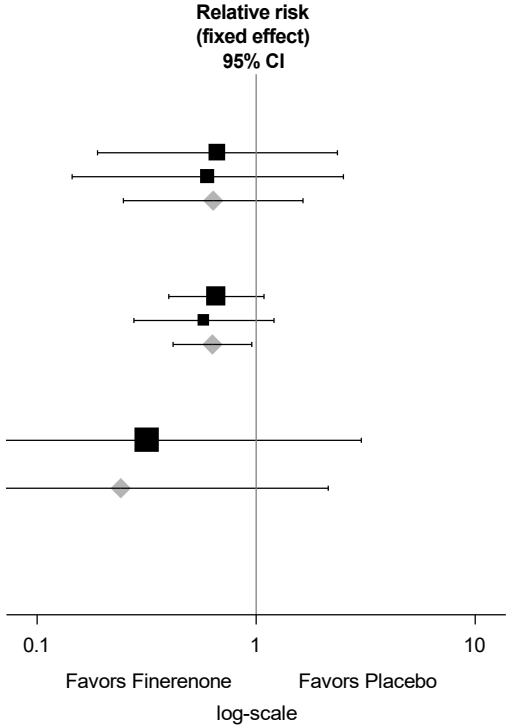


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.176.4: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

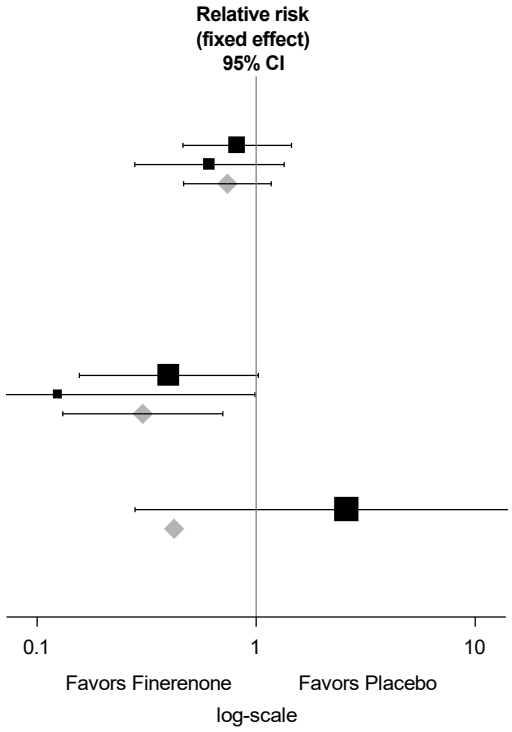
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 724	6 / 723	56.1	0.67 [0.19,2.35]	
FIGARO-DKD	3 / 494	5 / 495	43.9	0.60 [0.14,2.50]	
Total	7 / 1218	11 / 1218		0.64 [0.25,1.64]	Z=-0.94, p=0.3483
Heterogeneity:	Q=0.01 (df=1)	p=0.9164	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	25 / 1759	38 / 1760	68.4	0.66 [0.40,1.09]	
FIGARO-DKD	11 / 829	19 / 827	31.6	0.58 [0.28,1.21]	
Total	36 / 2588	57 / 2587		0.63 [0.42,0.95]	Z=-2.18, p=0.0293
Heterogeneity:	Q=0.08 (df=1)	p=0.7733	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	3 / 127	100.0	0.32 [0.03,3.02]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,11E296]	
Total	1 / 167	4 / 161		0.24 [0.03,2.13]	Z=-1.28, p=0.2008
Heterogeneity:	Q=0.06 (df=1)	p=0.8084	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=2)	p=0.6943	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.176.5: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

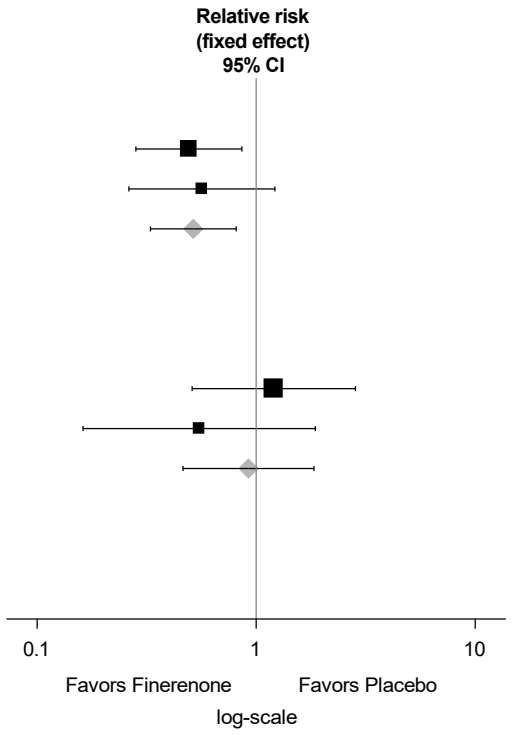
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1634	26 / 1657	65.4	0.82 [0.46,1.45]	
FIGARO-DKD	10 / 1010	16 / 989	34.6	0.61 [0.28,1.34]	
Total	31 / 2644	42 / 2646		0.74 [0.47,1.17]	Z=-1.28, p=0.1990
Heterogeneity:	Q=0.35 (df=1)	p=0.5563	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 129	0 / 115	0.0	121E9 [121E9,121E9]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	3 / 172	0 / 186		2.2E7 [2.2E7,2.2E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	6 / 678	15 / 677	82.9	0.40 [0.16,1.02]	
FIGARO-DKD	1 / 252	8 / 251	17.1	0.12 [0.02,0.99]	
Total	7 / 930	23 / 928		0.30 [0.13,0.70]	Z=-2.78, p=0.0055
Heterogeneity:	Q=1.04 (df=1)	p=0.3083	I^2=3.7%		
Others					
FIDELIO-DKD	0 / 176	6 / 161	0.0	0.00 [0.00,93E295]	
FIGARO-DKD	3 / 52	1 / 45	100.0	2.60 [0.28,24.09]	
Total	3 / 228	7 / 206		0.42 [0.42,0.42]	Z=. , p=.
Heterogeneity:	Q=2.55 (df=1)	p=0.1100	I^2=60.9%		
Subgroup Heterogeneity:	Q=3.31 (df=3)	p=0.3465	I^2=9.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.176.6: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

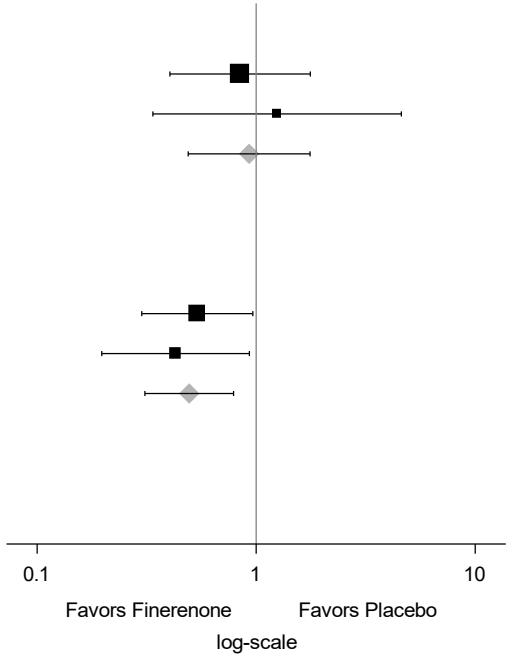
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	18 / 1797	38 / 1870	65.5	0.49 [0.28,0.86]	
FIGARO-DKD	10 / 917	18 / 933	34.5	0.57 [0.26,1.22]	
Total	28 / 2714	56 / 2803		0.52 [0.33,0.81]	Z=-2.87, p=0.0040
Heterogeneity:	Q=0.08 (df=1)	p=0.7772	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 820	9 / 740	66.9	1.20 [0.51,2.84]	
FIGARO-DKD	4 / 440	7 / 423	33.1	0.55 [0.16,1.86]	
Total	16 / 1260	16 / 1163		0.92 [0.46,1.84]	Z=-0.23, p=0.8181
Heterogeneity:	Q=1.06 (df=1)	p=0.3032	I^2=5.7%		
Subgroup Heterogeneity:	Q=1.91 (df=1)	p=0.1670	I^2=47.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.176.7: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

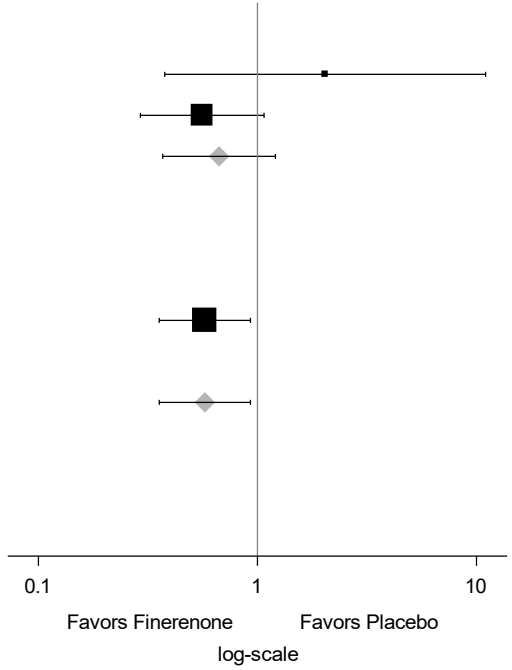
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	13 / 1103	15 / 1075	75.8	0.84 [0.40,1.77]	
FIGARO-DKD	5 / 336	4 / 335	24.2	1.25 [0.34,4.60]	
Total	18 / 1439	19 / 1410		0.93 [0.49,1.76]	Z=-0.23, p=0.8203
Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 1514	32 / 1535	63.8	0.54 [0.30,0.97]	
FIGARO-DKD	9 / 1021	21 / 1021	36.2	0.43 [0.20,0.93]	
Total	26 / 2535	53 / 2556		0.49 [0.31,0.79]	Z=-2.96, p=0.0031
Heterogeneity:	Q=0.21 (df=1)	p=0.6446	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1194	I^2=58.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.176.8: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

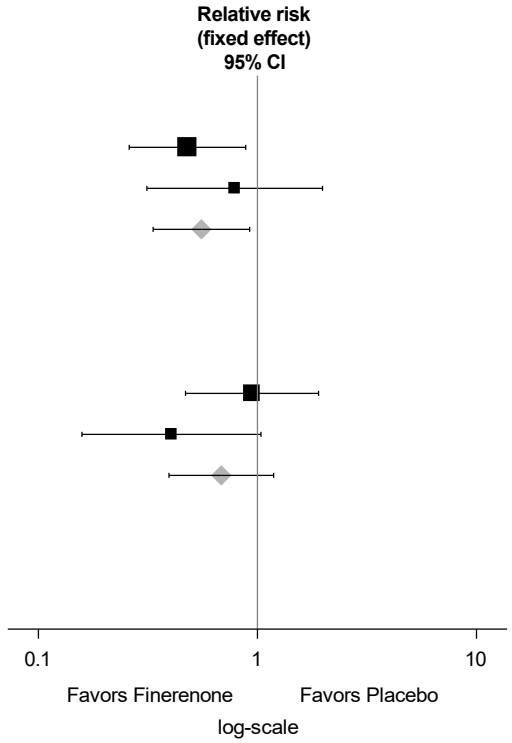
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	2 / 213	12.9	2.04 [0.38,11.01]	
FIGARO-DKD	14 / 1357	25 / 1356	87.1	0.56 [0.29,1.07]	
Total	18 / 1566	27 / 1569		0.67 [0.37,1.21]	Z=-1.34, p=0.1817
Heterogeneity:	Q=1.97 (df=1)	p=0.1609	I^2=49.1%		
Very High					
FIDELIO-DKD	26 / 2408	45 / 2397	100.0	0.58 [0.36,0.93]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	26 / 2408	45 / 2397		0.58 [0.36,0.93]	Z=-2.26, p=0.0238
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7005	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.176.9: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

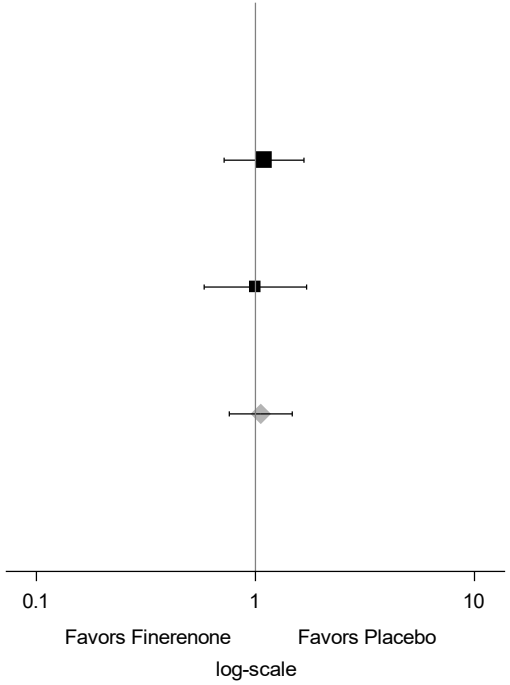
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	15 / 1556	31 / 1541	69.4	0.48 [0.26,0.88]	
FIGARO-DKD	8 / 637	10 / 627	30.6	0.79 [0.31,1.98]	
Total	23 / 2193	41 / 2168		0.55 [0.33,0.92]	Z=-2.28, p=0.0227
Heterogeneity:	Q=0.77 (df=1)	p=0.3794	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	15 / 1061	16 / 1069	64.4	0.94 [0.47,1.90]	
FIGARO-DKD	6 / 720	15 / 729	35.6	0.41 [0.16,1.04]	
Total	21 / 1781	31 / 1798		0.68 [0.39,1.19]	Z=-1.35, p=0.1758
Heterogeneity:	Q=2.01 (df=1)	p=0.1563	I^2=50.2%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5830	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.177: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

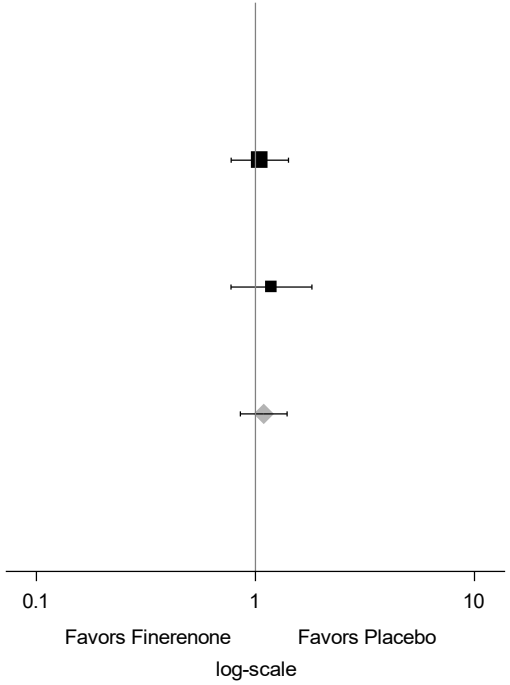
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	41 / 2610	62.2	1.09 [0.72,1.67]	
FIGARO-DKD	26 / 1357	26 / 1356	37.8	1.00 [0.58,1.71]	
Total	71 / 3974	67 / 3966		1.06 [0.76,1.47]	Z=0.33, p=0.7402
Heterogeneity:	Q=0.07 (df=1)	p=0.7935	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.178: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

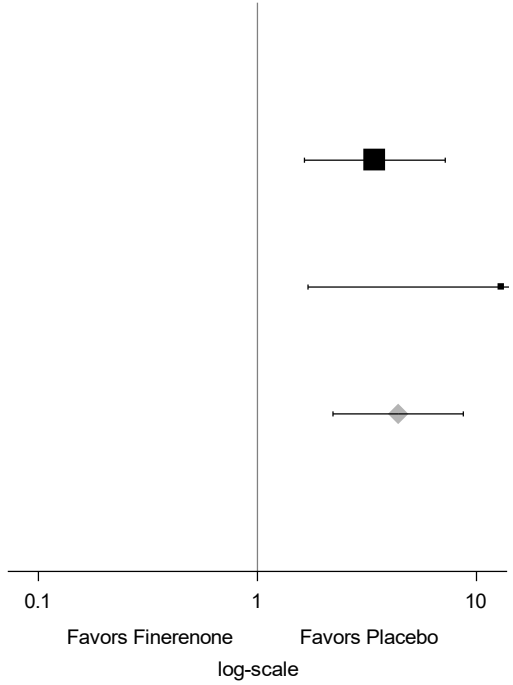
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	84 / 2617	80 / 2610	66.6	1.05 [0.77,1.42]	
FIGARO-DKD	45 / 1357	38 / 1356	33.4	1.18 [0.77,1.81]	
Total	129 / 3974	118 / 3966		1.09 [0.85,1.39]	Z=0.69, p=0.4874
Heterogeneity:	Q=0.21 (df=1)	p=0.6458	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.179: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

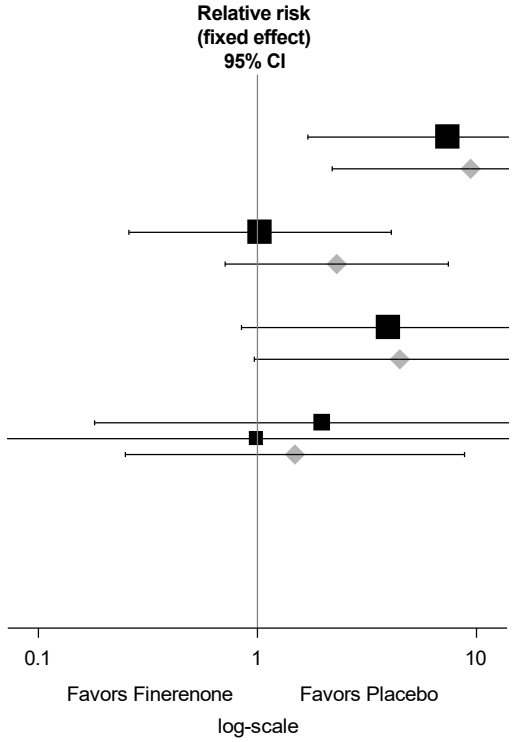
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	9 / 2610	88.3	3.44 [1.64,7.20]	
FIGARO-DKD	13 / 1357	1 / 1356	11.7	12.99 [1.70,99.16]	
Total	44 / 3974	10 / 3966		4.39 [2.21,8.71]	Z=4.23, p=<.0001
Heterogeneity:	Q=1.52 (df=1)	p=0.2182	I^2=34.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.179.1: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

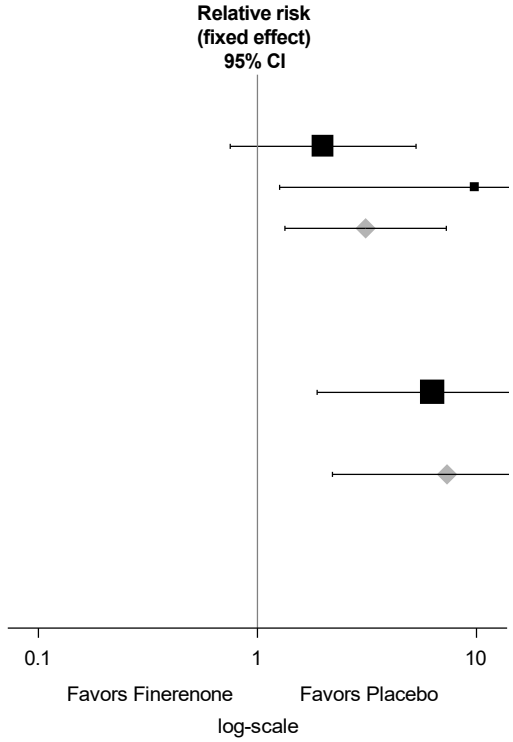
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	2 / 1062	100.0	7.41 [1.70,32.32]	
FIGARO-DKD	4 / 638	0 / 637	0.0	888E8 [888E8,888E8]	
Total	19 / 1713	2 / 1699		9.40 [2.19,40.29]	Z=3.02, p=0.0025
Heterogeneity:	Q=0.10 (df=1)	p=0.7514	I^2=0.0%		
North America					
FIDELIO-DKD	4 / 424	4 / 436	100.0	1.03 [0.26,4.09]	
FIGARO-DKD	5 / 267	0 / 271	0.0	975E8 [975E8,975E8]	
Total	9 / 691	4 / 707		2.30 [0.71,7.44]	Z=1.39, p=0.1636
Heterogeneity:	Q=1.31 (df=1)	p=0.2522	I^2=23.7%		
Asia					
FIDELIO-DKD	8 / 751	2 / 745	100.0	3.97 [0.85,18.62]	
FIGARO-DKD	1 / 289	0 / 290	0.0	133E9 [133E9,133E9]	
Total	9 / 1040	2 / 1035		4.47 [0.97,20.62]	Z=1.92, p=0.0551
Heterogeneity:	Q=0.02 (df=1)	p=0.8806	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	1 / 270	57.0	1.98 [0.18,21.69]	
FIGARO-DKD	1 / 102	1 / 101	43.0	0.99 [0.06,15.62]	
Total	3 / 375	2 / 371		1.48 [0.25,8.82]	Z=0.43, p=0.6648
Heterogeneity:	Q=0.14 (df=1)	p=0.7103	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	0 / 97	0.0	111E9 [111E9,111E9]	
FIGARO-DKD	2 / 61	0 / 57	0.0	171E9 [171E9,171E9]	
Total	4 / 155	0 / 154		132E9 [132E9,132E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.25 (df=4)	p=0.5170	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.179.2: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	12 / 1213	6 / 1210	81.5	2.00 [0.75,5.30]	
FIGARO-DKD	10 / 862	1 / 848	18.5	9.84 [1.26,76.68]	
Total	22 / 2075	7 / 2058		3.12 [1.33,7.28]	Z=2.63, p=0.0086
Heterogeneity:	Q=2.01 (df=1)	p=0.1567	I^2=50.1%		
Absent					
FIDELIO-DKD	19 / 1404	3 / 1400	100.0	6.32 [1.87,21.29]	
FIGARO-DKD	3 / 495	0 / 508	0.0	859E8 [859E8,859E8]	
Total	22 / 1899	3 / 1908		7.34 [2.20,24.46]	Z=3.24, p=0.0012
Heterogeneity:	Q=0.06 (df=1)	p=0.8091	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.30 (df=1)	p=0.2550	I^2=22.8%		

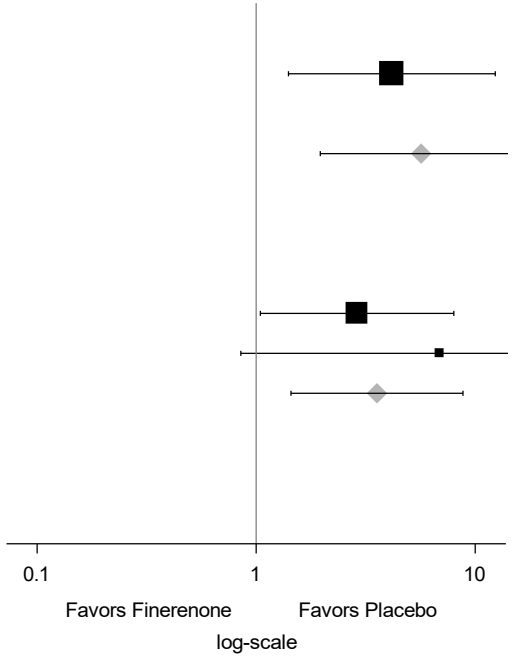


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.179.3: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

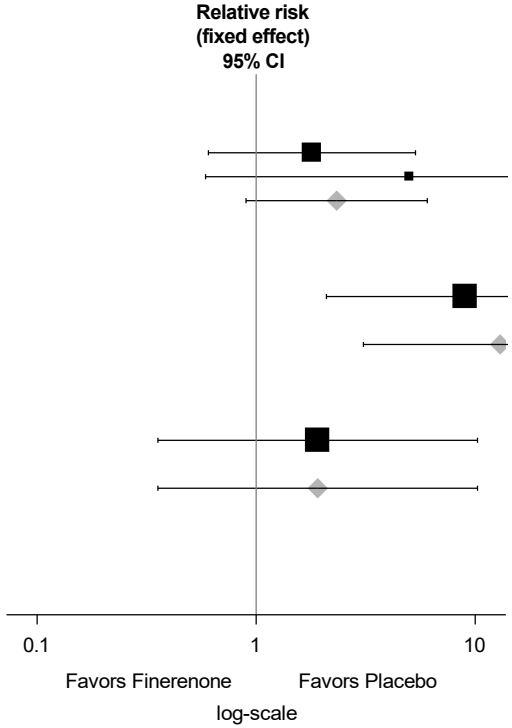
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	17 / 1735	4 / 1700	100.0	4.16 [1.40,12.35]	
FIGARO-DKD	6 / 924	0 / 929	0.0	92E9 [92E9,92E9]	
Total	23 / 2659	4 / 2629		5.66 [1.96,16.36]	Z=3.21, p=0.0013
Heterogeneity:	Q=0.31 (df=1)	p=0.5791	I^2=0.0%		
> 4.5					
FIDELIO-DKD	14 / 882	5 / 910	80.9	2.89 [1.04,7.99]	
FIGARO-DKD	7 / 433	1 / 426	19.1	6.89 [0.85,55.74]	
Total	21 / 1315	6 / 1336		3.56 [1.44,8.79]	Z=2.75, p=0.0059
Heterogeneity:	Q=0.54 (df=1)	p=0.4605	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.43 (df=1)	p=0.5137	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.179.4: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

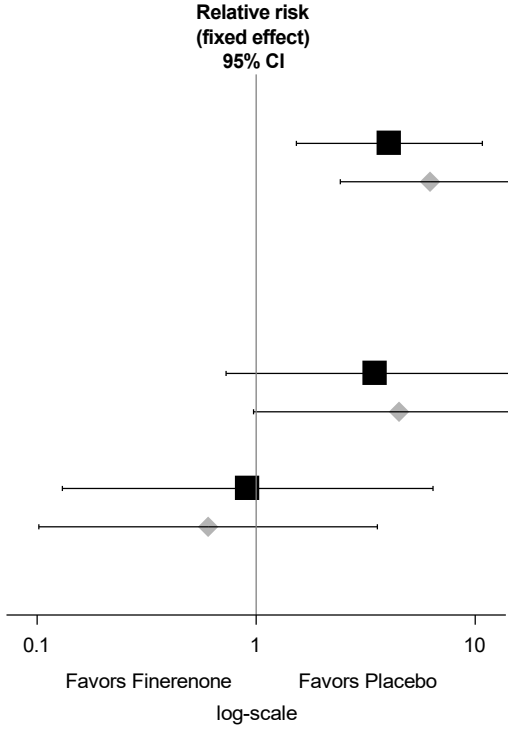
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 724	5 / 723	79.5	1.80 [0.61,5.34]	
FIGARO-DKD	5 / 494	1 / 495	20.5	5.01 [0.59,42.73]	
Total	14 / 1218	6 / 1218		2.33 [0.90,6.05]	Z=1.74, p=0.0817
Heterogeneity:	Q=0.71 (df=1)	p=0.3999	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	18 / 1759	2 / 1760	100.0	9.01 [2.09,38.75]	
FIGARO-DKD	8 / 829	0 / 827	0.0	137E9 [137E9,137E9]	
Total	26 / 2588	2 / 2587		13.00 [3.09,54.70]	Z=3.50, p=0.0005
Heterogeneity:	Q=0.24 (df=1)	p=0.6223	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	2 / 127	100.0	1.91 [0.36,10.25]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	4 / 167	2 / 161		1.91 [0.36,10.25]	Z=0.75, p=0.4503
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.40 (df=2)	p=0.1109	I^2=54.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.179.5: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

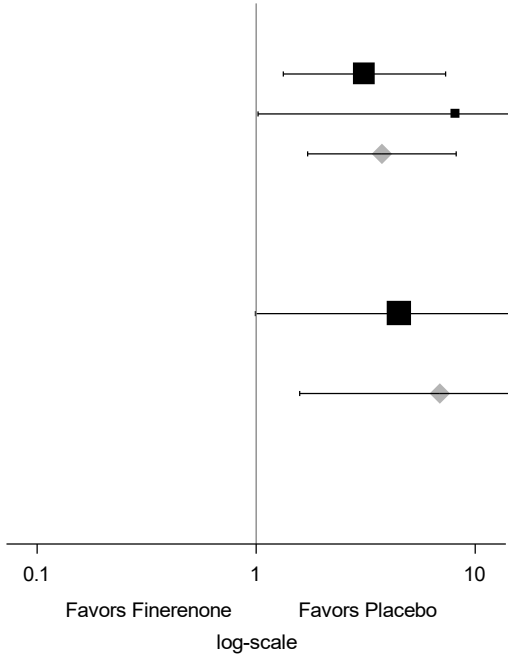
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	20 / 1634	5 / 1657	100.0	4.06 [1.53,10.78]	
FIGARO-DKD	11 / 1010	0 / 989	0.0	154E9 [154E9,154E9]	
Total	31 / 2644	5 / 2646		6.22 [2.42,15.97]	Z=3.80, p=0.0001
Heterogeneity:	Q=0.73 (df=1)	p=0.3916	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	0 / 115	0.0	808E8 [808E8,808E8]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	2 / 172	0 / 186		4.03E7 [4.03E7,4.03E7]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	7 / 678	2 / 677	100.0	3.49 [0.73,16.76]	
FIGARO-DKD	2 / 252	0 / 251	0.0	112E9 [112E9,112E9]	
Total	9 / 930	2 / 928		4.49 [0.97,20.72]	Z=1.92, p=0.0543
Heterogeneity:	Q=0.10 (df=1)	p=0.7542	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	2 / 161	100.0	0.91 [0.13,6.42]	
FIGARO-DKD	0 / 52	1 / 45	0.0	0.00 [0.00,16E296]	
Total	2 / 228	3 / 206		0.60 [0.10,3.58]	Z=-0.56, p=0.5779
Heterogeneity:	Q=0.18 (df=1)	p=0.6755	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.20 (df=3)	p=0.1578	I^2=42.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.179.6: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

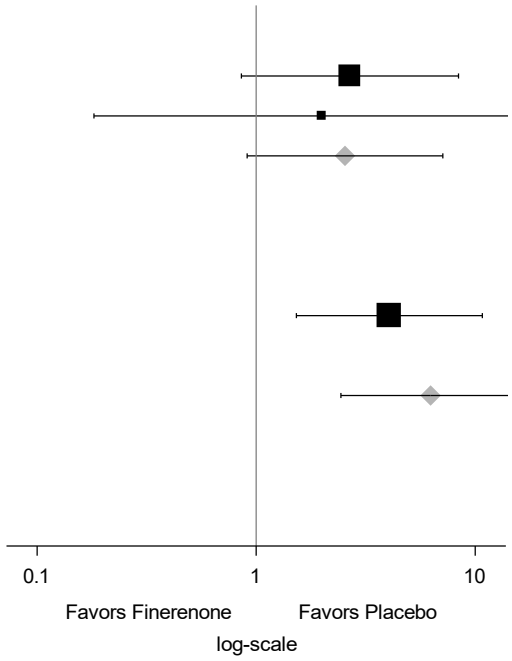
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	21 / 1797	7 / 1870	85.6	3.12 [1.33,7.33]	
FIGARO-DKD	8 / 917	1 / 933	14.4	8.14 [1.02,64.95]	
Total	29 / 2714	8 / 2803		3.75 [1.72,8.19]	Z=3.32, p=0.0009
Heterogeneity:	Q=0.71 (df=1)	p=0.3986	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	2 / 740	100.0	4.51 [0.99,20.53]	
FIGARO-DKD	5 / 440	0 / 423	0.0	161E9 [161E9,161E9]	
Total	15 / 1260	2 / 1163		6.90 [1.58,30.09]	Z=2.57, p=0.0102
Heterogeneity:	Q=0.30 (df=1)	p=0.5832	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4741	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.179.7: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

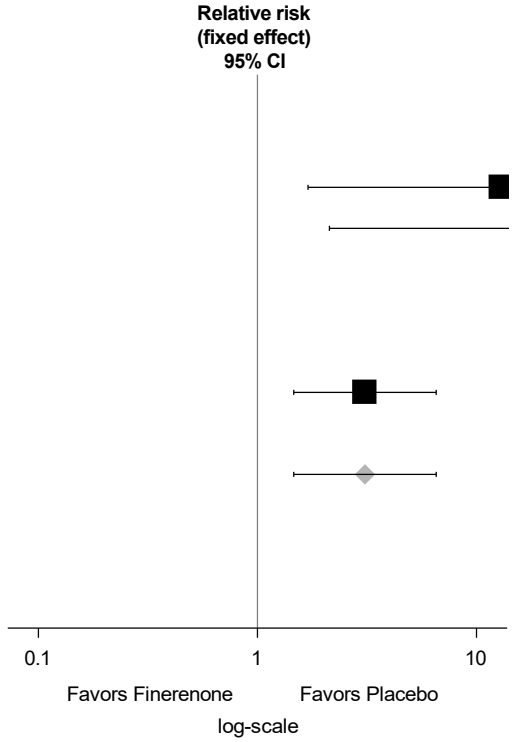
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1103	4 / 1075	81.5	2.68 [0.86,8.39]	
FIGARO-DKD	2 / 336	1 / 335	18.5	1.99 [0.18,21.89]	
Total	13 / 1439	5 / 1410		2.54 [0.91,7.12]	Z=1.78, p=0.0753
Heterogeneity:	Q=0.05 (df=1)	p=0.8271	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1514	5 / 1535	100.0	4.06 [1.53,10.78]	
FIGARO-DKD	11 / 1021	0 / 1021	0.0	153E9 [153E9,153E9]	
Total	31 / 2535	5 / 2556		6.26 [2.44,16.06]	Z=3.81, p=0.0001
Heterogeneity:	Q=0.76 (df=1)	p=0.3846	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2062	I^2=37.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.1.179.8: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	0 / 213	0.0	203E9 [203E9,203E9]	
FIGARO-DKD	13 / 1357	1 / 1356	100.0	12.99 [1.70,99.16]	
Total	16 / 1566	1 / 1569		16.05 [2.13,120.84]	Z=2.69, p=0.0071
Heterogeneity:	Q=0.04 (df=1)	p=0.8386	I^2=0.0%		
Very High					
FIDELIO-DKD	28 / 2408	9 / 2397	100.0	3.10 [1.46,6.55]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	28 / 2408	9 / 2397		3.10 [1.46,6.55]	Z=2.96, p=0.0031
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.24 (df=1)	p=0.1343	I^2=55.4%		

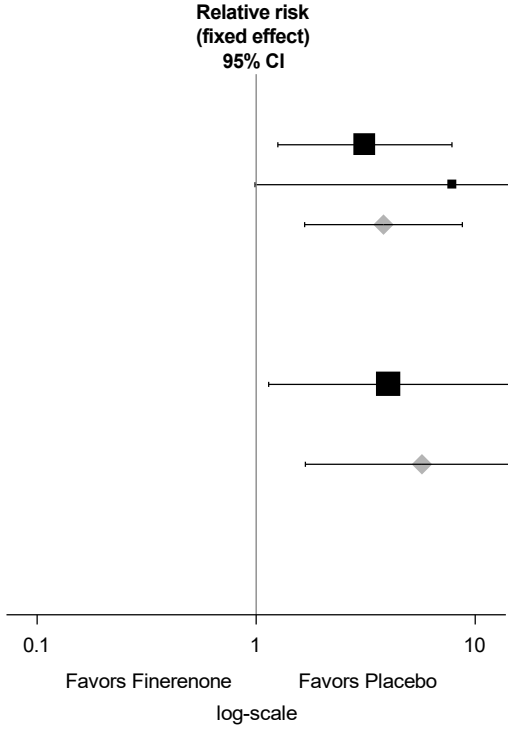


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.179.9: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

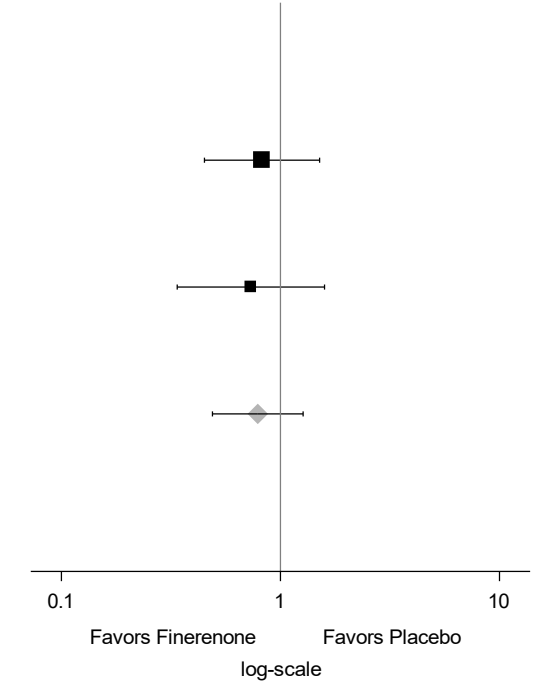
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	19 / 1556	6 / 1541	83.7	3.14 [1.26,7.83]	
FIGARO-DKD	8 / 637	1 / 627	16.3	7.87 [0.99,62.77]	
Total	27 / 2193	7 / 2168		3.81 [1.66,8.74]	Z=3.16, p=0.0016
Heterogeneity:	Q=0.64 (df=1)	p=0.4223	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	12 / 1061	3 / 1069	100.0	4.03 [1.14,14.24]	
FIGARO-DKD	5 / 720	0 / 729	0.0	984E8 [984E8,984E8]	
Total	17 / 1781	3 / 1798		5.71 [1.68,19.46]	Z=2.79, p=0.0053
Heterogeneity:	Q=0.29 (df=1)	p=0.5879	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.29 (df=1)	p=0.5923	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.1.180: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

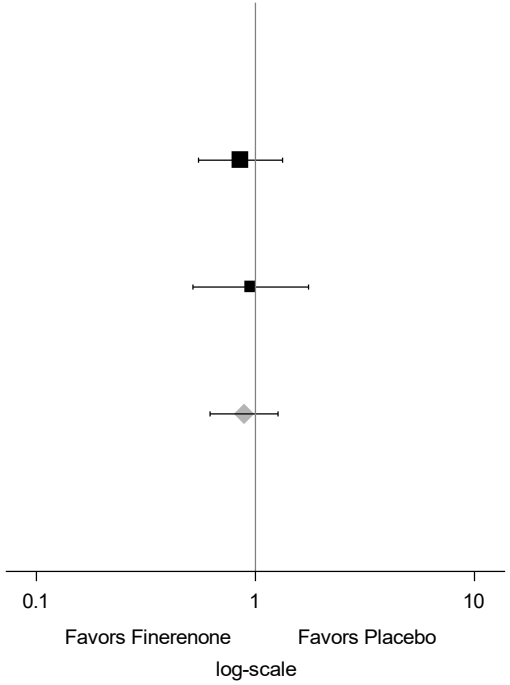
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	19 / 2617	23 / 2610	62.1	0.82 [0.45,1.51]	
FIGARO-DKD	11 / 1357	15 / 1356	37.9	0.73 [0.34,1.59]	
Total	30 / 3974	38 / 3966		0.79 [0.49,1.27]	Z=-0.98, p=0.3270
Heterogeneity:	Q=0.05 (df=1)	p=0.8153	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.181: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

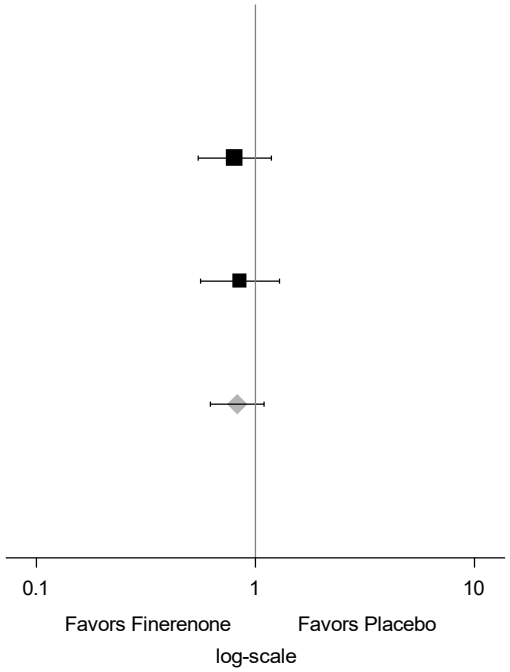
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	42 / 2610	65.4	0.85 [0.55,1.33]	
FIGARO-DKD	20 / 1357	21 / 1356	34.6	0.95 [0.52,1.75]	
Total	56 / 3974	63 / 3966		0.89 [0.62,1.27]	Z=-0.66, p=0.5111
Heterogeneity:	Q=0.08 (df=1)	p=0.7796	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.182: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

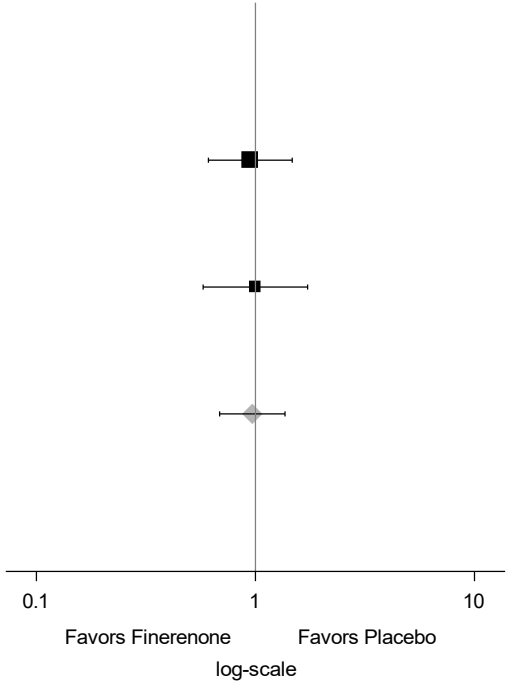
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	57 / 2610	53.8	0.80 [0.55,1.18]	
FIGARO-DKD	40 / 1357	47 / 1356	46.2	0.85 [0.56,1.29]	
Total	86 / 3974	104 / 3966		0.83 [0.62,1.09]	Z=-1.33, p=0.1829
Heterogeneity:	Q=0.04 (df=1)	p=0.8487	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.183: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

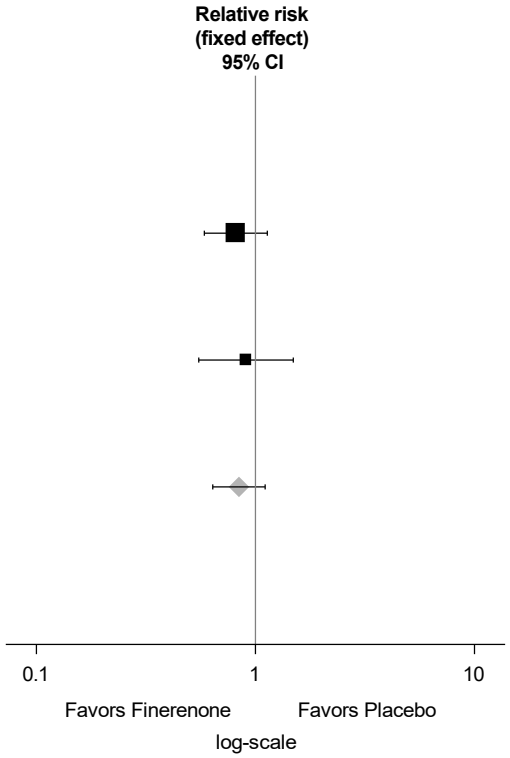
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	40 / 2610	60.8	0.95 [0.61,1.47]	
FIGARO-DKD	25 / 1357	25 / 1356	39.2	1.00 [0.58,1.73]	
Total	63 / 3974	65 / 3966		0.97 [0.69,1.36]	Z=-0.19, p=0.8502
Heterogeneity:	Q=0.02 (df=1)	p=0.8822	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.184: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

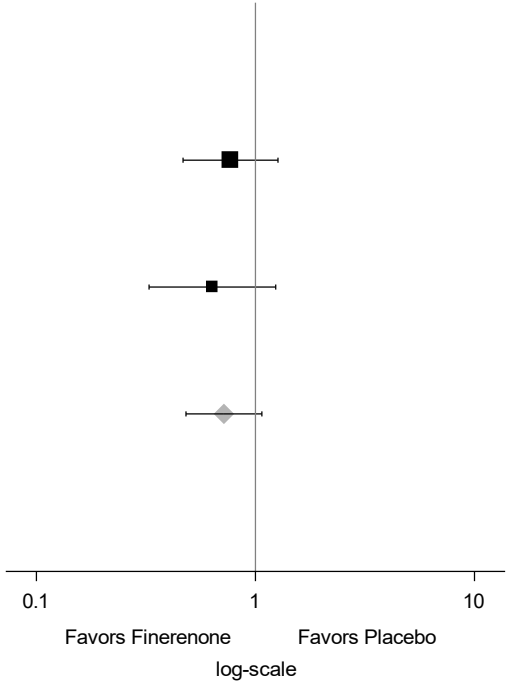
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2617	76 / 2610	69.3	0.81 [0.58,1.13]	
FIGARO-DKD	29 / 1357	32 / 1356	30.7	0.91 [0.55,1.49]	
Total	91 / 3974	108 / 3966		0.84 [0.64,1.11]	Z=-1.23, p=0.2170
Heterogeneity:	Q=0.12 (df=1)	p=0.7251	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.185: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

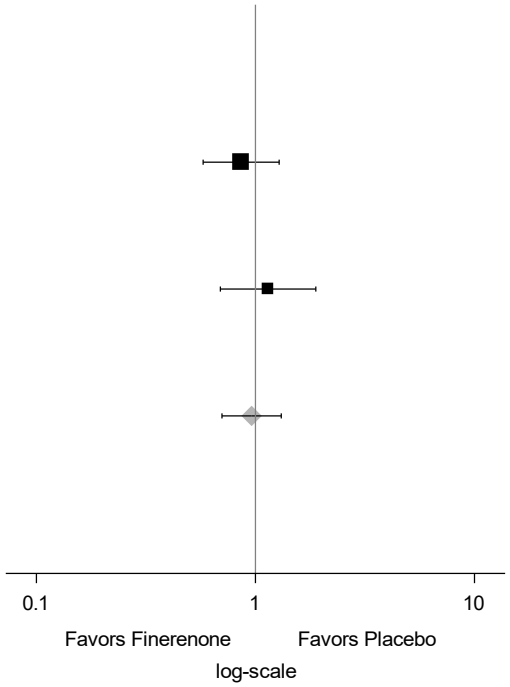
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	35 / 2610	64.0	0.77 [0.47,1.27]	
FIGARO-DKD	14 / 1357	22 / 1356	36.0	0.64 [0.33,1.24]	
Total	41 / 3974	57 / 3966		0.72 [0.48,1.07]	Z=-1.63, p=0.1034
Heterogeneity:	Q=0.20 (df=1)	p=0.6536	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.186: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

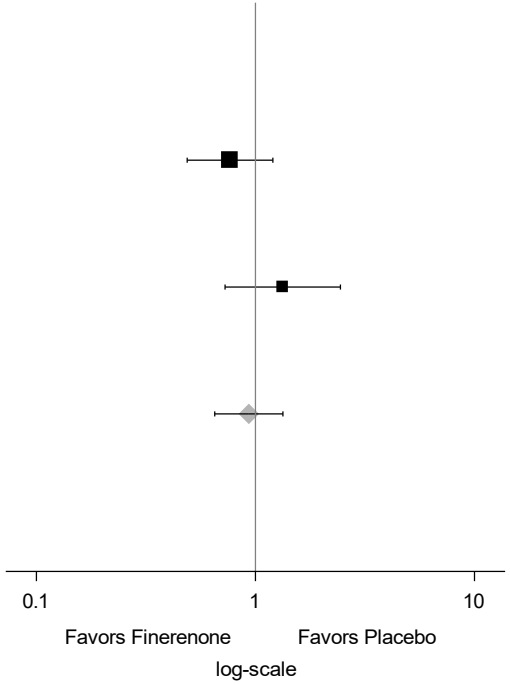
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2617	51 / 2610	61.2	0.86 [0.58,1.28]	
FIGARO-DKD	32 / 1357	28 / 1356	38.8	1.14 [0.69,1.89]	
Total	76 / 3974	79 / 3966		0.96 [0.70,1.31]	Z=-0.25, p=0.7997
Heterogeneity:	Q=0.75 (df=1)	p=0.3869	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.187: Forest Plot for Relative Risk of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

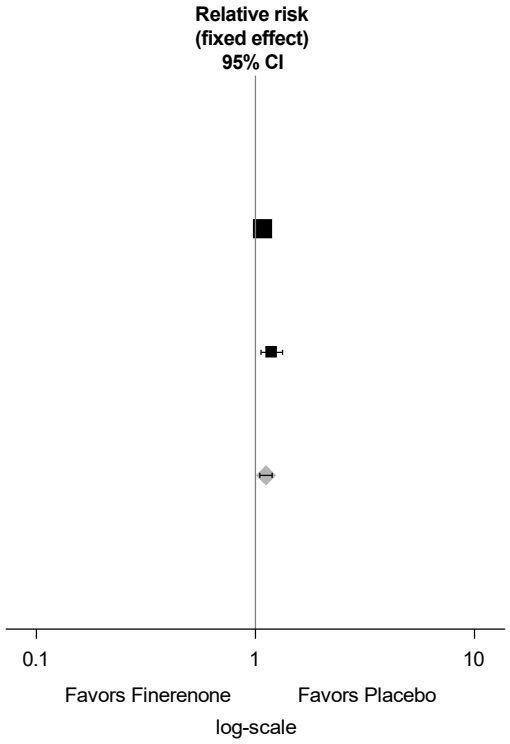
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2617	43 / 2610	64.5	0.77 [0.49,1.20]	
FIGARO-DKD	24 / 1357	18 / 1356	35.5	1.33 [0.73,2.44]	
Total	57 / 3974	61 / 3966		0.93 [0.65,1.33]	Z=-0.38, p=0.7031
Heterogeneity:	Q=2.07 (df=1)	p=0.1504	I^2=51.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, PT=preferred term, RR=relative risk, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.188: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment AEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

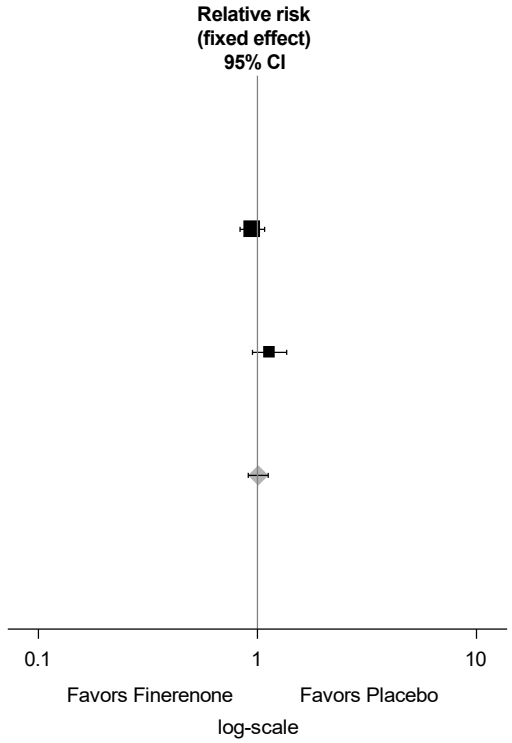
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	873 / 2617	803 / 2610	67.2	1.08 [1.00,1.17]	
FIGARO-DKD	455 / 1357	383 / 1356	32.8	1.19 [1.06,1.33]	
Total	1328 / 3974	1186 / 3966		1.12 [1.05,1.19]	Z=3.35, p=0.0008
Heterogeneity:	Q=1.66 (df=1)	p=0.1982	I^2=39.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.189: Forestplot for Relative Risk of Proportion of Subjects with Post-Treatment SAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

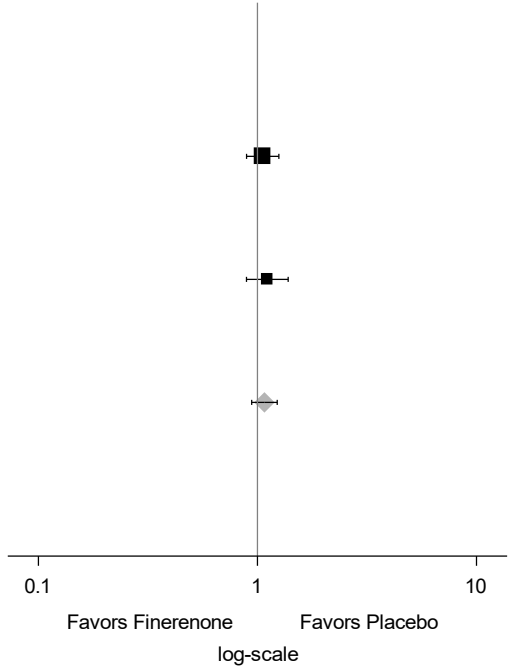
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	382 / 2617	402 / 2610	66.0	0.95 [0.83,1.08]	
FIGARO-DKD	216 / 1357	190 / 1356	34.0	1.14 [0.95,1.36]	
Total	598 / 3974	592 / 3966		1.01 [0.91,1.12]	Z=0.15, p=0.8803
Heterogeneity:	Q=2.57 (df=1)	p=0.1086	I^2=61.2%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.1.190: Forestplot for Relative Risk of Proportion of Subjects with Severe Post-Treatment AEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

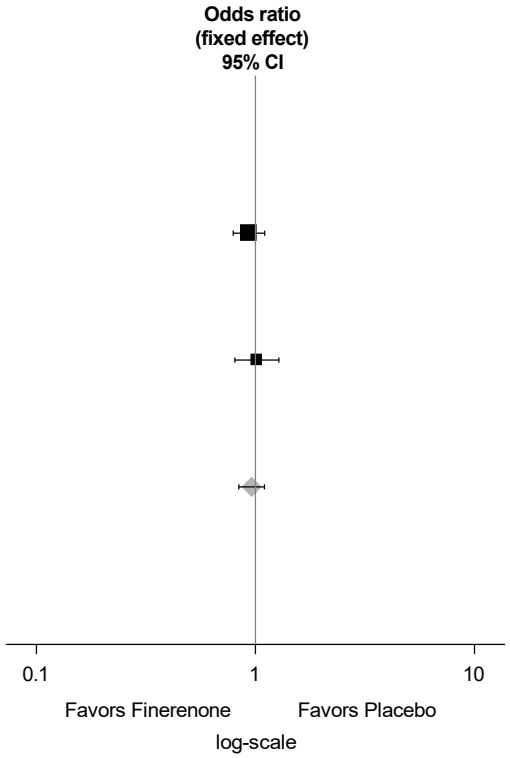
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Relative risk (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	249 / 2617	235 / 2610	62.5	1.06 [0.89,1.25]	
FIGARO-DKD	151 / 1357	136 / 1356	37.5	1.11 [0.89,1.38]	
Total	400 / 3974	371 / 3966		1.08 [0.94,1.23]	Z=1.07, p=0.2833
Heterogeneity:	Q=0.12 (df=1)	p=0.7306	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, RR=relative risk, (S)AE=(serious) adverse event, SoC=standard of care.
Note: Post-treatment AEs are AEs that occurred more than 3 days after temporary (study drug interruption) or permanent stop of study drug.
For single studies the RR is estimated by a GLM with classification term for treatment using a binomial distribution and log as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

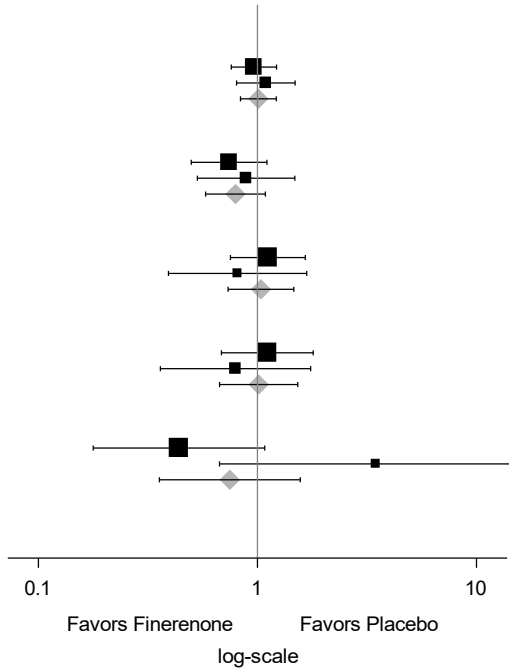
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2287 / 2617	2300 / 2610	66.2	0.93 [0.79,1.10]	
FIGARO-DKD	1195 / 1357	1192 / 1356	33.8	1.01 [0.81,1.28]	
Total	3482 / 3974	3492 / 3966		0.96 [0.84,1.10]	Z=-0.58, p=0.5590
Heterogeneity:	Q=0.33 (df=1)	p=0.5676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.1.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

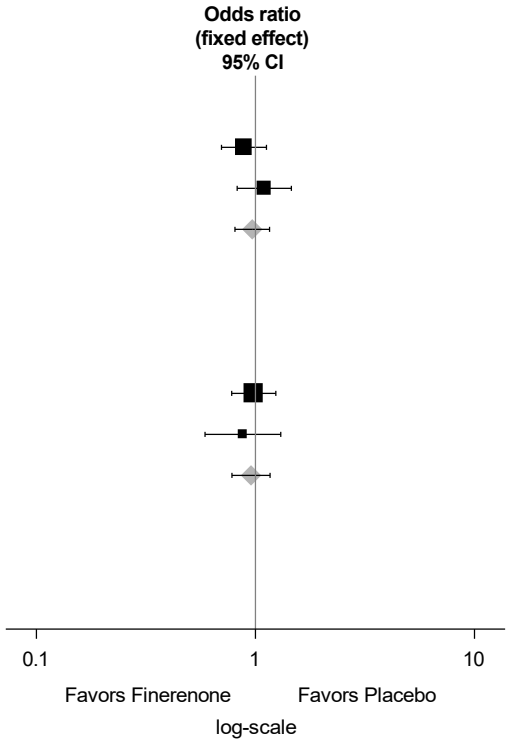
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	912 / 1075	906 / 1062	62.6	0.96 [0.76,1.22]	
FIGARO-DKD	546 / 638	538 / 637	37.4	1.09 [0.80,1.49]	
Total	1458 / 1713	1444 / 1699		1.01 [0.84,1.22]	Z=0.10, p=0.9201
Heterogeneity:	Q=0.40 (df=1)	p=0.5276	I^2=0.0%		
North America					
FIDELIO-DKD	361 / 424	386 / 436	62.4	0.74 [0.50,1.11]	
FIGARO-DKD	232 / 267	239 / 271	37.6	0.89 [0.53,1.48]	
Total	593 / 691	625 / 707		0.79 [0.58,1.09]	Z=-1.44, p=0.1495
Heterogeneity:	Q=0.29 (df=1)	p=0.5892	I^2=0.0%		
Asia					
FIDELIO-DKD	700 / 751	689 / 745	77.3	1.12 [0.75,1.65]	
FIGARO-DKD	272 / 289	276 / 290	22.7	0.81 [0.39,1.68]	
Total	972 / 1040	965 / 1035		1.04 [0.73,1.47]	Z=0.21, p=0.8341
Heterogeneity:	Q=0.57 (df=1)	p=0.4507	I^2=0.0%		
Latin America					
FIDELIO-DKD	236 / 273	230 / 270	72.8	1.11 [0.68,1.80]	
FIGARO-DKD	86 / 102	88 / 101	27.2	0.79 [0.36,1.75]	
Total	322 / 375	318 / 371		1.01 [0.67,1.53]	Z=0.06, p=0.9525
Heterogeneity:	Q=0.50 (df=1)	p=0.4790	I^2=0.0%		
Others					
FIDELIO-DKD	78 / 94	89 / 97	76.9	0.44 [0.18,1.08]	
FIGARO-DKD	59 / 61	51 / 57	23.1	3.47 [0.67,17.96]	
Total	137 / 155	140 / 154		0.75 [0.36,1.57]	Z=-0.77, p=0.4424
Heterogeneity:	Q=4.70 (df=1)	p=0.0301	I^2=78.7%		
Subgroup Heterogeneity:	Q=2.38 (df=4)	p=0.6664	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.1.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

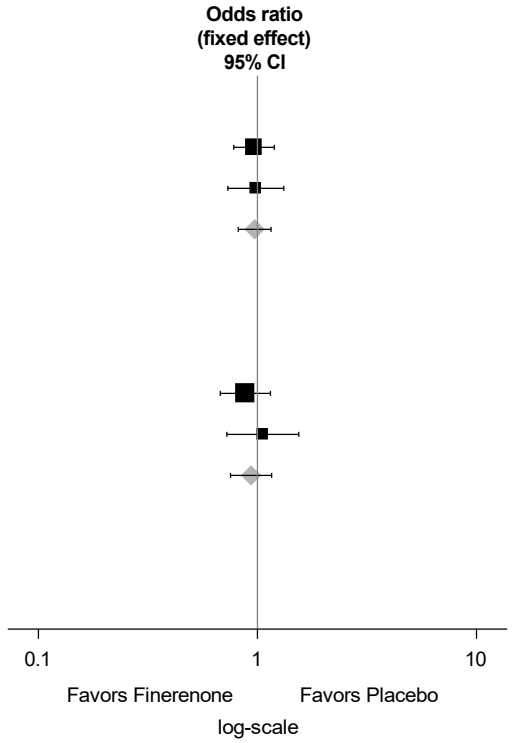
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	1046 / 1213	1060 / 1210	59.2	0.89 [0.70,1.12]	
FIGARO-DKD	757 / 862	736 / 848	40.8	1.10 [0.83,1.46]	
Total	1803 / 2075	1796 / 2058		0.97 [0.81,1.16]	Z=-0.36, p=0.7165
Heterogeneity:	Q=1.28 (df=1)	p=0.2588	I^2=21.6%		
Absent					
FIDELIO-DKD	1241 / 1404	1240 / 1400	74.7	0.98 [0.78,1.24]	
FIGARO-DKD	438 / 495	456 / 508	25.3	0.88 [0.59,1.30]	
Total	1679 / 1899	1696 / 1908		0.95 [0.78,1.17]	Z=-0.46, p=0.6474
Heterogeneity:	Q=0.24 (df=1)	p=0.6267	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9246	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.1.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

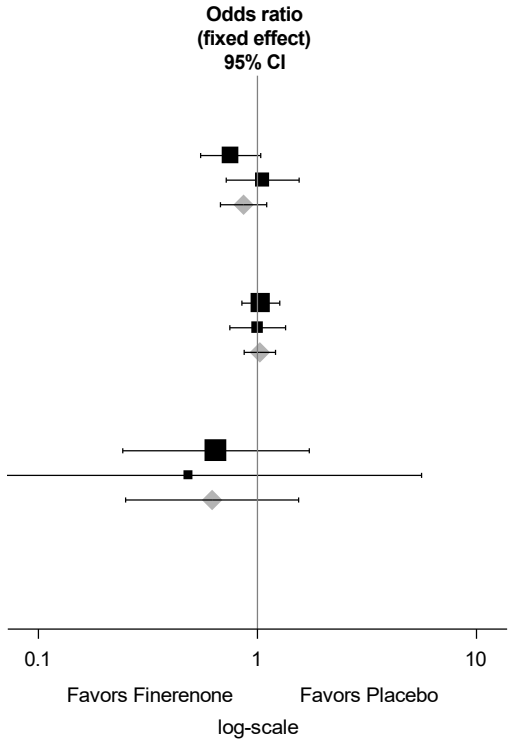
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	1539 / 1735	1514 / 1700	65.6	0.96 [0.78,1.19]	
FIGARO-DKD	824 / 924	830 / 929	34.4	0.98 [0.73,1.32]	
Total	2363 / 2659	2344 / 2629		0.97 [0.82,1.15]	Z=-0.34, p=0.7367
Heterogeneity:	Q=0.01 (df=1)	p=0.9196	I^2=0.0%		
> 4.5					
FIDELIO-DKD	748 / 882	786 / 910	67.2	0.88 [0.68,1.15]	
FIGARO-DKD	371 / 433	362 / 426	32.8	1.06 [0.72,1.54]	
Total	1119 / 1315	1148 / 1336		0.94 [0.75,1.16]	Z=-0.61, p=0.5437
Heterogeneity:	Q=0.61 (df=1)	p=0.4356	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7907	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.1.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

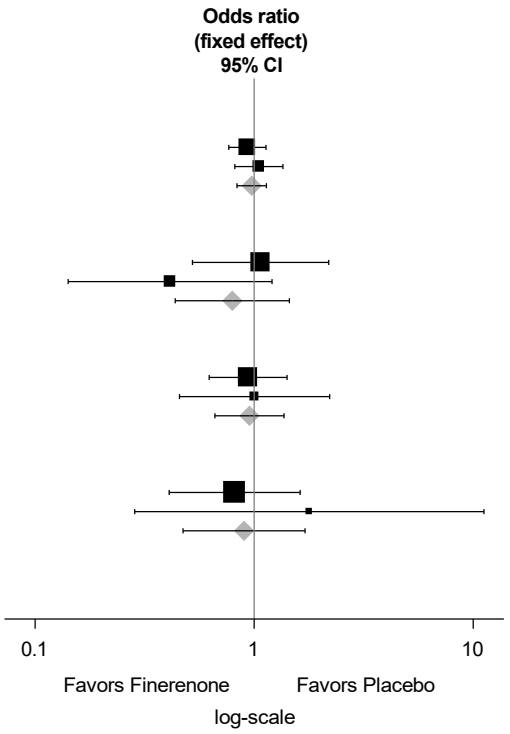
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	624 / 724	645 / 723	59.5	0.75 [0.55,1.03]	
FIGARO-DKD	436 / 494	434 / 495	40.5	1.06 [0.72,1.55]	
Total	1060 / 1218	1079 / 1218		0.86 [0.68,1.10]	Z=-1.18, p=0.2397
Heterogeneity:	Q=1.76 (df=1)	p=0.1841	I^2=43.3%		
130 - < 160					
FIDELIO-DKD	1541 / 1759	1535 / 1760	68.4	1.04 [0.85,1.26]	
FIGARO-DKD	727 / 829	725 / 827	31.6	1.00 [0.75,1.34]	
Total	2268 / 2588	2260 / 2587		1.03 [0.87,1.21]	Z=0.30, p=0.7647
Heterogeneity:	Q=0.03 (df=1)	p=0.8563	I^2=0.0%		
>= 160					
FIDELIO-DKD	122 / 133	120 / 127	86.2	0.65 [0.24,1.72]	
FIGARO-DKD	32 / 34	33 / 34	13.8	0.48 [0.04,5.61]	
Total	154 / 167	153 / 161		0.62 [0.25,1.54]	Z=-1.03, p=0.3043
Heterogeneity:	Q=0.05 (df=1)	p=0.8303	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.21 (df=2)	p=0.3306	I^2=9.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.1.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

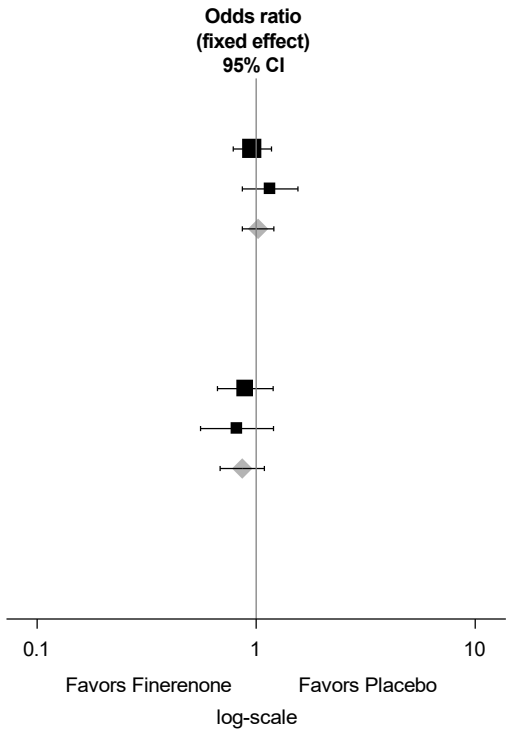
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	1394 / 1634	1428 / 1657	62.6	0.93 [0.77,1.13]	
FIGARO-DKD	872 / 1010	848 / 989	37.4	1.05 [0.82,1.35]	
Total	2266 / 2644	2276 / 2646		0.97 [0.83,1.14]	Z=-0.33, p=0.7419
Heterogeneity:	Q=0.54 (df=1)	p=0.4604	I^2=0.0%		
Black					
FIDELIO-DKD	111 / 129	98 / 115	69.1	1.07 [0.52,2.19]	
FIGARO-DKD	34 / 43	64 / 71	30.9	0.41 [0.14,1.21]	
Total	145 / 172	162 / 186		0.79 [0.44,1.45]	Z=-0.75, p=0.4525
Heterogeneity:	Q=2.09 (df=1)	p=0.1481	I^2=52.2%		
Asian					
FIDELIO-DKD	627 / 678	629 / 677	78.8	0.94 [0.62,1.41]	
FIGARO-DKD	239 / 252	238 / 251	21.2	1.00 [0.46,2.21]	
Total	866 / 930	867 / 928		0.95 [0.66,1.37]	Z=-0.27, p=0.7899
Heterogeneity:	Q=0.02 (df=1)	p=0.8809	I^2=0.0%		
Others					
FIDELIO-DKD	155 / 176	145 / 161	87.7	0.81 [0.41,1.62]	
FIGARO-DKD	50 / 52	42 / 45	12.3	1.79 [0.28,11.19]	
Total	205 / 228	187 / 206		0.90 [0.47,1.71]	Z=-0.32, p=0.7453
Heterogeneity:	Q=0.62 (df=1)	p=0.4325	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=3)	p=0.9280	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.1.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

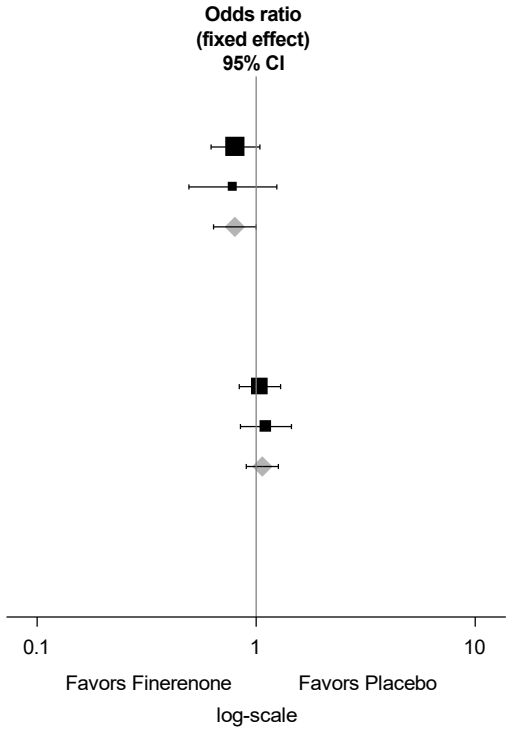
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	1582 / 1797	1654 / 1870	67.9	0.96 [0.79,1.17]	
FIGARO-DKD	823 / 917	824 / 933	32.1	1.16 [0.86,1.55]	
Total	2405 / 2714	2478 / 2803		1.02 [0.86,1.20]	Z=0.24, p=0.8110
Heterogeneity:	Q=1.06 (df=1)	p=0.3023	I^2=6.0%		
Female					
FIDELIO-DKD	705 / 820	646 / 740	63.2	0.89 [0.67,1.20]	
FIGARO-DKD	372 / 440	368 / 423	36.8	0.82 [0.56,1.20]	
Total	1077 / 1260	1014 / 1163		0.86 [0.68,1.09]	Z=-1.23, p=0.2176
Heterogeneity:	Q=0.13 (df=1)	p=0.7234	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.31 (df=1)	p=0.2530	I^2=23.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.1.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

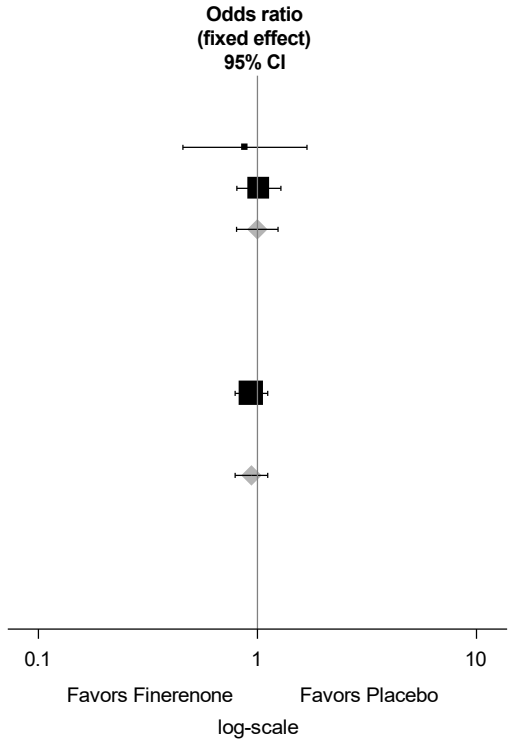
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	954 / 1103	955 / 1075	76.4	0.80 [0.62,1.04]	
FIGARO-DKD	290 / 336	298 / 335	23.6	0.78 [0.49,1.24]	
Total	1244 / 1439	1253 / 1410		0.80 [0.64,1.00]	Z=-1.96, p=0.0504
Heterogeneity:	Q=0.01 (df=1)	p=0.9190	I^2=0.0%		
>= 65					
FIDELIO-DKD	1333 / 1514	1345 / 1535	60.4	1.04 [0.84,1.29]	
FIGARO-DKD	905 / 1021	894 / 1021	39.6	1.11 [0.85,1.45]	
Total	2238 / 2535	2239 / 2556		1.07 [0.90,1.26]	Z=0.75, p=0.4529
Heterogeneity:	Q=0.13 (df=1)	p=0.7194	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.06 (df=1)	p=0.0439	I^2=75.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.1.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

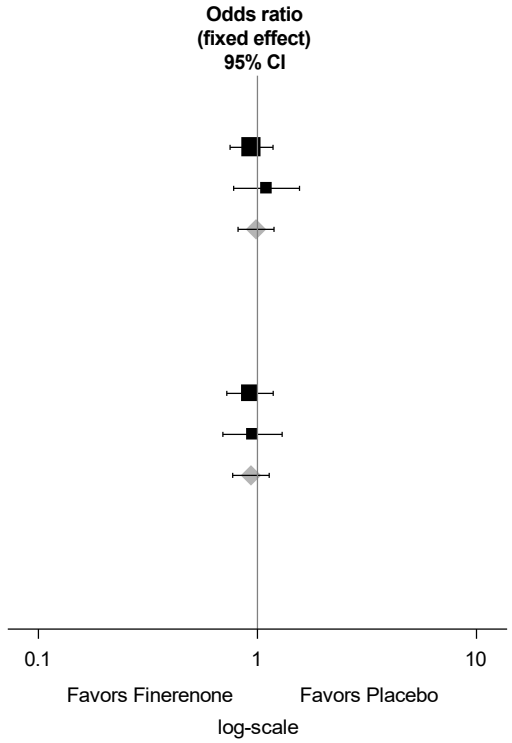
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	188 / 209	194 / 213	11.2	0.88 [0.46,1.68]	
FIGARO-DKD	1195 / 1357	1192 / 1356	88.8	1.01 [0.81,1.28]	
Total	1383 / 1566	1386 / 1569		1.00 [0.80,1.24]	Z=-0.01, p=0.9885
Heterogeneity:	Q=0.17 (df=1)	p=0.6787	I^2=0.0%		
Very High					
FIDELIO-DKD	2099 / 2408	2106 / 2397	100.0	0.94 [0.79,1.11]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	2099 / 2408	2106 / 2397		0.94 [0.79,1.11]	Z=-0.73, p=0.4681
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6625	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.1.9: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

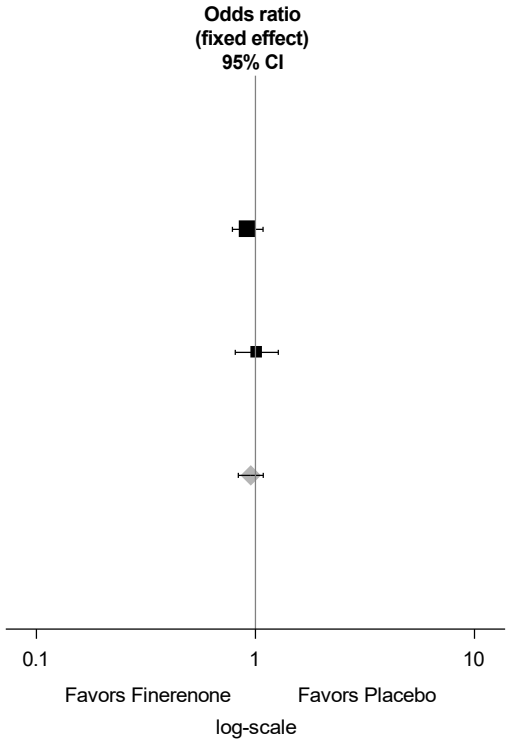
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	1381 / 1556	1377 / 1541	70.2	0.94 [0.75,1.18]	
FIGARO-DKD	567 / 637	552 / 627	29.8	1.10 [0.78,1.56]	
Total	1948 / 2193	1929 / 2168		0.99 [0.82,1.19]	Z=-0.15, p=0.8770
Heterogeneity:	Q=0.56 (df=1)	p=0.4541	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	906 / 1061	923 / 1069	62.0	0.92 [0.72,1.18]	
FIGARO-DKD	628 / 720	640 / 729	38.0	0.95 [0.70,1.30]	
Total	1534 / 1781	1563 / 1798		0.93 [0.77,1.13]	Z=-0.70, p=0.4851
Heterogeneity:	Q=0.02 (df=1)	p=0.8962	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.6973	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

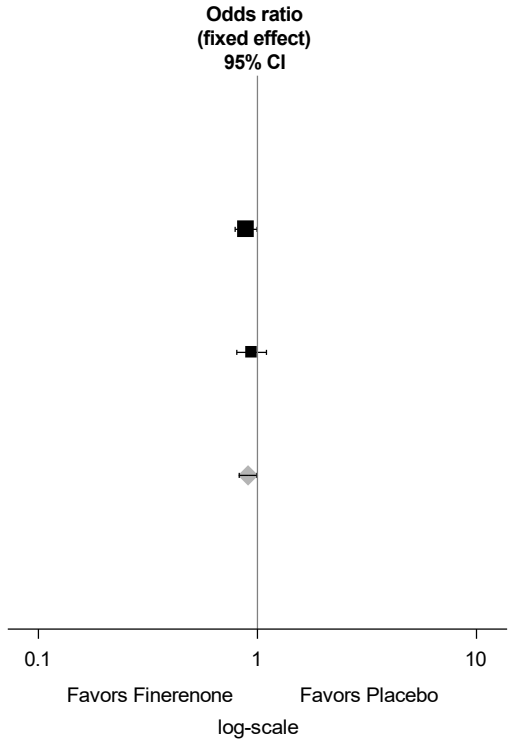
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	2263 / 2617	2281 / 2610	66.4	0.92 [0.78,1.08]	
FIGARO-DKD	1186 / 1357	1183 / 1356	33.6	1.01 [0.81,1.27]	
Total	3449 / 3974	3464 / 3966		0.95 [0.84,1.09]	Z=-0.73, p=0.4628
Heterogeneity:	Q=0.45 (df=1)	p=0.5009	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

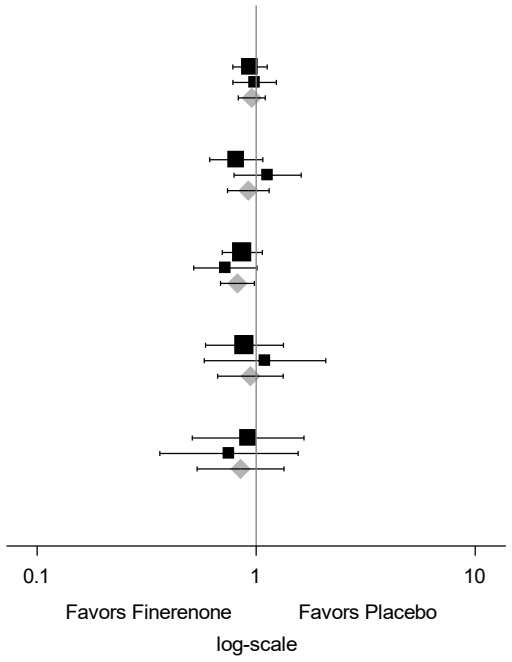
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	837 / 2617	904 / 2610	64.7	0.89 [0.79,1.00]	
FIGARO-DKD	492 / 1357	511 / 1356	35.3	0.94 [0.80,1.10]	
Total	1329 / 3974	1415 / 3966		0.91 [0.83,0.99]	Z=-2.09, p=0.0362
Heterogeneity:	Q=0.35 (df=1)	p=0.5563	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.3.1: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

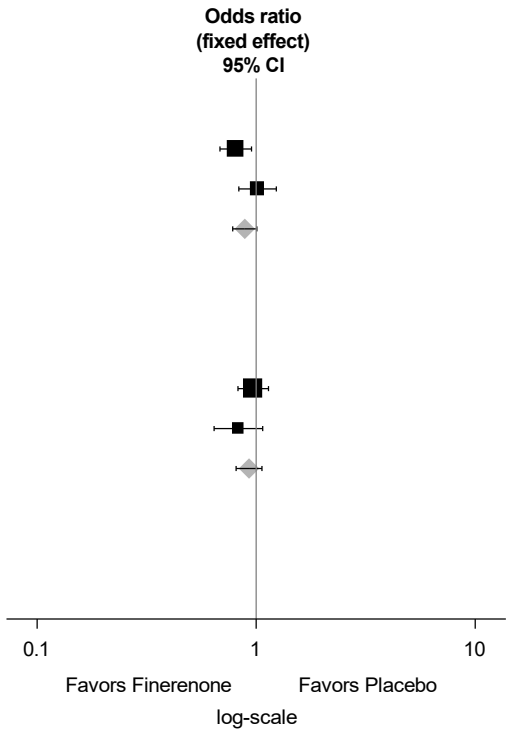
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	346 / 1075	357 / 1062	61.6	0.94 [0.78,1.12]	
FIGARO-DKD	229 / 638	231 / 637	38.4	0.98 [0.78,1.24]	
Total	575 / 1713	588 / 1699		0.95 [0.83,1.10]	Z=-0.64, p=0.5239
Heterogeneity:	Q=0.11 (df=1)	p=0.7431	I^2=0.0%		
North America					
FIDELIO-DKD	142 / 424	167 / 436	61.5	0.81 [0.61,1.07]	
FIGARO-DKD	99 / 267	93 / 271	38.5	1.13 [0.79,1.61]	
Total	241 / 691	260 / 707		0.92 [0.74,1.15]	Z=-0.74, p=0.4595
Heterogeneity:	Q=2.06 (df=1)	p=0.1510	I^2=51.5%		
Asia					
FIDELIO-DKD	259 / 751	282 / 745	71.3	0.86 [0.70,1.07]	
FIGARO-DKD	107 / 289	130 / 290	28.7	0.72 [0.52,1.01]	
Total	366 / 1040	412 / 1035		0.82 [0.69,0.98]	Z=-2.17, p=0.0302
Heterogeneity:	Q=0.78 (df=1)	p=0.3765	I^2=0.0%		
Latin America					
FIDELIO-DKD	56 / 273	61 / 270	70.9	0.88 [0.59,1.33]	
FIGARO-DKD	26 / 102	24 / 101	29.1	1.10 [0.58,2.08]	
Total	82 / 375	85 / 371		0.94 [0.67,1.33]	Z=-0.34, p=0.7323
Heterogeneity:	Q=0.31 (df=1)	p=0.5766	I^2=0.0%		
Others					
FIDELIO-DKD	34 / 94	37 / 97	60.5	0.92 [0.51,1.65]	
FIGARO-DKD	31 / 61	33 / 57	39.5	0.75 [0.36,1.55]	
Total	65 / 155	70 / 154		0.85 [0.54,1.34]	Z=-0.70, p=0.4813
Heterogeneity:	Q=0.18 (df=1)	p=0.6732	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.85 (df=4)	p=0.7639	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.3.2: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

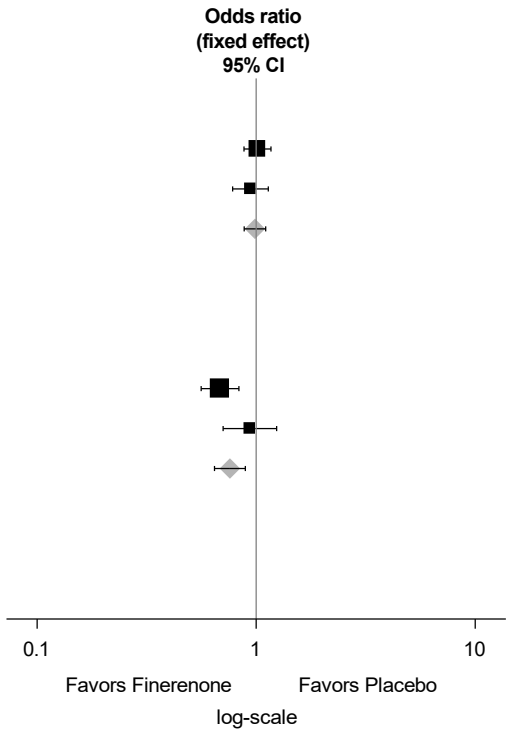
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	410 / 1213	469 / 1210	58.5	0.81 [0.68,0.95]	
FIGARO-DKD	315 / 862	307 / 848	41.5	1.01 [0.83,1.24]	
Total	725 / 2075	776 / 2058		0.89 [0.78,1.01]	Z=-1.85, p=0.0644
Heterogeneity:	Q=3.05 (df=1)	p=0.0808	I^2=67.2%		
Absent					
FIDELIO-DKD	427 / 1404	435 / 1400	71.7	0.97 [0.83,1.14]	
FIGARO-DKD	177 / 495	204 / 508	28.3	0.83 [0.64,1.07]	
Total	604 / 1899	639 / 1908		0.93 [0.81,1.06]	Z=-1.08, p=0.2784
Heterogeneity:	Q=1.03 (df=1)	p=0.3105	I^2=2.8%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6384	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.3.3: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

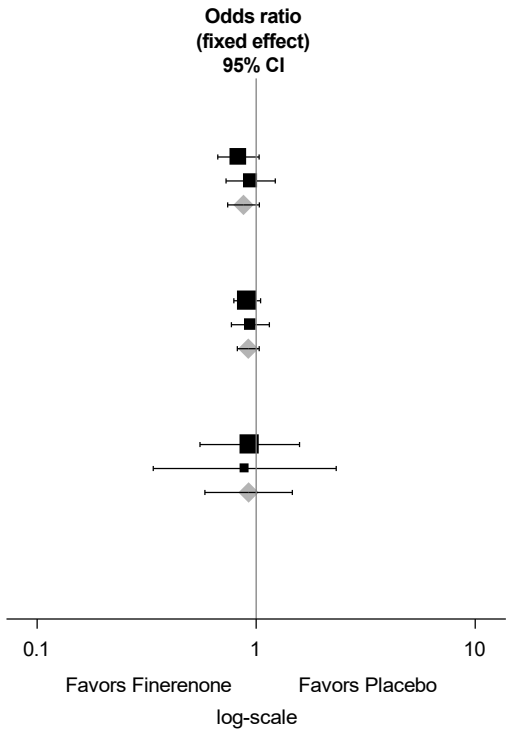
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	584 / 1735	567 / 1700	63.6	1.01 [0.88,1.17]	
FIGARO-DKD	346 / 924	361 / 929	36.4	0.94 [0.78,1.14]	
Total	930 / 2659	928 / 2629		0.99 [0.88,1.11]	Z=-0.23, p=0.8216
Heterogeneity:	Q=0.38 (df=1)	p=0.5390	I^2=0.0%		
> 4.5					
FIDELIO-DKD	253 / 882	337 / 910	66.8	0.68 [0.56,0.83]	
FIGARO-DKD	146 / 433	150 / 426	33.2	0.94 [0.71,1.24]	
Total	399 / 1315	487 / 1336		0.76 [0.65,0.89]	Z=-3.34, p=0.0008
Heterogeneity:	Q=3.19 (df=1)	p=0.0741	I^2=68.6%		
Subgroup Heterogeneity:	Q=6.81 (df=1)	p=0.0090	I^2=85.3%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.3.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

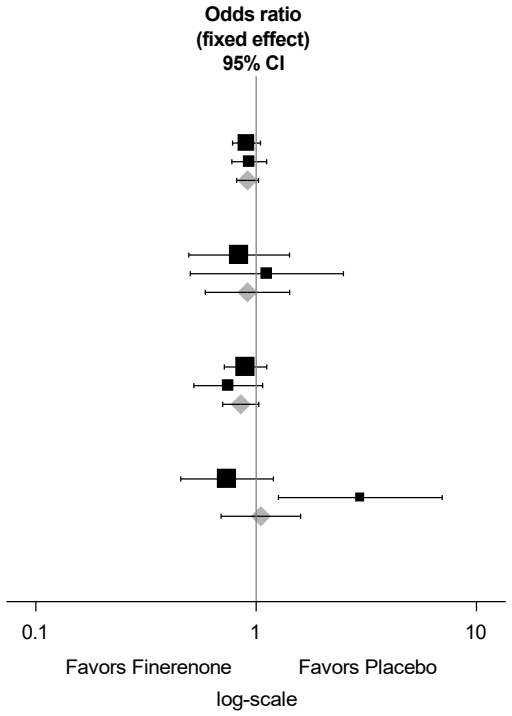
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	233 / 724	263 / 723	58.7	0.83 [0.67,1.03]	
FIGARO-DKD	177 / 494	184 / 495	41.3	0.94 [0.73,1.22]	
Total	410 / 1218	447 / 1218		0.88 [0.74,1.03]	Z=-1.57, p=0.1167
Heterogeneity:	Q=0.55 (df=1)	p=0.4566	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	563 / 1759	600 / 1760	66.8	0.91 [0.79,1.05]	
FIGARO-DKD	301 / 829	312 / 827	33.2	0.94 [0.77,1.15]	
Total	864 / 2588	912 / 2587		0.92 [0.82,1.03]	Z=-1.42, p=0.1561
Heterogeneity:	Q=0.07 (df=1)	p=0.7886	I^2=0.0%		
>= 160					
FIDELIO-DKD	41 / 133	41 / 127	77.2	0.93 [0.55,1.58]	
FIGARO-DKD	14 / 34	15 / 34	22.8	0.89 [0.34,2.32]	
Total	55 / 167	56 / 161		0.92 [0.58,1.46]	Z=-0.34, p=0.7345
Heterogeneity:	Q=0.01 (df=1)	p=0.9246	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=2)	p=0.8857	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.3.5: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

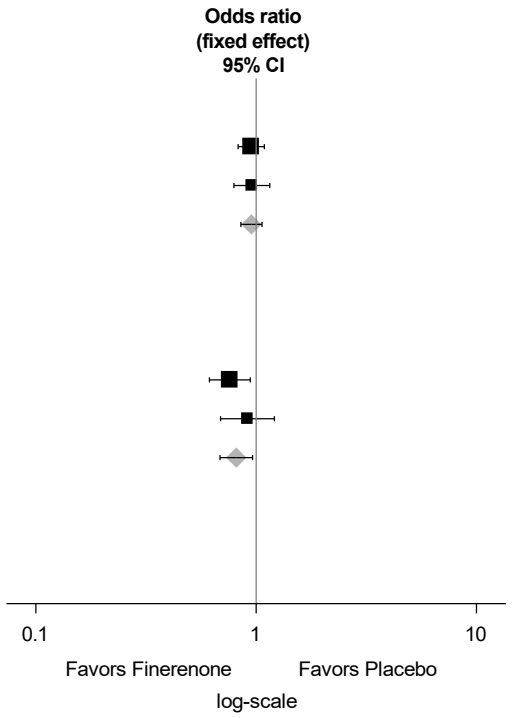
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	516 / 1634	560 / 1657	60.9	0.90 [0.78,1.05]	
FIGARO-DKD	361 / 1010	370 / 989	39.1	0.93 [0.78,1.12]	
Total	877 / 2644	930 / 2646		0.91 [0.82,1.02]	Z=-1.54, p=0.1230
Heterogeneity:	Q=0.06 (df=1)	p=0.8085	I^2=0.0%		
Black					
FIDELIO-DKD	43 / 129	43 / 115	69.8	0.84 [0.49,1.42]	
FIGARO-DKD	15 / 43	23 / 71	30.2	1.12 [0.50,2.49]	
Total	58 / 172	66 / 186		0.91 [0.59,1.42]	Z=-0.40, p=0.6860
Heterogeneity:	Q=0.35 (df=1)	p=0.5539	I^2=0.0%		
Asian					
FIDELIO-DKD	236 / 678	253 / 677	72.5	0.89 [0.72,1.12]	
FIGARO-DKD	89 / 252	106 / 251	27.5	0.75 [0.52,1.07]	
Total	325 / 930	359 / 928		0.85 [0.70,1.03]	Z=-1.67, p=0.0946
Heterogeneity:	Q=0.70 (df=1)	p=0.4021	I^2=0.0%		
Others					
FIDELIO-DKD	42 / 176	48 / 161	75.8	0.74 [0.45,1.20]	
FIGARO-DKD	27 / 52	12 / 45	24.2	2.97 [1.26,6.99]	
Total	69 / 228	60 / 206		1.05 [0.69,1.59]	Z=0.23, p=0.8173
Heterogeneity:	Q=7.71 (df=1)	p=0.0055	I^2=87.0%		
Subgroup Heterogeneity:	Q=0.93 (df=3)	p=0.8185	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.3.6: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

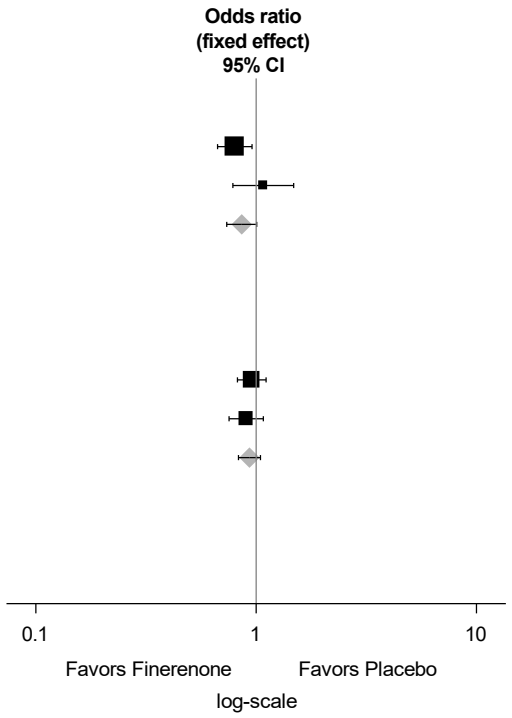
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	599 / 1797	645 / 1870	65.3	0.95 [0.83,1.09]	
FIGARO-DKD	346 / 917	362 / 933	34.7	0.96 [0.79,1.15]	
Total	945 / 2714	1007 / 2803		0.95 [0.85,1.06]	Z=-0.88, p=0.3805
Heterogeneity:	Q=0.00 (df=1)	p=0.9563	I^2=0.0%		
Female					
FIDELIO-DKD	238 / 820	259 / 740	63.5	0.76 [0.61,0.94]	
FIGARO-DKD	146 / 440	149 / 423	36.5	0.91 [0.69,1.21]	
Total	384 / 1260	408 / 1163		0.81 [0.69,0.96]	Z=-2.40, p=0.0166
Heterogeneity:	Q=1.05 (df=1)	p=0.3062	I^2=4.5%		
Subgroup Heterogeneity:	Q=2.35 (df=1)	p=0.1257	I^2=57.4%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.3.7: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

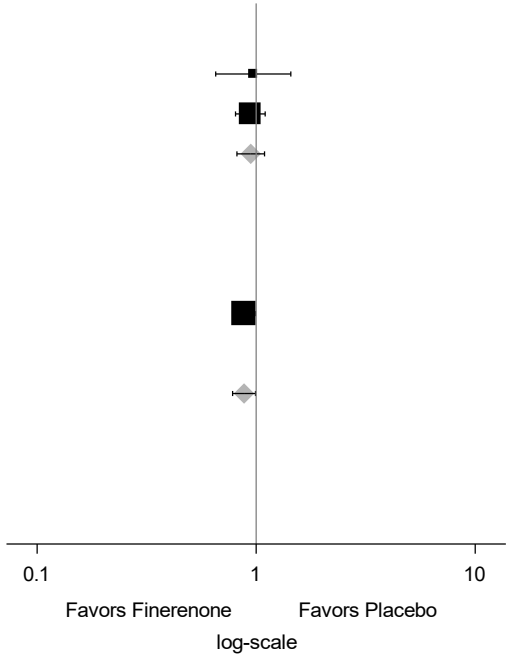
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	328 / 1103	372 / 1075	75.7	0.80 [0.67,0.96]	
FIGARO-DKD	120 / 336	114 / 335	24.3	1.08 [0.78,1.48]	
Total	448 / 1439	486 / 1410		0.86 [0.74,1.01]	Z=-1.89, p=0.0588
Heterogeneity:	Q=2.55 (df=1)	p=0.1102	I^2=60.8%		
>= 65					
FIDELIO-DKD	509 / 1514	532 / 1535	58.9	0.95 [0.82,1.11]	
FIGARO-DKD	372 / 1021	397 / 1021	41.1	0.90 [0.75,1.08]	
Total	881 / 2535	929 / 2556		0.93 [0.83,1.05]	Z=-1.20, p=0.2316
Heterogeneity:	Q=0.24 (df=1)	p=0.6255	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.67 (df=1)	p=0.4143	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.3.8: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

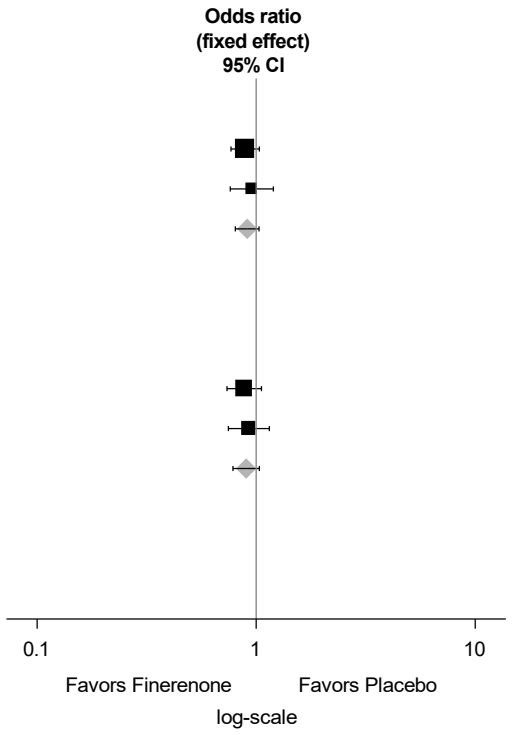
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	77 / 209	80 / 213	13.5	0.97 [0.65,1.44]	
FIGARO-DKD	492 / 1357	511 / 1356	86.5	0.94 [0.80,1.10]	
Total	569 / 1566	591 / 1569		0.94 [0.82,1.09]	Z=-0.77, p=0.4399
Heterogeneity:	Q=0.02 (df=1)	p=0.8876	I^2=0.0%		
Very High					
FIDELIO-DKD	760 / 2408	824 / 2397	100.0	0.88 [0.78,0.99]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	760 / 2408	824 / 2397		0.88 [0.78,0.99]	Z=-2.07, p=0.0380
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4649	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.3.9: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

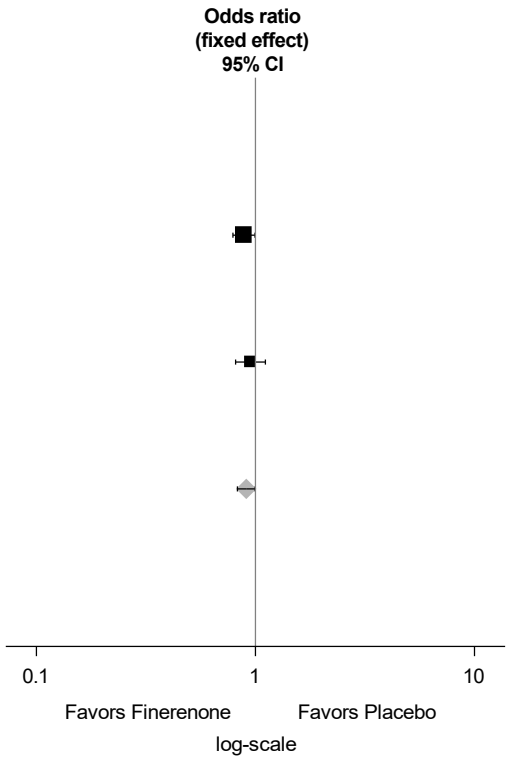
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	505 / 1556	540 / 1541	69.8	0.89 [0.77,1.03]	
FIGARO-DKD	242 / 637	245 / 627	30.2	0.96 [0.76,1.20]	
Total	747 / 2193	785 / 2168		0.91 [0.80,1.03]	Z=-1.49, p=0.1363
Heterogeneity:	Q=0.26 (df=1)	p=0.6131	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	332 / 1061	364 / 1069	58.5	0.88 [0.74,1.06]	
FIGARO-DKD	250 / 720	266 / 729	41.5	0.93 [0.75,1.15]	
Total	582 / 1781	630 / 1798		0.90 [0.78,1.03]	Z=-1.49, p=0.1361
Heterogeneity:	Q=0.11 (df=1)	p=0.7356	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9099	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.4: Forestplot for Odds Ratio of Proportion of Subjects with TESAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

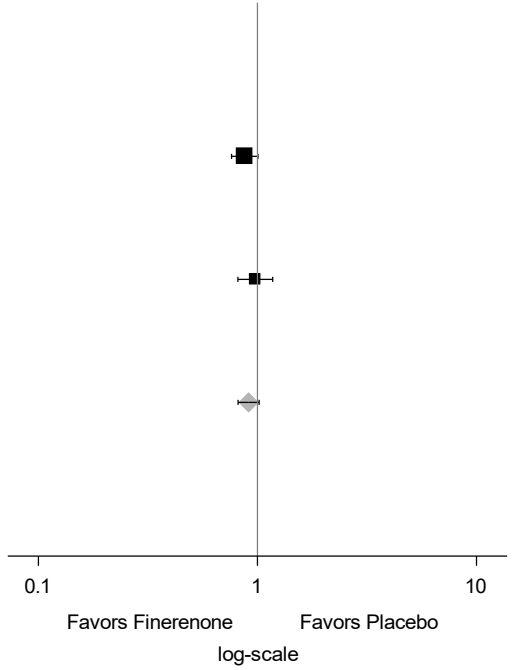
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	814 / 2617	881 / 2610	64.6	0.89 [0.79,0.99]	
FIGARO-DKD	484 / 1357	500 / 1356	35.4	0.95 [0.81,1.11]	
Total	1298 / 3974	1381 / 3966		0.91 [0.83,1.00]	Z=-2.03, p=0.0420
Heterogeneity:	Q=0.48 (df=1)	p=0.4886	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

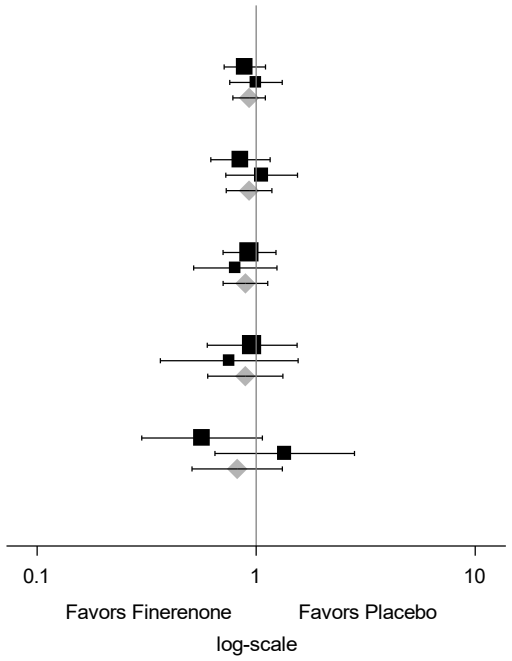
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	466 / 2617	518 / 2610	63.5	0.87 [0.76,1.01]	
FIGARO-DKD	290 / 1357	295 / 1356	36.5	0.98 [0.81,1.17]	
Total	756 / 3974	813 / 3966		0.91 [0.82,1.02]	Z=-1.65, p=0.0989
Heterogeneity:	Q=0.89 (df=1)	p=0.3442	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.5.1: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

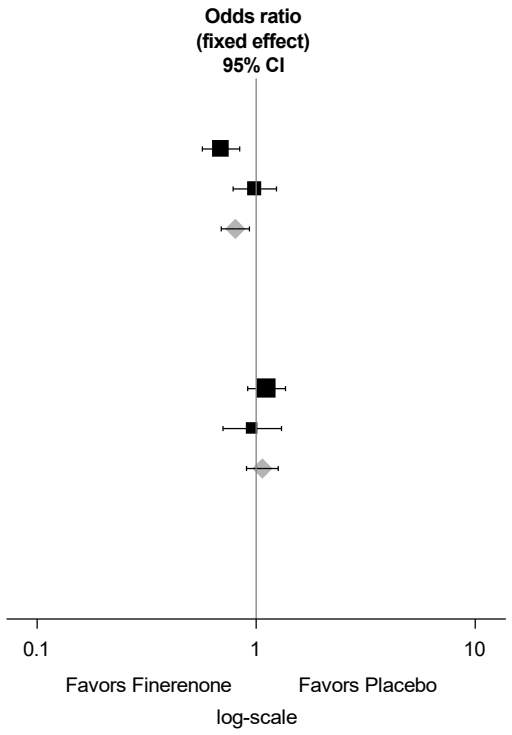
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	192 / 1075	209 / 1062	61.7	0.89 [0.71,1.10]	
FIGARO-DKD	126 / 638	126 / 637	38.3	1.00 [0.76,1.31]	
Total	318 / 1713	335 / 1699		0.93 [0.78,1.10]	Z=-0.85, p=0.3928
Heterogeneity:	Q=0.43 (df=1)	p=0.5120	I^2=0.0%		
North America					
FIDELIO-DKD	97 / 424	113 / 436	59.4	0.85 [0.62,1.16]	
FIGARO-DKD	76 / 267	74 / 271	40.6	1.06 [0.73,1.54]	
Total	173 / 691	187 / 707		0.93 [0.73,1.18]	Z=-0.61, p=0.5423
Heterogeneity:	Q=0.80 (df=1)	p=0.3725	I^2=0.0%		
Asia					
FIDELIO-DKD	115 / 751	121 / 745	71.2	0.93 [0.71,1.23]	
FIGARO-DKD	44 / 289	53 / 290	28.8	0.80 [0.52,1.24]	
Total	159 / 1040	174 / 1035		0.89 [0.71,1.13]	Z=-0.94, p=0.3454
Heterogeneity:	Q=0.32 (df=1)	p=0.5724	I^2=0.0%		
Latin America					
FIDELIO-DKD	40 / 273	41 / 270	70.2	0.96 [0.60,1.54]	
FIGARO-DKD	16 / 102	20 / 101	29.8	0.75 [0.37,1.55]	
Total	56 / 375	61 / 371		0.89 [0.60,1.32]	Z=-0.57, p=0.5711
Heterogeneity:	Q=0.30 (df=1)	p=0.5847	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 94	34 / 97	57.2	0.57 [0.30,1.07]	
FIGARO-DKD	28 / 61	22 / 57	42.8	1.35 [0.65,2.81]	
Total	50 / 155	56 / 154		0.82 [0.51,1.32]	Z=-0.82, p=0.4100
Heterogeneity:	Q=3.09 (df=1)	p=0.0790	I^2=67.6%		
Subgroup Heterogeneity:	Q=0.30 (df=4)	p=0.9898	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.5.2: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

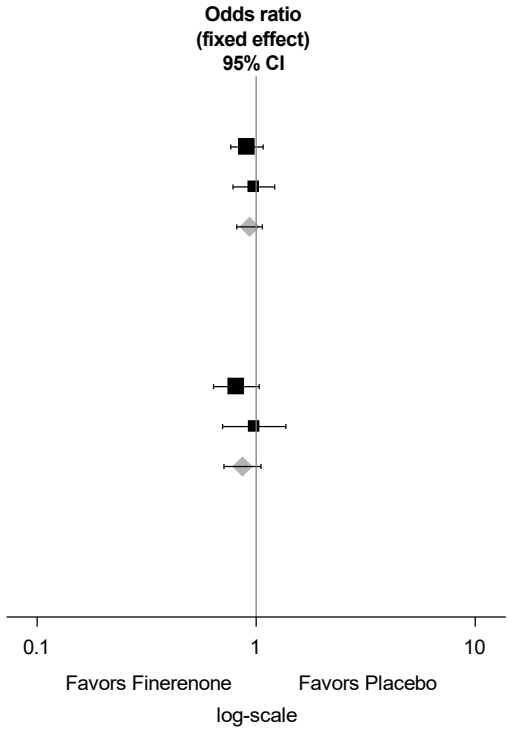
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	221 / 1213	295 / 1210	57.4	0.69 [0.57,0.84]	
FIGARO-DKD	191 / 862	190 / 848	42.6	0.99 [0.78,1.24]	
Total	412 / 2075	485 / 2058		0.80 [0.69,0.93]	Z=-2.89, p=0.0038
Heterogeneity:	Q=5.37 (df=1)	p=0.0205	I^2=81.4%		
Absent					
FIDELIO-DKD	245 / 1404	223 / 1400	70.6	1.12 [0.91,1.36]	
FIGARO-DKD	99 / 495	105 / 508	29.4	0.96 [0.71,1.31]	
Total	344 / 1899	328 / 1908		1.07 [0.90,1.26]	Z=0.76, p=0.4444
Heterogeneity:	Q=0.65 (df=1)	p=0.4196	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.22 (df=1)	p=0.0126	I^2=83.9%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.5.3: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

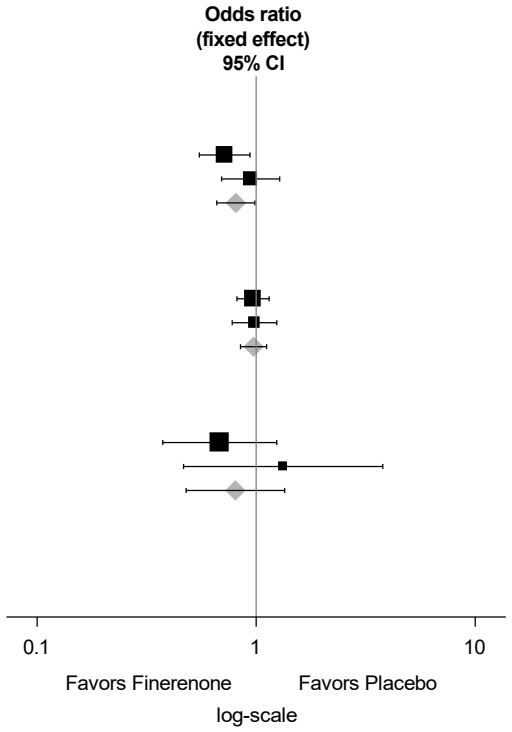
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	318 / 1735	337 / 1700	62.4	0.91 [0.77,1.08]	
FIGARO-DKD	203 / 924	208 / 929	37.6	0.98 [0.78,1.22]	
Total	521 / 2659	545 / 2629		0.93 [0.82,1.07]	Z=-1.01, p=0.3106
Heterogeneity:	Q=0.26 (df=1)	p=0.6085	I^2=0.0%		
> 4.5					
FIDELIO-DKD	148 / 882	181 / 910	65.8	0.81 [0.64,1.03]	
FIGARO-DKD	87 / 433	87 / 426	34.2	0.98 [0.70,1.37]	
Total	235 / 1315	268 / 1336		0.87 [0.71,1.05]	Z=-1.45, p=0.1470
Heterogeneity:	Q=0.80 (df=1)	p=0.3701	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.38 (df=1)	p=0.5377	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.5.4: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

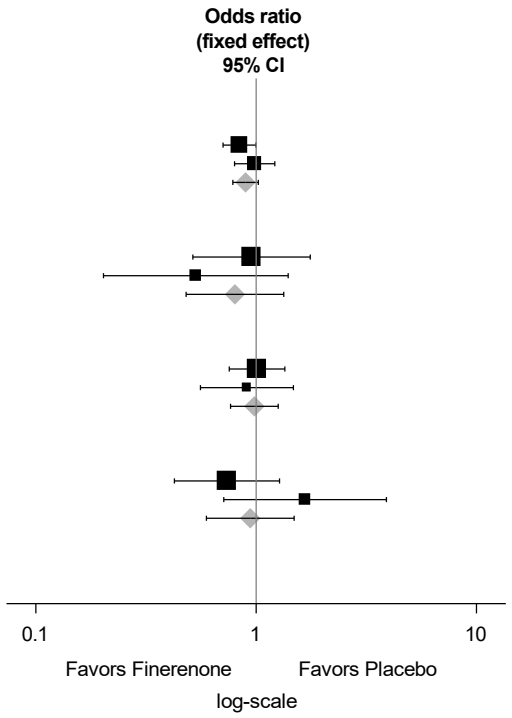
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	117 / 724	153 / 723	56.8	0.72 [0.55,0.94]	
FIGARO-DKD	102 / 494	107 / 495	43.2	0.94 [0.70,1.28]	
Total	219 / 1218	260 / 1218		0.81 [0.66,0.99]	Z=-2.09, p=0.0368
Heterogeneity:	Q=1.74 (df=1)	p=0.1867	I^2=42.6%		
130 - < 160					
FIDELIO-DKD	325 / 1759	334 / 1760	65.7	0.97 [0.82,1.15]	
FIGARO-DKD	177 / 829	179 / 827	34.3	0.98 [0.78,1.24]	
Total	502 / 2588	513 / 2587		0.97 [0.85,1.12]	Z=-0.39, p=0.6937
Heterogeneity:	Q=0.01 (df=1)	p=0.9163	I^2=0.0%		
>= 160					
FIDELIO-DKD	24 / 133	31 / 127	75.3	0.68 [0.37,1.24]	
FIGARO-DKD	11 / 34	9 / 34	24.7	1.33 [0.47,3.79]	
Total	35 / 167	40 / 161		0.80 [0.48,1.35]	Z=-0.83, p=0.4086
Heterogeneity:	Q=1.17 (df=1)	p=0.2786	I^2=14.8%		
Subgroup Heterogeneity:	Q=2.49 (df=2)	p=0.2885	I^2=19.6%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.5.5: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

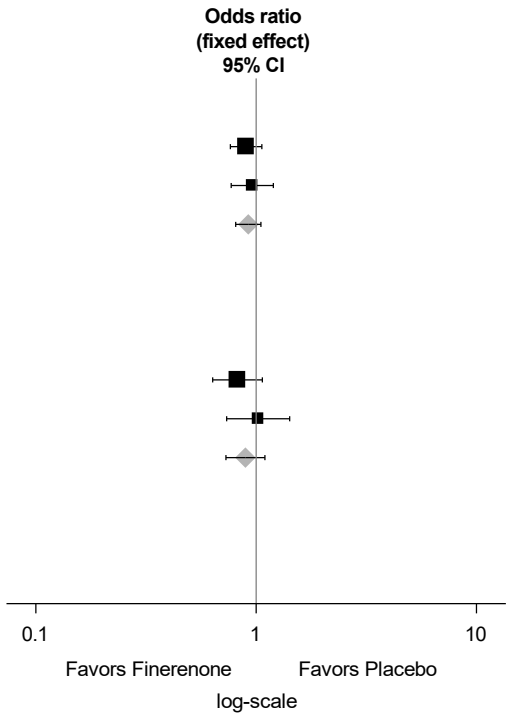
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	301 / 1634	351 / 1657	60.0	0.84 [0.71,1.00]	
FIGARO-DKD	225 / 1010	223 / 989	40.0	0.98 [0.80,1.21]	
Total	526 / 2644	574 / 2646		0.90 [0.78,1.02]	Z=-1.63, p=0.1028
Heterogeneity:	Q=1.31 (df=1)	p=0.2524	I^2=23.7%		
Black					
FIDELIO-DKD	27 / 129	25 / 115	71.2	0.95 [0.52,1.76]	
FIGARO-DKD	7 / 43	19 / 71	28.8	0.53 [0.20,1.40]	
Total	34 / 172	44 / 186		0.80 [0.48,1.33]	Z=-0.85, p=0.3934
Heterogeneity:	Q=1.00 (df=1)	p=0.3179	I^2=0.0%		
Asian					
FIDELIO-DKD	109 / 678	108 / 677	73.7	1.01 [0.75,1.35]	
FIGARO-DKD	37 / 252	40 / 251	26.3	0.91 [0.56,1.48]	
Total	146 / 930	148 / 928		0.98 [0.76,1.26]	Z=-0.15, p=0.8831
Heterogeneity:	Q=0.13 (df=1)	p=0.7136	I^2=0.0%		
Others					
FIDELIO-DKD	29 / 176	34 / 161	70.5	0.74 [0.43,1.28]	
FIGARO-DKD	21 / 52	13 / 45	29.5	1.67 [0.71,3.90]	
Total	50 / 228	47 / 206		0.94 [0.59,1.49]	Z=-0.26, p=0.7917
Heterogeneity:	Q=2.50 (df=1)	p=0.1137	I^2=60.0%		
Subgroup Heterogeneity:	Q=0.67 (df=3)	p=0.8796	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.5.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

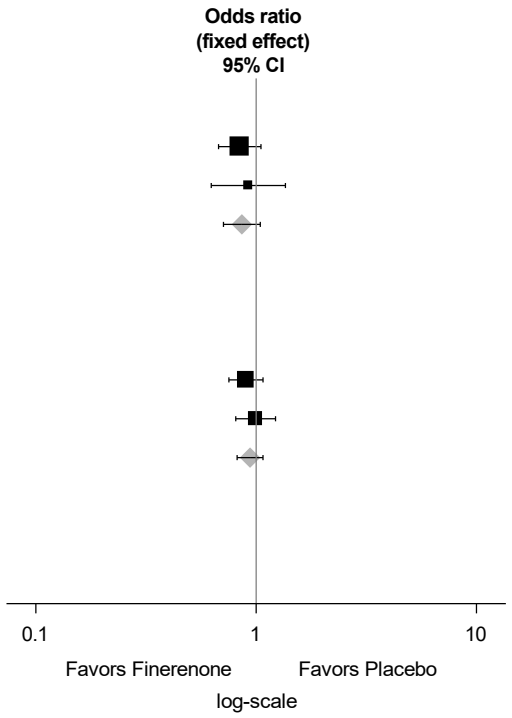
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	331 / 1797	375 / 1870	64.2	0.90 [0.76,1.06]	
FIGARO-DKD	198 / 917	208 / 933	35.8	0.96 [0.77,1.20]	
Total	529 / 2714	583 / 2803		0.92 [0.81,1.05]	Z=-1.22, p=0.2212
Heterogeneity:	Q=0.21 (df=1)	p=0.6468	I^2=0.0%		
Female					
FIDELIO-DKD	135 / 820	143 / 740	61.7	0.82 [0.63,1.07]	
FIGARO-DKD	92 / 440	87 / 423	38.3	1.02 [0.73,1.42]	
Total	227 / 1260	230 / 1163		0.89 [0.73,1.10]	Z=-1.08, p=0.2799
Heterogeneity:	Q=1.02 (df=1)	p=0.3129	I^2=1.8%		
Subgroup Heterogeneity:	Q=0.06 (df=1)	p=0.8078	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.5.7: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

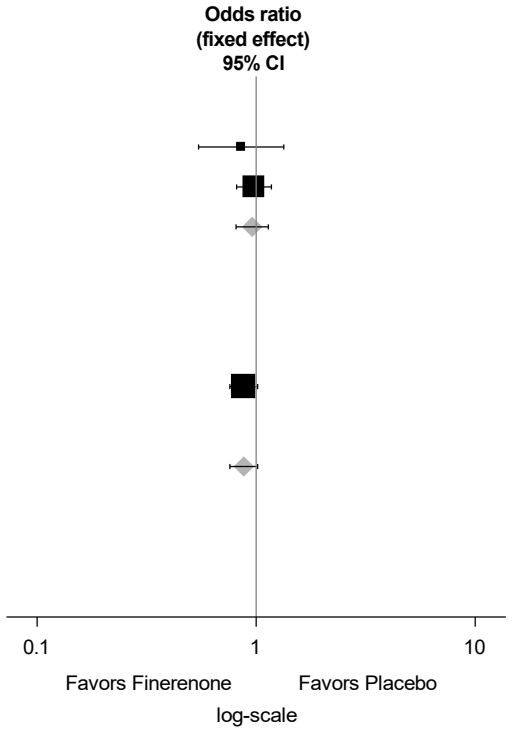
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	179 / 1103	201 / 1075	75.4	0.84 [0.67,1.05]	
FIGARO-DKD	61 / 336	65 / 335	24.6	0.92 [0.63,1.36]	
Total	240 / 1439	266 / 1410		0.86 [0.71,1.04]	Z=-1.52, p=0.1278
Heterogeneity:	Q=0.15 (df=1)	p=0.6938	I^2=0.0%		
>= 65					
FIDELIO-DKD	287 / 1514	317 / 1535	57.6	0.90 [0.75,1.07]	
FIGARO-DKD	229 / 1021	230 / 1021	42.4	0.99 [0.81,1.22]	
Total	516 / 2535	547 / 2556		0.94 [0.82,1.07]	Z=-0.93, p=0.3545
Heterogeneity:	Q=0.52 (df=1)	p=0.4690	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4758	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.5.8: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

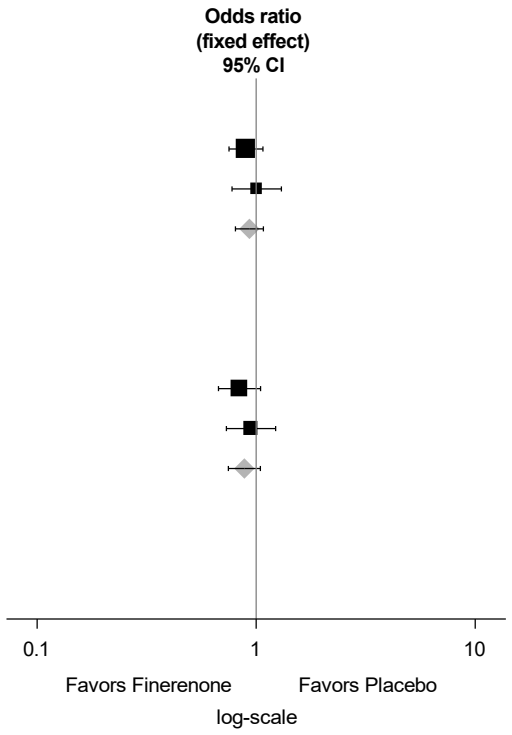
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	54 / 213	14.3	0.85 [0.55,1.34]	
FIGARO-DKD	290 / 1357	295 / 1356	85.7	0.98 [0.81,1.17]	
Total	337 / 1566	349 / 1569		0.96 [0.81,1.14]	Z=-0.49, p=0.6267
Heterogeneity:	Q=0.30 (df=1)	p=0.5851	I^2=0.0%		
Very High					
FIDELIO-DKD	419 / 2408	464 / 2397	100.0	0.88 [0.76,1.02]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	419 / 2408	464 / 2397		0.88 [0.76,1.02]	Z=-1.75, p=0.0800
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.60 (df=1)	p=0.4380	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.5.9: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

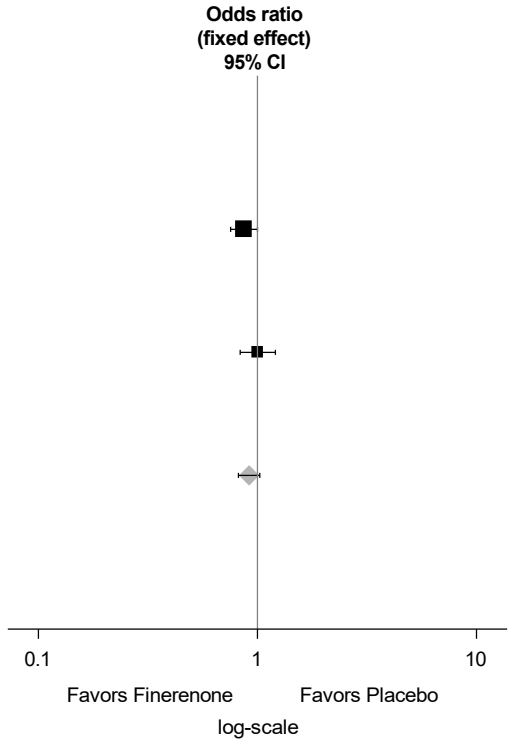
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	288 / 1556	311 / 1541	67.9	0.90 [0.75,1.07]	
FIGARO-DKD	151 / 637	148 / 627	32.1	1.01 [0.78,1.30]	
Total	439 / 2193	459 / 2168		0.93 [0.80,1.08]	Z=-0.95, p=0.3435
Heterogeneity:	Q=0.49 (df=1)	p=0.4826	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	178 / 1061	207 / 1069	57.8	0.84 [0.67,1.05]	
FIGARO-DKD	139 / 720	147 / 729	42.2	0.95 [0.73,1.23]	
Total	317 / 1781	354 / 1798		0.88 [0.75,1.05]	Z=-1.45, p=0.1481
Heterogeneity:	Q=0.48 (df=1)	p=0.4869	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6416	I^2=0.0%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.6: Forestplot for Odds Ratio of Proportion of Subjects with Severe TEAEs Excluding Progression-Related Events
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

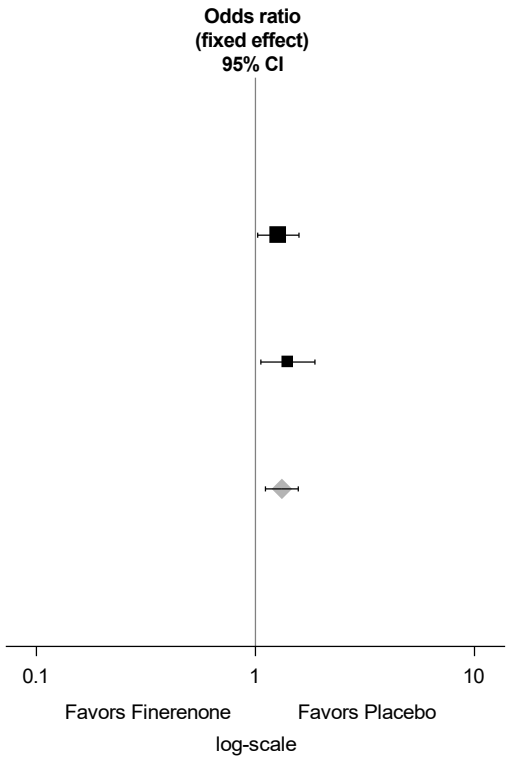
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	444 / 2617	497 / 2610	63.2	0.87 [0.75,1.00]	
FIGARO-DKD	284 / 1357	283 / 1356	36.8	1.00 [0.83,1.21]	
Total	728 / 3974	780 / 3966		0.92 [0.82,1.02]	Z=-1.53, p=0.1259
Heterogeneity:	Q=1.47 (df=1)	p=0.2246	I^2=32.2%		



Abbreviations: CI=confidence interval, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse
event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

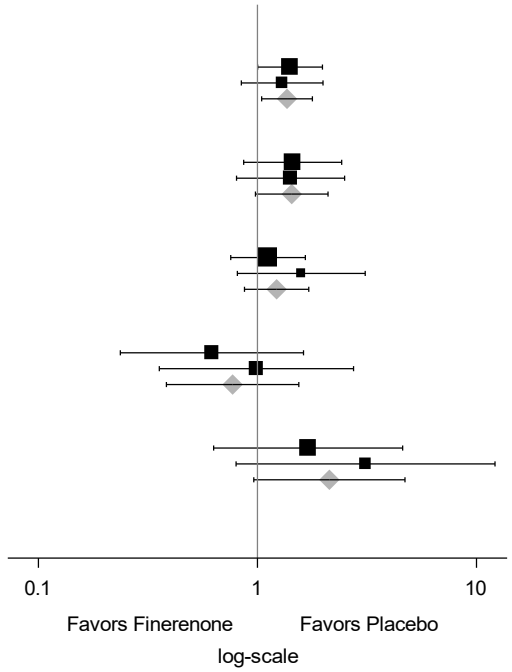
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	197 / 2617	157 / 2610	63.2	1.27 [1.02,1.58]	
FIGARO-DKD	122 / 1357	89 / 1356	36.8	1.41 [1.06,1.87]	
Total	319 / 3974	246 / 3966		1.32 [1.11,1.57]	Z=3.15, p=0.0016
Heterogeneity:	Q=0.30 (df=1)	p=0.5819	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.7.1: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Region
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

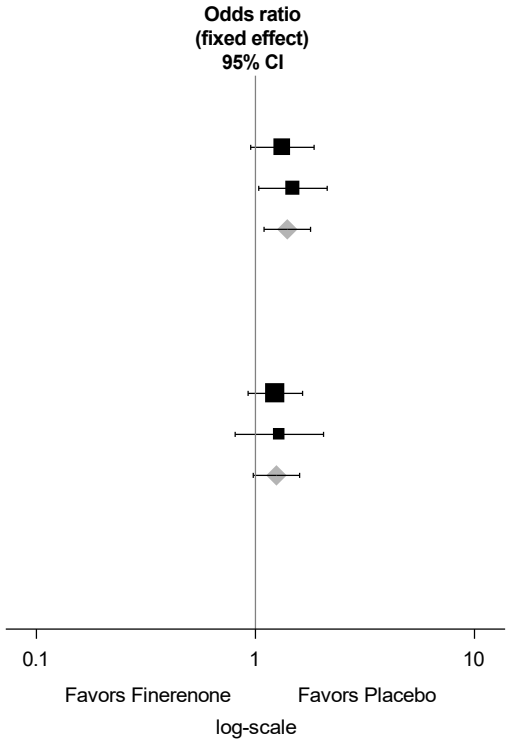
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	85 / 1075	61 / 1062	61.4	1.41 [1.00,1.98]	
FIGARO-DKD	51 / 638	40 / 637	38.6	1.30 [0.84,1.99]	
Total	136 / 1713	101 / 1699		1.36 [1.05,1.78]	Z=2.28, p=0.0223
Heterogeneity:	Q=0.09 (df=1)	p=0.7666	I^2=0.0%		
North America					
FIDELIO-DKD	37 / 424	27 / 436	54.9	1.45 [0.87,2.42]	
FIGARO-DKD	31 / 267	23 / 271	45.1	1.42 [0.80,2.50]	
Total	68 / 691	50 / 707		1.43 [0.98,2.10]	Z=1.85, p=0.0642
Heterogeneity:	Q=0.00 (df=1)	p=0.9546	I^2=0.0%		
Asia					
FIDELIO-DKD	57 / 751	51 / 745	74.6	1.12 [0.76,1.65]	
FIGARO-DKD	23 / 289	15 / 290	25.4	1.59 [0.81,3.10]	
Total	80 / 1040	66 / 1035		1.22 [0.87,1.72]	Z=1.17, p=0.2425
Heterogeneity:	Q=0.78 (df=1)	p=0.3786	I^2=0.0%		
Latin America					
FIDELIO-DKD	7 / 273	11 / 270	52.9	0.62 [0.24,1.62]	
FIGARO-DKD	8 / 102	8 / 101	47.1	0.99 [0.36,2.75]	
Total	15 / 375	19 / 371		0.77 [0.38,1.54]	Z=-0.74, p=0.4622
Heterogeneity:	Q=0.43 (df=1)	p=0.5134	I^2=0.0%		
Others					
FIDELIO-DKD	11 / 94	7 / 97	65.2	1.70 [0.63,4.60]	
FIGARO-DKD	9 / 61	3 / 57	34.8	3.12 [0.80,12.15]	
Total	20 / 155	10 / 154		2.13 [0.96,4.72]	Z=1.86, p=0.0622
Heterogeneity:	Q=0.49 (df=1)	p=0.4823	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.13 (df=4)	p=0.3888	I^2=3.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.7.2: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by History of CVD
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

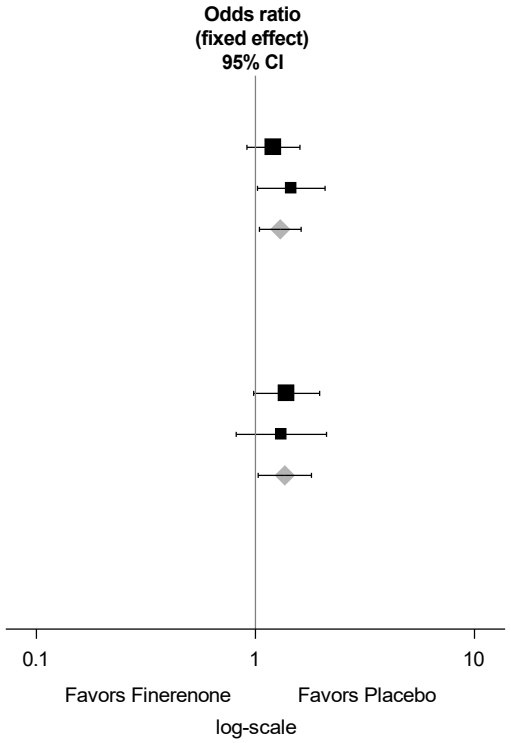
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	85 / 1213	65 / 1210	53.8	1.33 [0.95,1.85]	
FIGARO-DKD	79 / 862	54 / 848	46.2	1.48 [1.04,2.13]	
Total	164 / 2075	119 / 2058		1.40 [1.09,1.78]	Z=2.68, p=0.0073
Heterogeneity:	Q=0.20 (df=1)	p=0.6568	I^2=0.0%		
Absent					
FIDELIO-DKD	112 / 1404	92 / 1400	72.5	1.23 [0.93,1.64]	
FIGARO-DKD	43 / 495	35 / 508	27.5	1.29 [0.81,2.05]	
Total	155 / 1899	127 / 1908		1.25 [0.98,1.59]	Z=1.77, p=0.0760
Heterogeneity:	Q=0.02 (df=1)	p=0.8794	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5171	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.7.3: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Serum Potassium (mmol/L) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

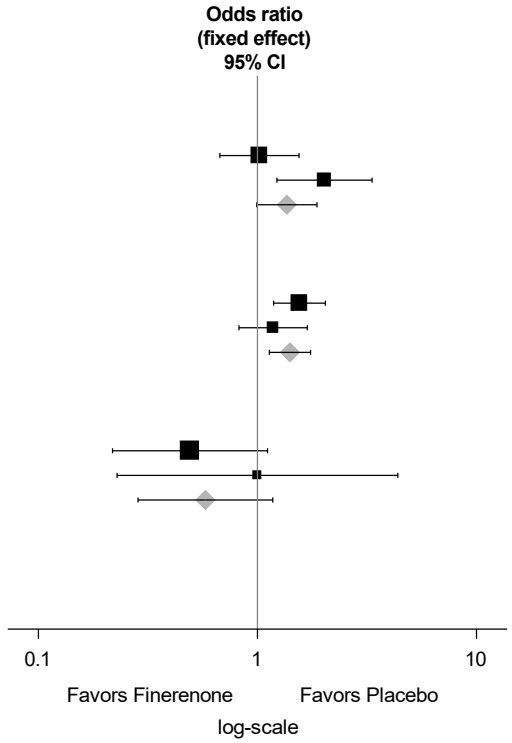
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	117 / 1735	96 / 1700	61.9	1.21 [0.91,1.60]	
FIGARO-DKD	79 / 924	56 / 929	38.1	1.46 [1.02,2.08]	
Total	196 / 2659	152 / 2629		1.30 [1.04,1.62]	Z=2.34, p=0.0195
Heterogeneity:	Q=0.66 (df=1)	p=0.4155	I^2=0.0%		
> 4.5					
FIDELIO-DKD	80 / 882	61 / 910	65.2	1.39 [0.98,1.96]	
FIGARO-DKD	43 / 433	33 / 426	34.8	1.31 [0.82,2.11]	
Total	123 / 1315	94 / 1336		1.36 [1.03,1.80]	Z=2.16, p=0.0307
Heterogeneity:	Q=0.03 (df=1)	p=0.8526	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7927	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.7.4: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Systolic Blood Pressure (mmHg) Category at Baseline
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

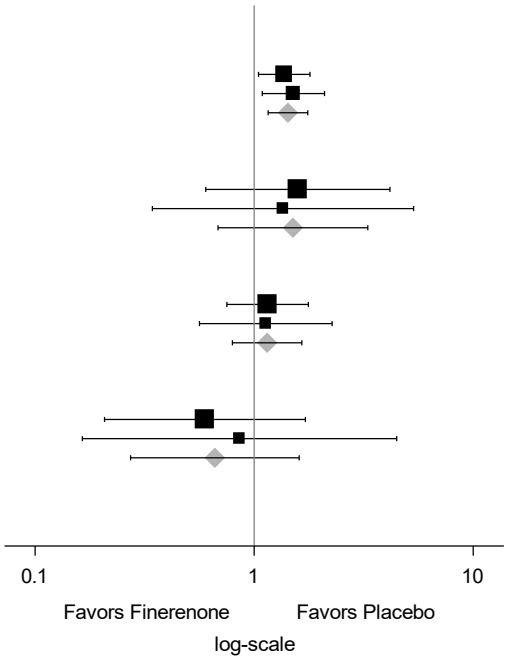
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	48 / 724	47 / 723	59.1	1.02 [0.67,1.55]	
FIGARO-DKD	48 / 494	25 / 495	40.9	2.02 [1.23,3.34]	
Total	96 / 1218	72 / 1218		1.36 [0.99,1.87]	Z=1.91, p=0.0557
Heterogeneity:	Q=4.24 (df=1)	p=0.0394	I^2=76.4%		
130 - < 160					
FIDELIO-DKD	139 / 1759	92 / 1760	63.5	1.56 [1.18,2.04]	
FIGARO-DKD	70 / 829	60 / 827	36.5	1.18 [0.82,1.69]	
Total	209 / 2588	152 / 2587		1.41 [1.13,1.75]	Z=3.09, p=0.0020
Heterogeneity:	Q=1.45 (df=1)	p=0.2278	I^2=31.2%		
>= 160					
FIDELIO-DKD	10 / 133	18 / 127	76.6	0.49 [0.22,1.11]	
FIGARO-DKD	4 / 34	4 / 34	23.4	1.00 [0.23,4.37]	
Total	14 / 167	22 / 161		0.58 [0.28,1.17]	Z=-1.51, p=0.1300
Heterogeneity:	Q=0.68 (df=1)	p=0.4099	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.58 (df=2)	p=0.0613	I^2=64.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.7.5: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Race
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

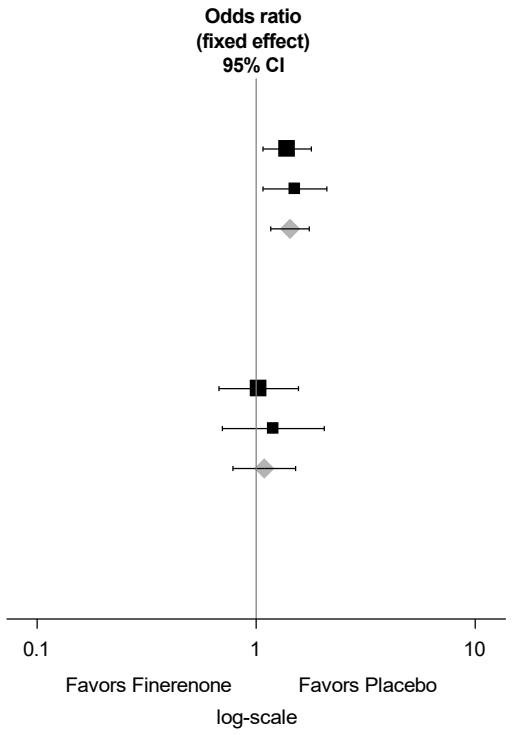
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	131 / 1634	99 / 1657	59.4	1.37 [1.05,1.80]	
FIGARO-DKD	97 / 1010	65 / 989	40.6	1.51 [1.09,2.09]	
Total	228 / 2644	164 / 2646		1.43 [1.16,1.76]	Z=3.34, p=0.0008
Heterogeneity:	Q=0.20 (df=1)	p=0.6567	I^2=0.0%		
Black					
FIDELIO-DKD	12 / 129	7 / 115	66.8	1.58 [0.60,4.17]	
FIGARO-DKD	4 / 43	5 / 71	33.2	1.35 [0.34,5.34]	
Total	16 / 172	12 / 186		1.50 [0.68,3.30]	Z=1.01, p=0.3107
Heterogeneity:	Q=0.03 (df=1)	p=0.8556	I^2=0.0%		
Asian					
FIDELIO-DKD	48 / 678	42 / 677	72.6	1.15 [0.75,1.77]	
FIGARO-DKD	18 / 252	16 / 251	27.4	1.13 [0.56,2.27]	
Total	66 / 930	58 / 928		1.15 [0.80,1.65]	Z=0.73, p=0.4649
Heterogeneity:	Q=0.00 (df=1)	p=0.9630	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 176	9 / 161	71.0	0.60 [0.21,1.71]	
FIGARO-DKD	3 / 52	3 / 45	29.0	0.86 [0.16,4.47]	
Total	9 / 228	12 / 206		0.66 [0.27,1.61]	Z=-0.91, p=0.3610
Heterogeneity:	Q=0.13 (df=1)	p=0.7166	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.55 (df=3)	p=0.3147	I^2=15.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.7.6: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Sex
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

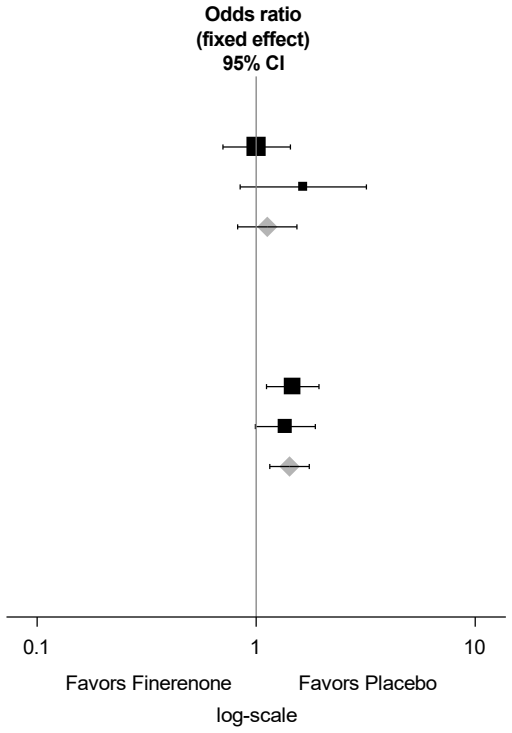
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	147 / 1797	113 / 1870	63.6	1.39 [1.07,1.79]	
FIGARO-DKD	90 / 917	63 / 933	36.4	1.50 [1.07,2.10]	
Total	237 / 2714	176 / 2803		1.43 [1.17,1.75]	Z=3.44, p=0.0006
Heterogeneity:	Q=0.14 (df=1)	p=0.7045	I^2=0.0%		
Female					
FIDELIO-DKD	50 / 820	44 / 740	62.2	1.03 [0.68,1.56]	
FIGARO-DKD	32 / 440	26 / 423	37.8	1.20 [0.70,2.05]	
Total	82 / 1260	70 / 1163		1.09 [0.78,1.51]	Z=0.51, p=0.6127
Heterogeneity:	Q=0.20 (df=1)	p=0.6578	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.88 (df=1)	p=0.1703	I^2=46.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.7.7: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Age Group (years)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

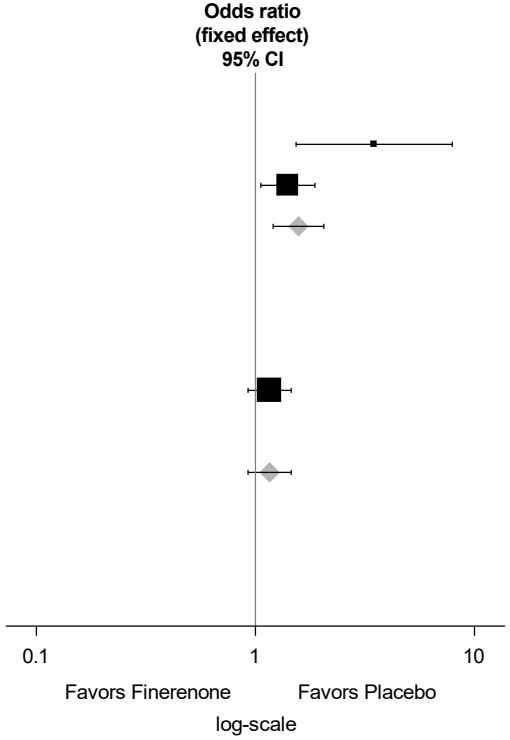
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	66 / 1103	64 / 1075	77.8	1.01 [0.71,1.43]	
FIGARO-DKD	24 / 336	15 / 335	22.2	1.64 [0.85,3.19]	
Total	90 / 1439	79 / 1410		1.12 [0.82,1.53]	Z=0.73, p=0.4624
Heterogeneity:	Q=1.63 (df=1)	p=0.2019	I^2=38.6%		
>= 65					
FIDELIO-DKD	131 / 1514	93 / 1535	56.6	1.47 [1.11,1.94]	
FIGARO-DKD	98 / 1021	74 / 1021	43.4	1.36 [0.99,1.86]	
Total	229 / 2535	167 / 2556		1.42 [1.15,1.75]	Z=3.31, p=0.0009
Heterogeneity:	Q=0.13 (df=1)	p=0.7158	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.50 (df=1)	p=0.2207	I^2=33.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.7.8: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by Type of Albuminuria at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

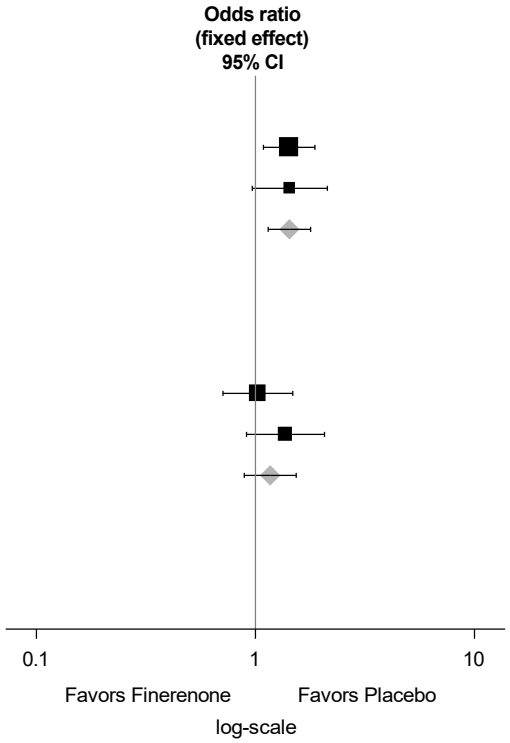
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	25 / 209	8 / 213	10.7	3.48 [1.53,7.91]	
FIGARO-DKD	122 / 1357	89 / 1356	89.3	1.41 [1.06,1.87]	
Total	147 / 1566	97 / 1569		1.57 [1.20,2.05]	Z=3.33, p=0.0009
Heterogeneity:	Q=4.20 (df=1)	p=0.0405	I^2=76.2%		
Very High					
FIDELIO-DKD	172 / 2408	149 / 2397	100.0	1.16 [0.92,1.46]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	172 / 2408	149 / 2397		1.16 [0.92,1.46]	Z=1.29, p=0.1986
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.89 (df=1)	p=0.0893	I^2=65.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.7.9: Forestplot for Odds Ratio of Proportion of Subjects with TEAEs leading to Discontinuation of Study Drug by eGFR (mL/min/1.73m2) Category at Screening
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

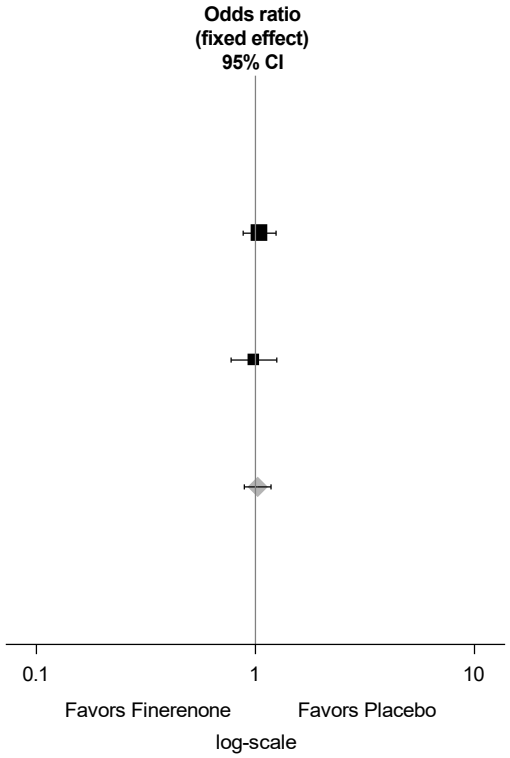
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	136 / 1556	97 / 1541	68.0	1.43 [1.09,1.87]	
FIGARO-DKD	65 / 637	46 / 627	32.0	1.44 [0.97,2.13]	
Total	201 / 2193	143 / 2168		1.43 [1.14,1.79]	Z=3.13, p=0.0017
Heterogeneity:	Q=0.00 (df=1)	p=0.9783	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	61 / 1061	60 / 1069	55.5	1.03 [0.71,1.48]	
FIGARO-DKD	57 / 720	43 / 729	44.5	1.37 [0.91,2.07]	
Total	118 / 1781	103 / 1798		1.17 [0.89,1.53]	Z=1.12, p=0.2645
Heterogeneity:	Q=1.07 (df=1)	p=0.3008	I^2=6.6%		
Subgroup Heterogeneity:	Q=1.25 (df=1)	p=0.2627	I^2=20.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, OR=odds ratio, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood And Lymphatic System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

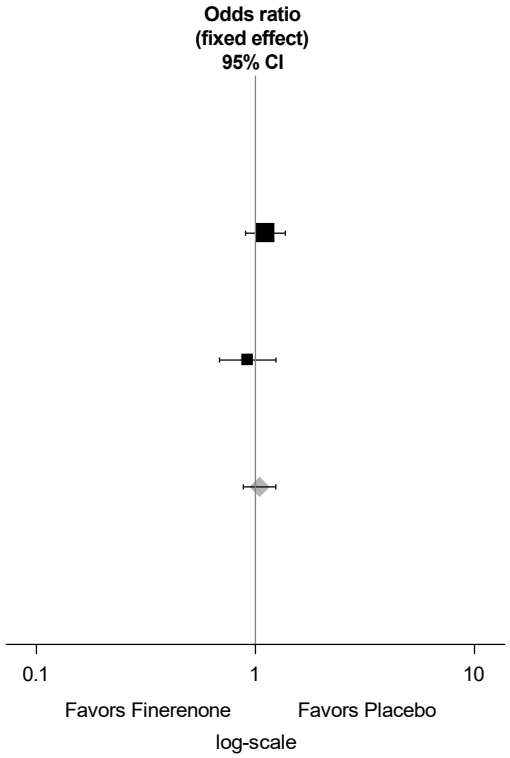
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	295 / 2617	283 / 2610	65.8	1.04 [0.88,1.24]	
FIGARO-DKD	149 / 1357	151 / 1356	34.2	0.98 [0.77,1.25]	
Total	444 / 3974	434 / 3966		1.02 [0.89,1.18]	Z=0.33, p=0.7443
Heterogeneity:	Q=0.16 (df=1)	p=0.6934	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

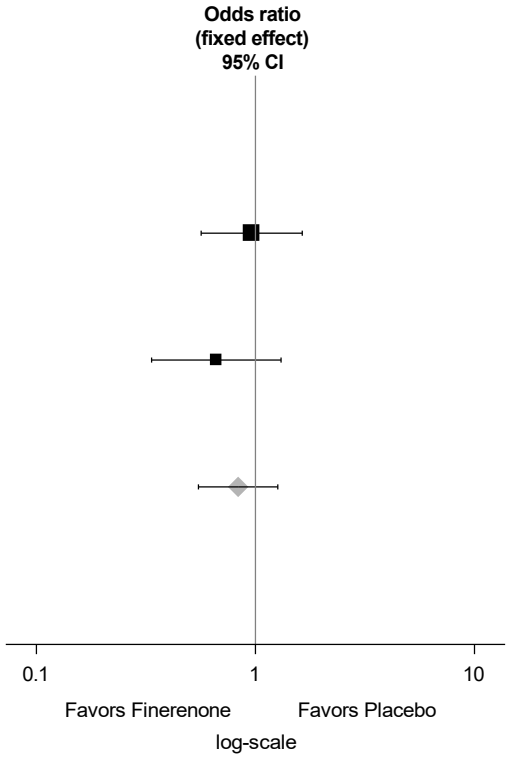
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	200 / 2617	181 / 2610	67.0	1.11 [0.90,1.37]	
FIGARO-DKD	90 / 1357	97 / 1356	33.0	0.92 [0.68,1.24]	
Total	290 / 3974	278 / 3966		1.04 [0.88,1.24]	Z=0.50, p=0.6190
Heterogeneity:	Q=1.01 (df=1)	p=0.3156	I^2=0.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.10: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Iron deficiency anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

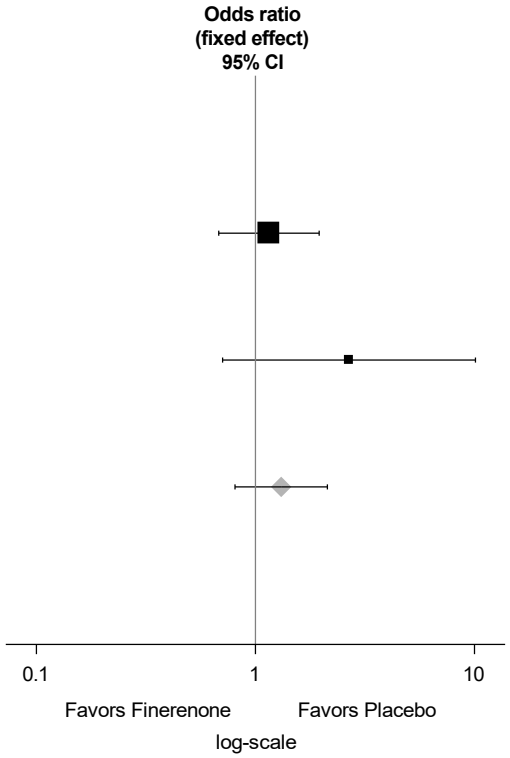
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	28 / 2610	62.1	0.96 [0.57,1.64]	
FIGARO-DKD	14 / 1357	21 / 1356	37.9	0.66 [0.34,1.31]	
Total	41 / 3974	49 / 3966		0.83 [0.55,1.26]	Z=-0.86, p=0.3919
Heterogeneity:	Q=0.71 (df=1)	p=0.3984	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.11: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nephrogenic anaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

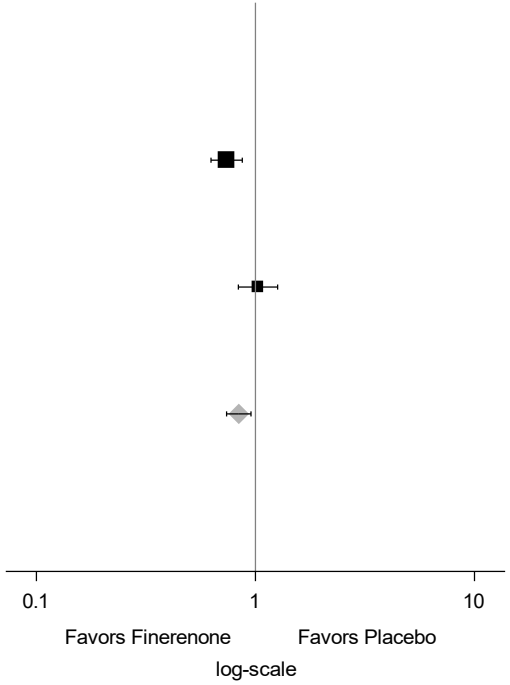
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	26 / 2610	86.4	1.15 [0.68,1.95]	
FIGARO-DKD	8 / 1357	3 / 1356	13.6	2.67 [0.71,10.10]	
Total	38 / 3974	29 / 3966		1.31 [0.81,2.13]	Z=1.09, p=0.2749
Heterogeneity:	Q=1.33 (df=1)	p=0.2481	I^2=25.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.12: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

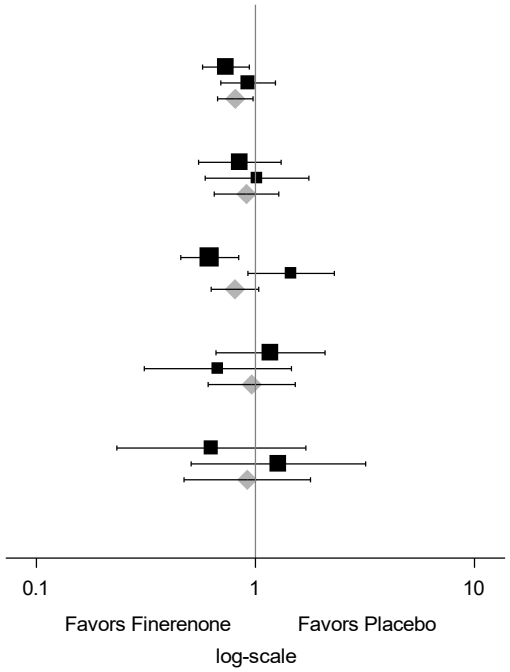
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	287 / 2617	373 / 2610	61.1	0.74 [0.63,0.87]	
FIGARO-DKD	217 / 1357	212 / 1356	38.9	1.03 [0.84,1.26]	
Total	504 / 3974	585 / 3966		0.84 [0.74,0.95]	Z=-2.68, p=0.0074
Heterogeneity:	Q=6.00 (df=1)	p=0.0143	I^2=83.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.12.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

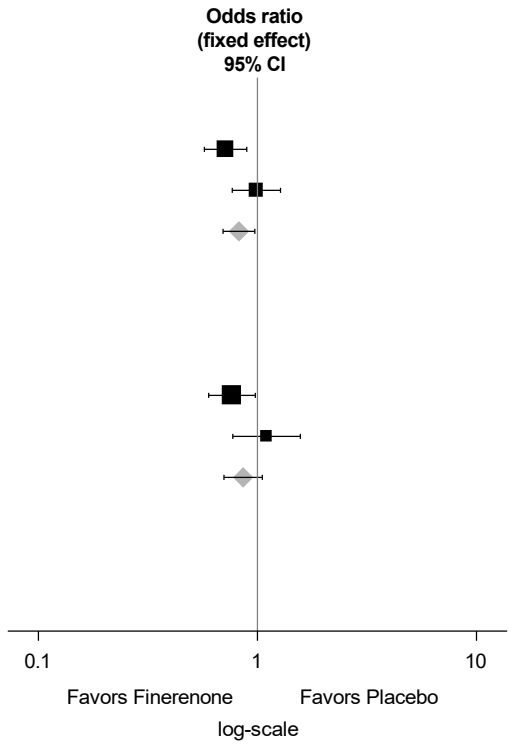
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	131 / 1075	169 / 1062	57.7	0.73 [0.57,0.94]	
FIGARO-DKD	110 / 638	117 / 637	42.3	0.93 [0.69,1.23]	
Total	241 / 1713	286 / 1699		0.81 [0.67,0.97]	Z=-2.23, p=0.0259
Heterogeneity:	Q=1.46 (df=1)	p=0.2264	I^2=31.7%		
North America					
FIDELIO-DKD	42 / 424	50 / 436	61.2	0.85 [0.55,1.31]	
FIGARO-DKD	29 / 267	29 / 271	38.8	1.02 [0.59,1.75]	
Total	71 / 691	79 / 707		0.91 [0.65,1.28]	Z=-0.54, p=0.5871
Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		
Asia					
FIDELIO-DKD	79 / 751	119 / 745	69.0	0.62 [0.46,0.84]	
FIGARO-DKD	52 / 289	38 / 290	31.0	1.46 [0.92,2.29]	
Total	131 / 1040	157 / 1035		0.81 [0.63,1.04]	Z=-1.69, p=0.0910
Heterogeneity:	Q=9.40 (df=1)	p=0.0022	I^2=89.4%		
Latin America					
FIDELIO-DKD	28 / 273	24 / 270	64.6	1.17 [0.66,2.08]	
FIGARO-DKD	13 / 102	18 / 101	35.4	0.67 [0.31,1.46]	
Total	41 / 375	42 / 371		0.96 [0.61,1.52]	Z=-0.17, p=0.8664
Heterogeneity:	Q=1.27 (df=1)	p=0.2599	I^2=21.2%		
Others					
FIDELIO-DKD	7 / 94	11 / 97	46.0	0.63 [0.23,1.70]	
FIGARO-DKD	13 / 61	10 / 57	54.0	1.27 [0.51,3.19]	
Total	20 / 155	21 / 154		0.92 [0.47,1.78]	Z=-0.25, p=0.7997
Heterogeneity:	Q=1.04 (df=1)	p=0.3069	I^2=4.2%		
Subgroup Heterogeneity:	Q=0.88 (df=4)	p=0.9281	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.12.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

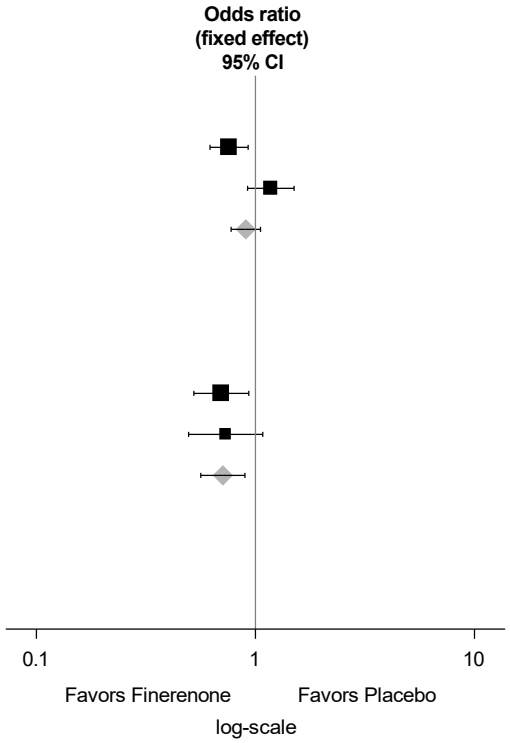
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	160 / 1213	212 / 1210	56.5	0.72 [0.57,0.89]	
FIGARO-DKD	144 / 862	143 / 848	43.5	0.99 [0.77,1.27]	
Total	304 / 2075	355 / 2058		0.82 [0.70,0.97]	Z=-2.28, p=0.0223
Heterogeneity:	Q=3.53 (df=1)	p=0.0602	I^2=71.7%		
Absent					
FIDELIO-DKD	127 / 1404	161 / 1400	67.7	0.77 [0.60,0.98]	
FIGARO-DKD	73 / 495	69 / 508	32.3	1.10 [0.77,1.57]	
Total	200 / 1899	230 / 1908		0.86 [0.70,1.05]	Z=-1.46, p=0.1432
Heterogeneity:	Q=2.72 (df=1)	p=0.0991	I^2=63.2%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7406	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.12.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	198 / 1735	247 / 1700	59.8	0.76 [0.62,0.93]	
FIGARO-DKD	165 / 924	145 / 929	40.2	1.18 [0.92,1.50]	
Total	363 / 2659	392 / 2629		0.90 [0.77,1.05]	Z=-1.29, p=0.1982
Heterogeneity:	Q=7.41 (df=1)	p=0.0065	I^2=86.5%		
> 4.5					
FIDELIO-DKD	89 / 882	126 / 910	64.6	0.70 [0.52,0.93]	
FIGARO-DKD	52 / 433	67 / 426	35.4	0.73 [0.50,1.08]	
Total	141 / 1315	193 / 1336		0.71 [0.56,0.90]	Z=-2.90, p=0.0038
Heterogeneity:	Q=0.03 (df=1)	p=0.8522	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.88 (df=1)	p=0.0896	I^2=65.3%		

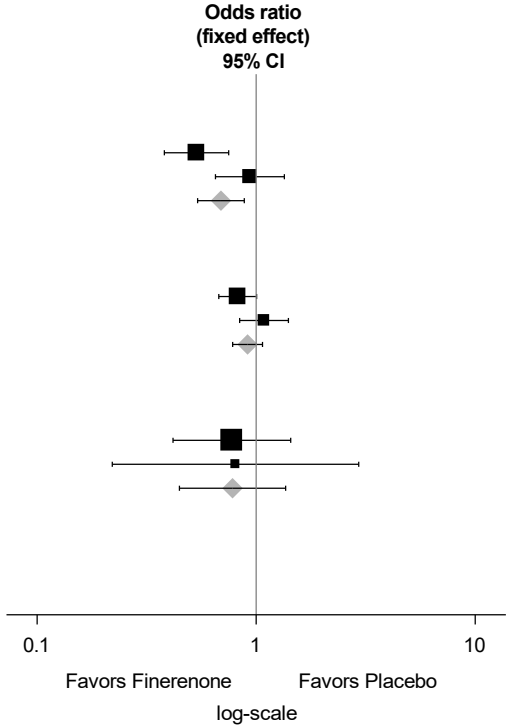


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.12.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

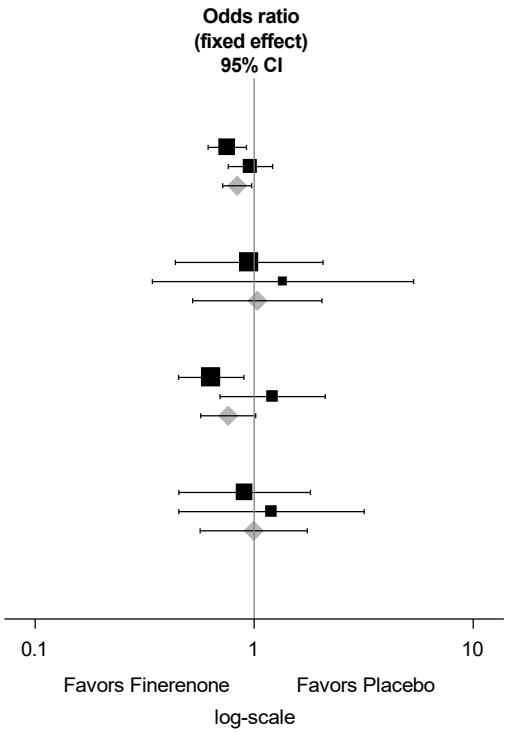
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	59 / 724	103 / 723	53.4	0.53 [0.38,0.75]	
FIGARO-DKD	66 / 494	70 / 495	46.6	0.94 [0.65,1.34]	
Total	125 / 1218	173 / 1218		0.69 [0.54,0.88]	Z=-2.96, p=0.0031
Heterogeneity:	Q=4.93 (df=1)	p=0.0263	I^2=79.7%		
130 - < 160					
FIDELIO-DKD	205 / 1759	243 / 1760	62.4	0.82 [0.68,1.00]	
FIGARO-DKD	146 / 829	136 / 827	37.6	1.09 [0.84,1.40]	
Total	351 / 2588	379 / 2587		0.91 [0.78,1.07]	Z=-1.13, p=0.2592
Heterogeneity:	Q=2.79 (df=1)	p=0.0946	I^2=64.2%		
>= 160					
FIDELIO-DKD	23 / 133	27 / 127	81.4	0.77 [0.42,1.44]	
FIGARO-DKD	5 / 34	6 / 34	18.6	0.80 [0.22,2.94]	
Total	28 / 167	33 / 161		0.78 [0.45,1.36]	Z=-0.87, p=0.3828
Heterogeneity:	Q=0.00 (df=1)	p=0.9584	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.62 (df=2)	p=0.1639	I^2=44.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.12.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

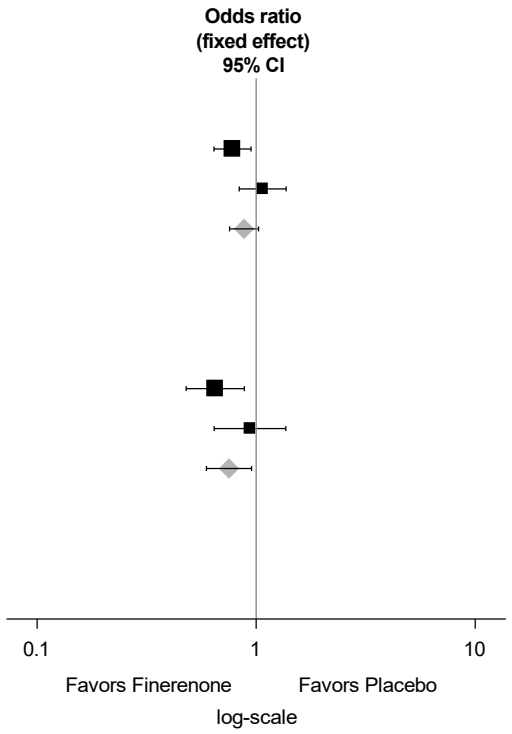
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	193 / 1634	250 / 1657	57.1	0.75 [0.62,0.92]	
FIGARO-DKD	170 / 1010	172 / 989	42.9	0.96 [0.76,1.21]	
Total	363 / 2644	422 / 2646		0.84 [0.72,0.97]	Z=-2.30, p=0.0213
Heterogeneity:	Q=2.39 (df=1)	p=0.1217	I^2=58.2%		
Black					
FIDELIO-DKD	15 / 129	14 / 115	75.8	0.95 [0.44,2.06]	
FIGARO-DKD	4 / 43	5 / 71	24.2	1.35 [0.34,5.34]	
Total	19 / 172	19 / 186		1.03 [0.52,2.04]	Z=0.09, p=0.9245
Heterogeneity:	Q=0.19 (df=1)	p=0.6591	I^2=0.0%		
Asian					
FIDELIO-DKD	61 / 678	91 / 677	72.2	0.64 [0.45,0.90]	
FIGARO-DKD	31 / 252	26 / 251	27.8	1.21 [0.70,2.11]	
Total	92 / 930	117 / 928		0.76 [0.57,1.02]	Z=-1.85, p=0.0646
Heterogeneity:	Q=3.77 (df=1)	p=0.0521	I^2=73.5%		
Others					
FIDELIO-DKD	18 / 176	18 / 161	66.5	0.91 [0.45,1.81]	
FIGARO-DKD	12 / 52	9 / 45	33.5	1.20 [0.45,3.18]	
Total	30 / 228	27 / 206		1.00 [0.57,1.75]	Z=-0.02, p=0.9865
Heterogeneity:	Q=0.21 (df=1)	p=0.6436	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.15 (df=3)	p=0.7660	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.12.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

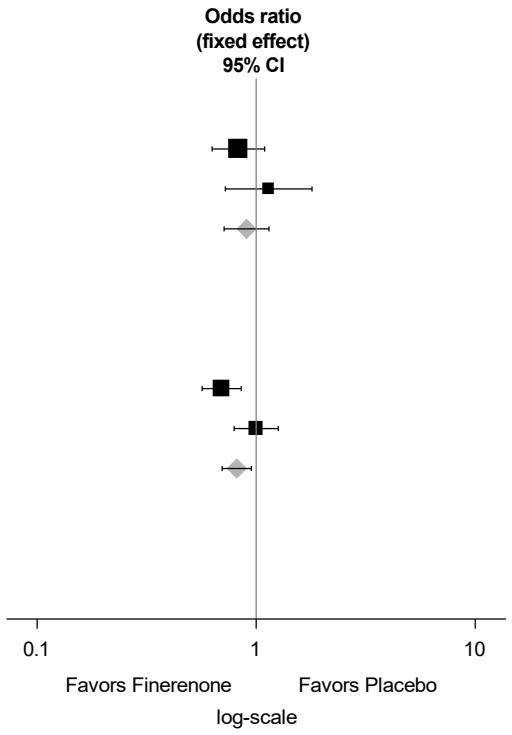
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	205 / 1797	265 / 1870	61.5	0.78 [0.64,0.95]	
FIGARO-DKD	154 / 917	148 / 933	38.5	1.07 [0.84,1.37]	
Total	359 / 2714	413 / 2803		0.88 [0.76,1.03]	Z=-1.63, p=0.1026
Heterogeneity:	Q=3.90 (df=1)	p=0.0483	I^2=74.3%		
Female					
FIDELIO-DKD	82 / 820	108 / 740	60.2	0.65 [0.48,0.88]	
FIGARO-DKD	63 / 440	64 / 423	39.8	0.94 [0.64,1.37]	
Total	145 / 1260	172 / 1163		0.75 [0.59,0.95]	Z=-2.36, p=0.0181
Heterogeneity:	Q=2.18 (df=1)	p=0.1396	I^2=54.2%		
Subgroup Heterogeneity:	Q=1.22 (df=1)	p=0.2700	I^2=17.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.12.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

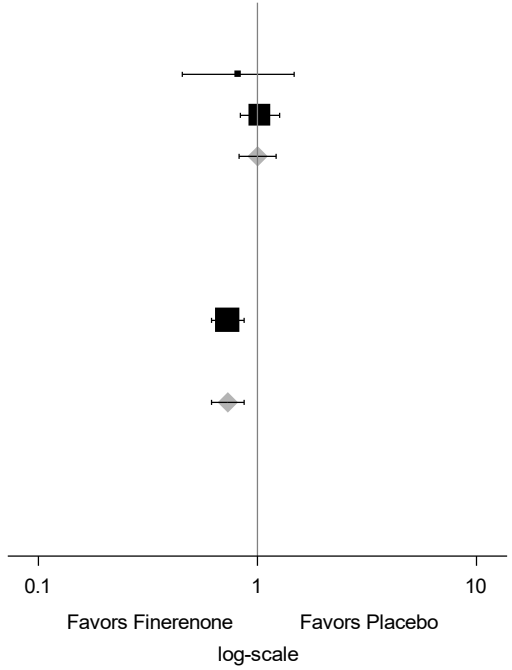
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	105 / 1103	121 / 1075	73.2	0.83 [0.63,1.09]	
FIGARO-DKD	45 / 336	40 / 335	26.8	1.14 [0.72,1.80]	
Total	150 / 1439	161 / 1410		0.90 [0.71,1.14]	Z=-0.84, p=0.3991
Heterogeneity:	Q=1.37 (df=1)	p=0.2415	I^2=27.1%		
>= 65					
FIDELIO-DKD	182 / 1514	252 / 1535	56.0	0.70 [0.57,0.85]	
FIGARO-DKD	172 / 1021	172 / 1021	44.0	1.00 [0.79,1.26]	
Total	354 / 2535	424 / 2556		0.82 [0.70,0.95]	Z=-2.61, p=0.0091
Heterogeneity:	Q=5.27 (df=1)	p=0.0217	I^2=81.0%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4743	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.12.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

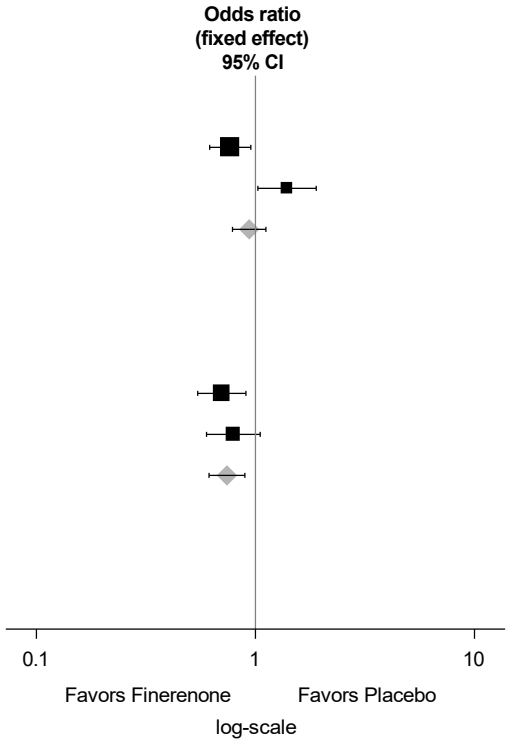
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	23 / 209	28 / 213	11.0	0.82 [0.45,1.47]	
FIGARO-DKD	217 / 1357	212 / 1356	89.0	1.03 [0.84,1.26]	
Total	240 / 1566	240 / 1569		1.00 [0.82,1.22]	Z=0.02, p=0.9871
Heterogeneity:	Q=0.52 (df=1)	p=0.4715	I^2=0.0%		
Very High					
FIDELIO-DKD	264 / 2408	345 / 2397	100.0	0.73 [0.62,0.87]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	264 / 2408	345 / 2397		0.73 [0.62,0.87]	Z=-3.56, p=0.0004
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.60 (df=1)	p=0.0179	I^2=82.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.12.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

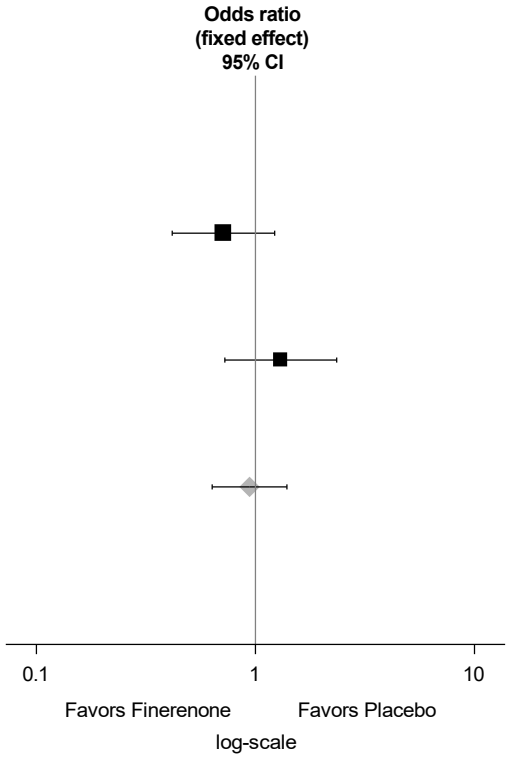
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	168 / 1556	210 / 1541	66.8	0.77 [0.62,0.95]	
FIGARO-DKD	113 / 637	84 / 627	33.2	1.39 [1.03,1.89]	
Total	281 / 2193	294 / 2168		0.94 [0.79,1.12]	Z=-0.73, p=0.4628
Heterogeneity:	Q=9.72 (df=1)	p=0.0018	I^2=89.7%		
45 - < 60					
FIDELIO-DKD	119 / 1061	163 / 1069	55.4	0.70 [0.55,0.90]	
FIGARO-DKD	104 / 720	128 / 729	44.6	0.79 [0.60,1.05]	
Total	223 / 1781	291 / 1798		0.74 [0.61,0.89]	Z=-3.12, p=0.0018
Heterogeneity:	Q=0.39 (df=1)	p=0.5306	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.16 (df=1)	p=0.0752	I^2=68.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.13: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Angina pectoris (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

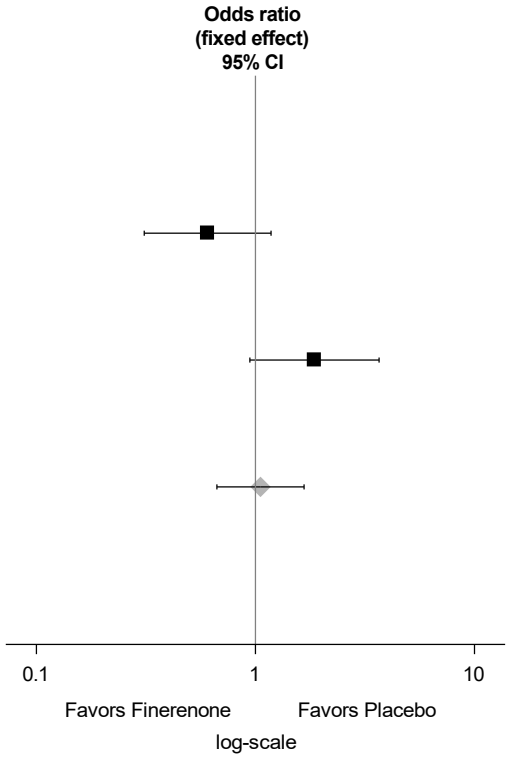
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	32 / 2610	54.4	0.71 [0.42,1.22]	
FIGARO-DKD	26 / 1357	20 / 1356	45.6	1.30 [0.72,2.35]	
Total	49 / 3974	52 / 3966		0.94 [0.63,1.39]	Z=-0.31, p=0.7569
Heterogeneity:	Q=2.19 (df=1)	p=0.1385	I^2=54.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.14: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Bradycardia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

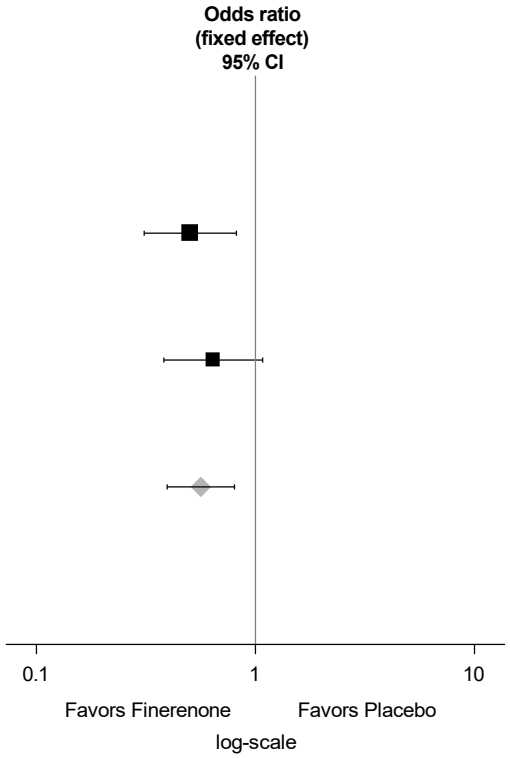
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	14 / 2617	23 / 2610	50.9	0.60 [0.31,1.18]	
FIGARO-DKD	24 / 1357	13 / 1356	49.1	1.86 [0.94,3.67]	
Total	38 / 3974	36 / 3966		1.05 [0.67,1.67]	Z=0.23, p=0.8210
Heterogeneity:	Q=5.35 (df=1)	p=0.0207	I^2=81.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.15: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

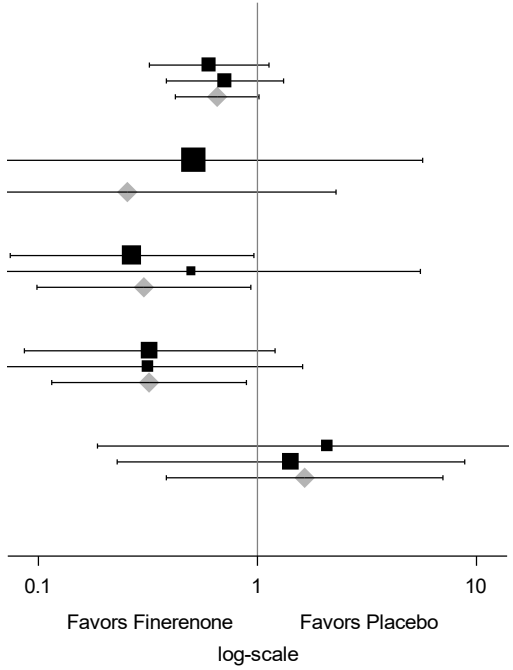
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	49 / 2610	53.4	0.50 [0.31,0.82]	
FIGARO-DKD	24 / 1357	37 / 1356	46.6	0.64 [0.38,1.08]	
Total	49 / 3974	86 / 3966		0.56 [0.40,0.80]	Z=-3.18, p=0.0015
Heterogeneity:	Q=0.44 (df=1)	p=0.5051	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.15.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

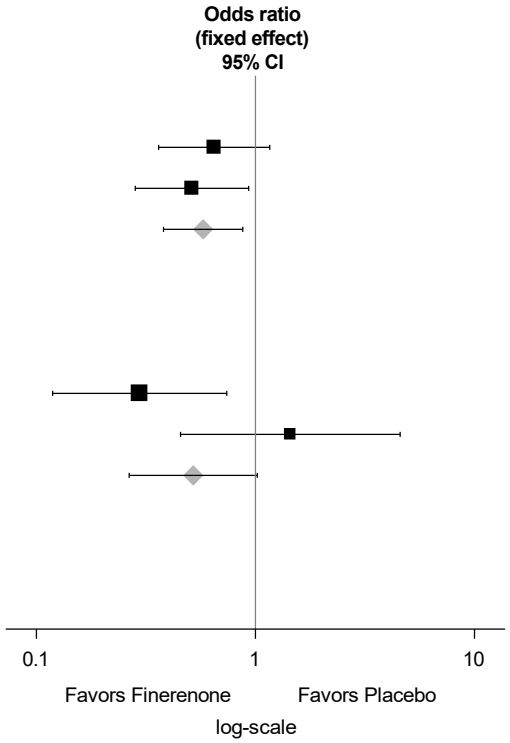
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	26 / 1062	49.0	0.60 [0.32,1.13]	
FIGARO-DKD	18 / 638	25 / 637	51.0	0.71 [0.38,1.32]	
Total	34 / 1713	51 / 1699		0.65 [0.42,1.02]	Z=-1.89, p=0.0590
Heterogeneity:	Q=0.14 (df=1)	p=0.7117	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 424	2 / 436	100.0	0.51 [0.05,5.68]	
FIGARO-DKD	0 / 267	2 / 271	0.0	0.00 [0.00,16E296]	
Total	1 / 691	4 / 707		0.25 [0.03,2.28]	Z=-1.22, p=0.2217
Heterogeneity:	Q=0.33 (df=1)	p=0.5680	I^2=0.0%		
Asia					
FIDELIO-DKD	3 / 751	11 / 745	77.9	0.27 [0.07,0.96]	
FIGARO-DKD	1 / 289	2 / 290	22.1	0.50 [0.05,5.54]	
Total	4 / 1040	13 / 1035		0.30 [0.10,0.93]	Z=-2.08, p=0.0374
Heterogeneity:	Q=0.20 (df=1)	p=0.6526	I^2=0.0%		
Latin America					
FIDELIO-DKD	3 / 273	9 / 270	60.3	0.32 [0.09,1.20]	
FIGARO-DKD	2 / 102	6 / 101	39.7	0.32 [0.06,1.61]	
Total	5 / 375	15 / 371		0.32 [0.11,0.89]	Z=-2.18, p=0.0291
Heterogeneity:	Q=0.00 (df=1)	p=0.9870	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	1 / 97	36.3	2.09 [0.19,23.41]	
FIGARO-DKD	3 / 61	2 / 57	63.7	1.42 [0.23,8.84]	
Total	5 / 155	3 / 154		1.64 [0.38,7.03]	Z=0.67, p=0.5036
Heterogeneity:	Q=0.06 (df=1)	p=0.8041	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.37 (df=4)	p=0.2513	I^2=25.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.15.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

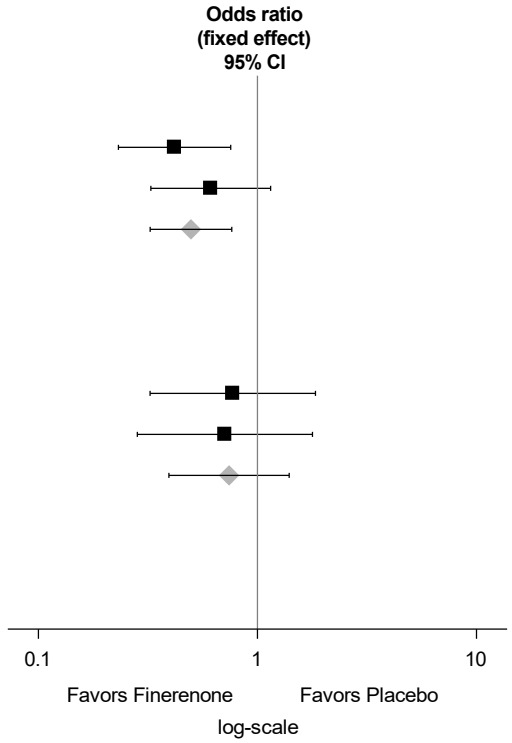
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 1213	29 / 1210	51.0	0.65 [0.36,1.16]	
FIGARO-DKD	17 / 862	32 / 848	49.0	0.51 [0.28,0.93]	
Total	36 / 2075	61 / 2058		0.58 [0.38,0.88]	Z=-2.59, p=0.0097
Heterogeneity:	Q=0.30 (df=1)	p=0.5831	I^2=0.0%		
Absent					
FIDELIO-DKD	6 / 1404	20 / 1400	61.4	0.30 [0.12,0.74]	
FIGARO-DKD	7 / 495	5 / 508	38.6	1.44 [0.45,4.58]	
Total	13 / 1899	25 / 1908		0.52 [0.27,1.02]	Z=-1.90, p=0.0569
Heterogeneity:	Q=4.46 (df=1)	p=0.0348	I^2=77.6%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7965	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.15.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	16 / 1735	37 / 1700	53.2	0.42 [0.23,0.75]	
FIGARO-DKD	16 / 924	26 / 929	46.8	0.61 [0.33,1.15]	
Total	32 / 2659	63 / 2629		0.50 [0.32,0.76]	Z=-3.19, p=0.0014
Heterogeneity:	Q=0.75 (df=1)	p=0.3874	I^2=0.0%		
> 4.5					
FIDELIO-DKD	9 / 882	12 / 910	52.9	0.77 [0.32,1.84]	
FIGARO-DKD	8 / 433	11 / 426	47.1	0.71 [0.28,1.78]	
Total	17 / 1315	23 / 1336		0.74 [0.39,1.40]	Z=-0.93, p=0.3545
Heterogeneity:	Q=0.02 (df=1)	p=0.8980	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.05 (df=1)	p=0.3044	I^2=5.2%		

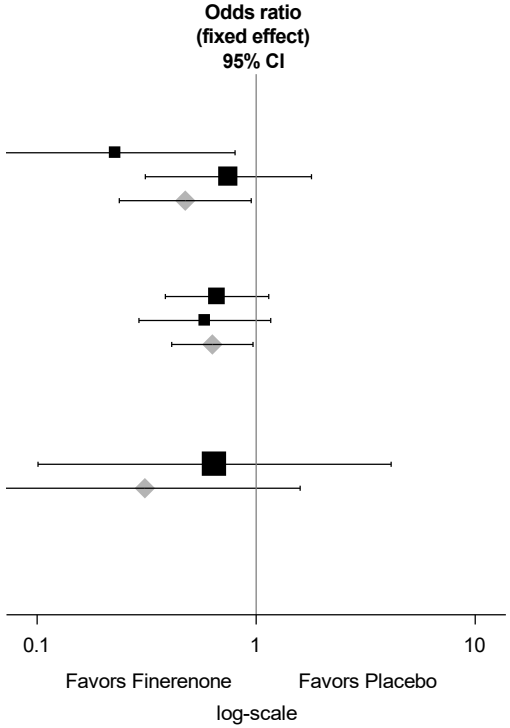


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.15.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

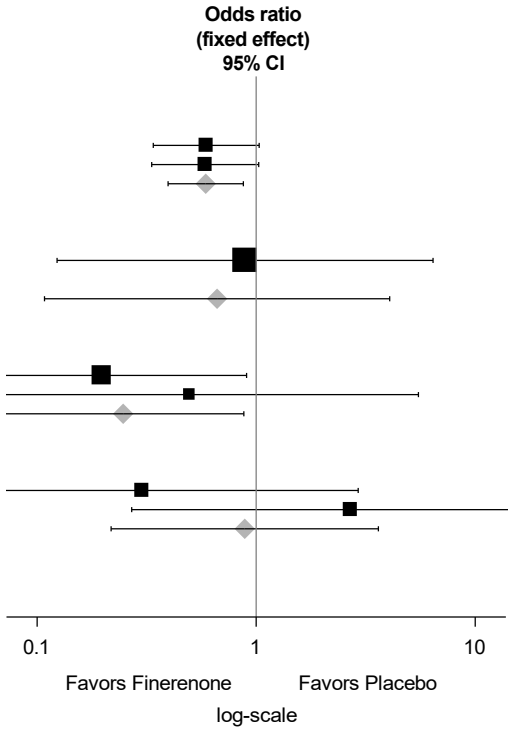
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 724	13 / 723	32.5	0.23 [0.06,0.80]	
FIGARO-DKD	9 / 494	12 / 495	67.5	0.75 [0.31,1.79]	
Total	12 / 1218	25 / 1218		0.47 [0.24,0.95]	Z=-2.11, p=0.0351
Heterogeneity:	Q=2.35 (df=1)	p=0.1254	I^2=57.4%		
130 - < 160					
FIDELIO-DKD	22 / 1759	33 / 1760	61.9	0.66 [0.38,1.14]	
FIGARO-DKD	13 / 829	22 / 827	38.1	0.58 [0.29,1.17]	
Total	35 / 2588	55 / 2587		0.63 [0.41,0.97]	Z=-2.11, p=0.0347
Heterogeneity:	Q=0.08 (df=1)	p=0.7749	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	3 / 127	0.0	0.00 [0.00,13E296]	
FIGARO-DKD	2 / 34	3 / 34	100.0	0.65 [0.10,4.13]	
Total	2 / 167	6 / 161		0.31 [0.06,1.59]	Z=-1.40, p=0.1601
Heterogeneity:	Q=0.60 (df=1)	p=0.4391	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.02 (df=2)	p=0.6016	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.15.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

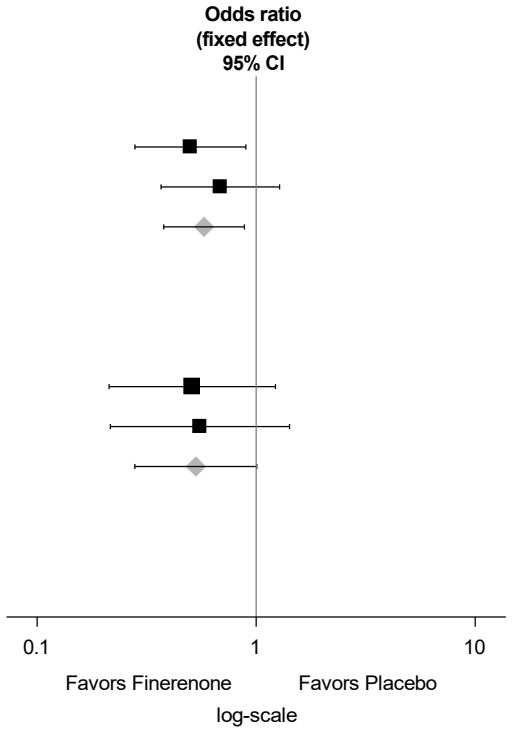
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	20 / 1634	34 / 1657	50.5	0.59 [0.34,1.03]	
FIGARO-DKD	20 / 1010	33 / 989	49.5	0.59 [0.33,1.03]	
Total	40 / 2644	67 / 2646		0.59 [0.40,0.87]	Z=-2.63, p=0.0086
Heterogeneity:	Q=0.00 (df=1)	p=0.9789	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	2 / 115	100.0	0.89 [0.12,6.42]	
FIGARO-DKD	0 / 43	1 / 71	0.0	0.00 [0.00,22E296]	
Total	2 / 172	3 / 186		0.66 [0.11,4.07]	Z=-0.44, p=0.6572
Heterogeneity:	Q=0.09 (df=1)	p=0.7706	I^2=0.0%		
Asian					
FIDELIO-DKD	2 / 678	10 / 677	71.4	0.20 [0.04,0.90]	
FIGARO-DKD	1 / 252	2 / 251	28.6	0.50 [0.04,5.51]	
Total	3 / 930	12 / 928		0.25 [0.07,0.88]	Z=-2.16, p=0.0307
Heterogeneity:	Q=0.41 (df=1)	p=0.5241	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	3 / 161	50.6	0.30 [0.03,2.92]	
FIGARO-DKD	3 / 52	1 / 45	49.4	2.69 [0.27,26.86]	
Total	4 / 228	4 / 206		0.89 [0.22,3.61]	Z=-0.17, p=0.8670
Heterogeneity:	Q=1.76 (df=1)	p=0.1840	I^2=43.3%		
Subgroup Heterogeneity:	Q=2.10 (df=3)	p=0.5519	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.15.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

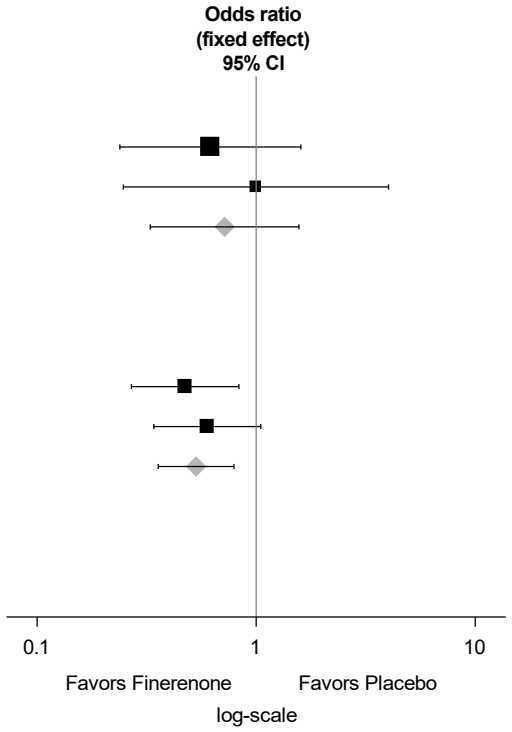
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	35 / 1870	53.3	0.50 [0.28,0.90]	
FIGARO-DKD	17 / 917	25 / 933	46.7	0.69 [0.37,1.28]	
Total	34 / 2714	60 / 2803		0.58 [0.38,0.88]	Z=-2.53, p=0.0114
Heterogeneity:	Q=0.52 (df=1)	p=0.4694	I^2=0.0%		
Female					
FIDELIO-DKD	8 / 820	14 / 740	53.7	0.51 [0.21,1.22]	
FIGARO-DKD	7 / 440	12 / 423	46.3	0.55 [0.22,1.42]	
Total	15 / 1260	26 / 1163		0.53 [0.28,1.01]	Z=-1.94, p=0.0523
Heterogeneity:	Q=0.02 (df=1)	p=0.9024	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8250	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.15.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

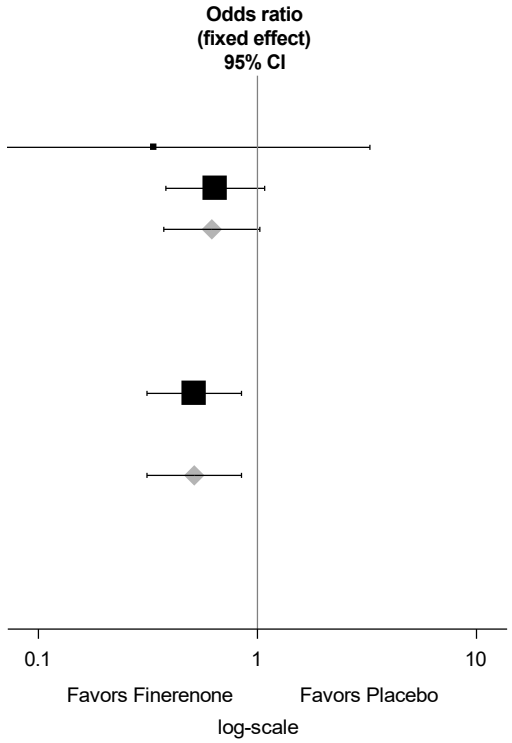
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	7 / 1103	11 / 1075	68.2	0.62 [0.24,1.60]	
FIGARO-DKD	4 / 336	4 / 335	31.8	1.00 [0.25,4.02]	
Total	11 / 1439	15 / 1410		0.72 [0.33,1.57]	Z=-0.83, p=0.4052
Heterogeneity:	Q=0.31 (df=1)	p=0.5784	I^2=0.0%		
>= 65					
FIDELIO-DKD	18 / 1514	38 / 1535	49.7	0.47 [0.27,0.83]	
FIGARO-DKD	20 / 1021	33 / 1021	50.3	0.60 [0.34,1.05]	
Total	38 / 2535	71 / 2556		0.53 [0.36,0.79]	Z=-3.11, p=0.0019
Heterogeneity:	Q=0.33 (df=1)	p=0.5673	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.45 (df=1)	p=0.5033	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.15.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

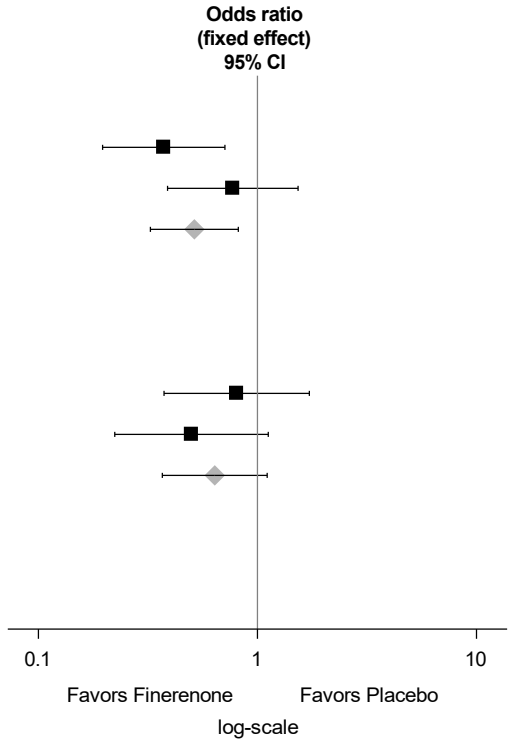
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	3 / 213	5.0	0.34 [0.03,3.26]	
FIGARO-DKD	24 / 1357	37 / 1356	95.0	0.64 [0.38,1.08]	
Total	25 / 1566	40 / 1569		0.62 [0.37,1.03]	Z=-1.86, p=0.0626
Heterogeneity:	Q=0.30 (df=1)	p=0.5869	I^2=0.0%		
Very High					
FIDELIO-DKD	24 / 2408	46 / 2397	100.0	0.51 [0.31,0.85]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	24 / 2408	46 / 2397		0.51 [0.31,0.85]	Z=-2.62, p=0.0088
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6092	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.15.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

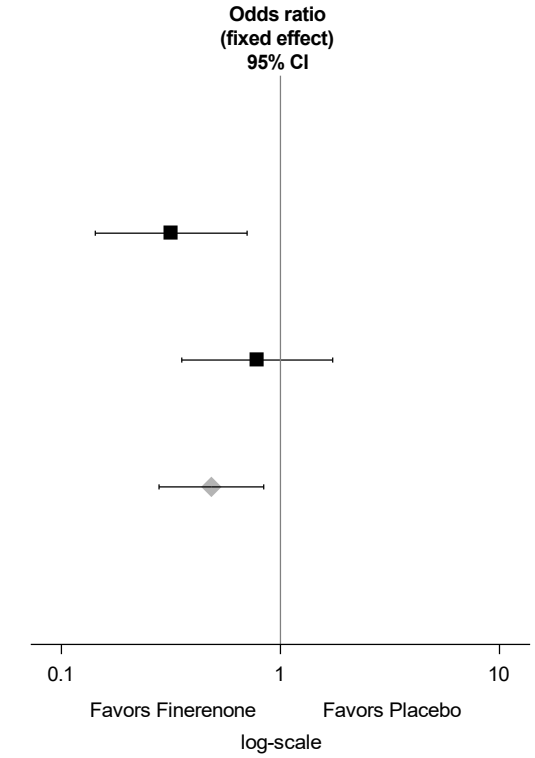
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	34 / 1541	53.2	0.37 [0.20,0.71]	
FIGARO-DKD	15 / 637	19 / 627	46.8	0.77 [0.39,1.53]	
Total	28 / 2193	53 / 2168		0.52 [0.32,0.82]	Z=-2.81, p=0.0049
Heterogeneity:	Q=2.29 (df=1)	p=0.1299	I^2=56.4%		
45 - < 60					
FIDELIO-DKD	12 / 1061	15 / 1069	52.7	0.80 [0.37,1.73]	
FIGARO-DKD	9 / 720	18 / 729	47.3	0.50 [0.22,1.12]	
Total	21 / 1781	33 / 1798		0.64 [0.37,1.11]	Z=-1.60, p=0.1104
Heterogeneity:	Q=0.70 (df=1)	p=0.4022	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5592	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

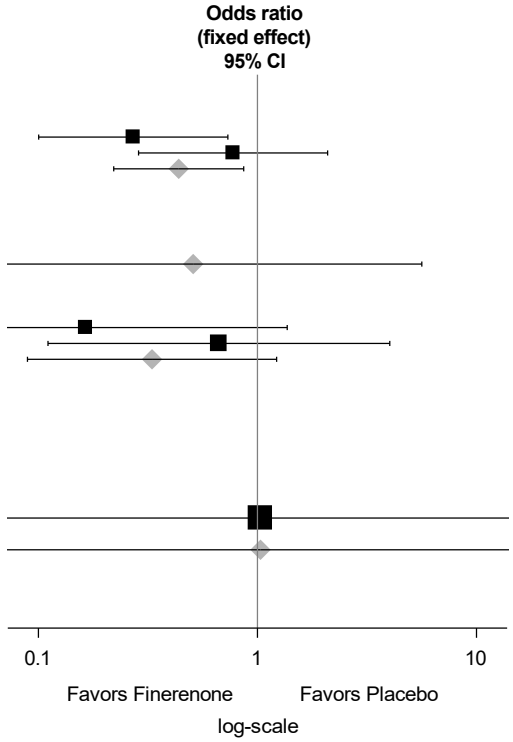
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	8 / 2617	25 / 2610	49.7	0.32 [0.14,0.70]	
FIGARO-DKD	11 / 1357	14 / 1356	50.3	0.78 [0.35,1.73]	
Total	19 / 3974	39 / 3966		0.48 [0.28,0.84]	Z=-2.59, p=0.0097
Heterogeneity:	Q=2.50 (df=1)	p=0.1142	I^2=59.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.16.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

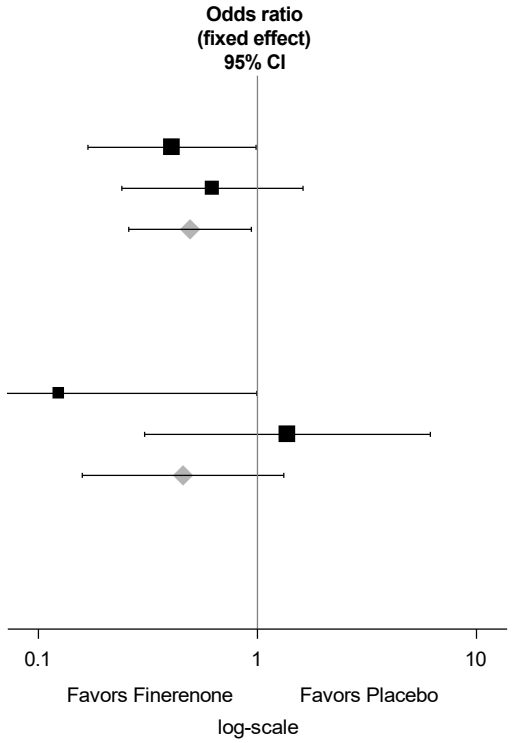
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	5 / 1075	18 / 1062	50.0	0.27 [0.10,0.73]	
FIGARO-DKD	7 / 638	9 / 637	50.0	0.77 [0.29,2.09]	
Total	12 / 1713	27 / 1699		0.44 [0.22,0.87]	Z=-2.37, p=0.0176
Heterogeneity:	Q=2.16 (df=1)	p=0.1419	I^2=53.7%		
North America					
FIDELIO-DKD	1 / 424	0 / 436	0.0	989E8 [989E8,989E8]	
FIGARO-DKD	0 / 267	2 / 271	0.0	0.00 [0.00,16E296]	
Total	1 / 691	2 / 707		0.51 [0.05,5.63]	Z=-0.55, p=0.5816
Heterogeneity:	Q=.	p=.	I^2=.		
Asia					
FIDELIO-DKD	1 / 751	6 / 745	41.8	0.16 [0.02,1.37]	
FIGARO-DKD	2 / 289	3 / 290	58.2	0.67 [0.11,4.02]	
Total	3 / 1040	9 / 1035		0.33 [0.09,1.22]	Z=-1.66, p=0.0972
Heterogeneity:	Q=1.00 (df=1)	p=0.3162	I^2=0.5%		
Latin America					
FIDELIO-DKD	0 / 273	0 / 270	0.0	-	
FIGARO-DKD	2 / 102	0 / 101	0.0	113E9 [113E9,113E9]	
Total	2 / 375	0 / 371		462E9 [462E9,462E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	1 / 97	100.0	1.03 [0.06,16.75]	
FIGARO-DKD	0 / 61	0 / 57	0.0	-	
Total	1 / 155	1 / 154		1.03 [0.06,16.75]	Z=0.02, p=0.9822
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=4)	p=0.9678	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

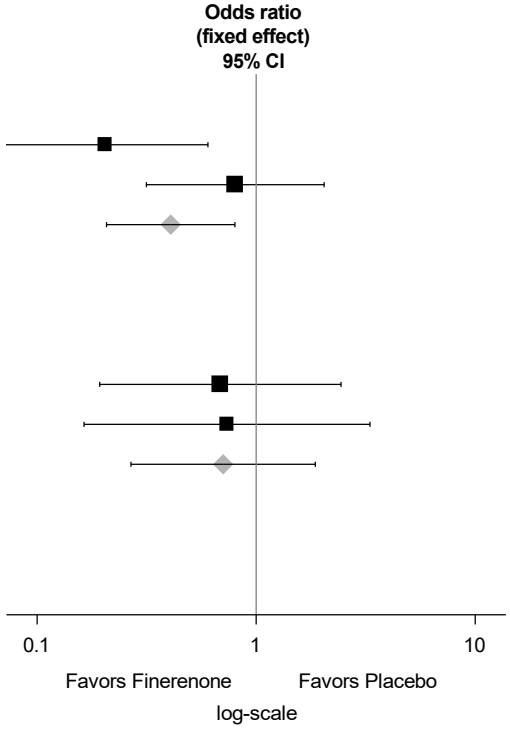
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	7 / 1213	17 / 1210	53.7	0.41 [0.17,0.99]	
FIGARO-DKD	7 / 862	11 / 848	46.3	0.62 [0.24,1.61]	
Total	14 / 2075	28 / 2058		0.49 [0.26,0.94]	Z=-2.15, p=0.0312
Heterogeneity:	Q=0.41 (df=1)	p=0.5214	I^2=0.0%		
Absent					
FIDELIO-DKD	1 / 1404	8 / 1400	34.3	0.12 [0.02,0.99]	
FIGARO-DKD	4 / 495	3 / 508	65.7	1.37 [0.31,6.16]	
Total	5 / 1899	11 / 1908		0.46 [0.16,1.32]	Z=-1.45, p=0.1478
Heterogeneity:	Q=3.56 (df=1)	p=0.0590	I^2=71.9%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9071	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

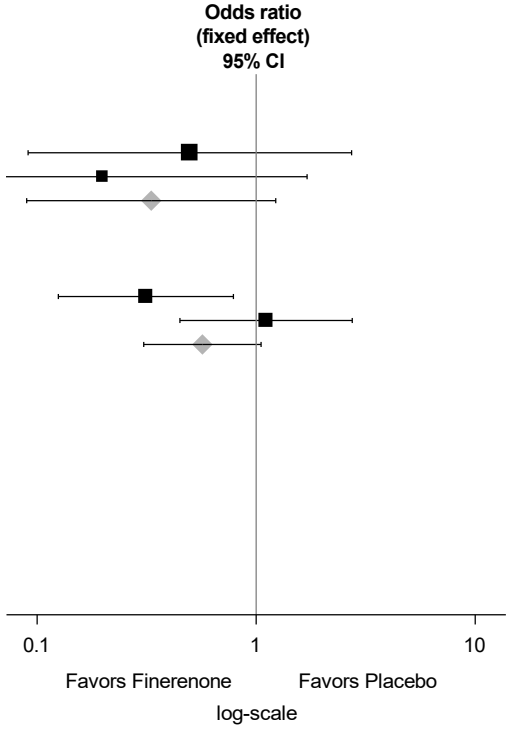
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	4 / 1735	19 / 1700	42.8	0.20 [0.07,0.60]	
FIGARO-DKD	8 / 924	10 / 929	57.2	0.80 [0.32,2.04]	
Total	12 / 2659	29 / 2629		0.41 [0.21,0.80]	Z=-2.61, p=0.0091
Heterogeneity:	Q=3.59 (df=1)	p=0.0582	I^2=72.1%		
> 4.5					
FIDELIO-DKD	4 / 882	6 / 910	58.4	0.69 [0.19,2.44]	
FIGARO-DKD	3 / 433	4 / 426	41.6	0.74 [0.16,3.31]	
Total	7 / 1315	10 / 1336		0.71 [0.27,1.86]	Z=-0.70, p=0.4824
Heterogeneity:	Q=0.00 (df=1)	p=0.9445	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.84 (df=1)	p=0.3606	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

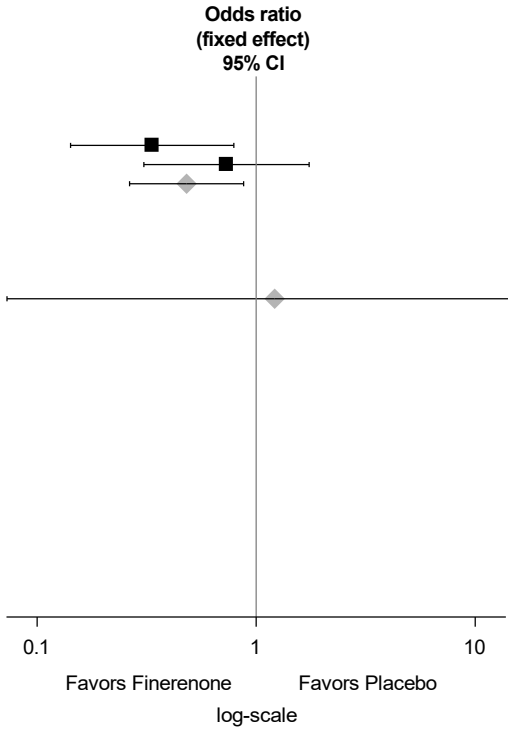
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	2 / 724	4 / 723	61.5	0.50 [0.09,2.73]	
FIGARO-DKD	1 / 494	5 / 495	38.5	0.20 [0.02,1.71]	
Total	3 / 1218	9 / 1218		0.33 [0.09,1.23]	Z=-1.65, p=0.0985
Heterogeneity:	Q=0.44 (df=1)	p=0.5086	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	6 / 1759	19 / 1760	49.2	0.31 [0.12,0.79]	
FIGARO-DKD	10 / 829	9 / 827	50.8	1.11 [0.45,2.75]	
Total	16 / 2588	28 / 2587		0.57 [0.31,1.05]	Z=-1.80, p=0.0725
Heterogeneity:	Q=3.70 (df=1)	p=0.0544	I^2=73.0%		
>= 160					
FIDELIO-DKD	0 / 133	2 / 127	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	2 / 161		0.00 [0.00,98E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.53 (df=2)	p=0.7668	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

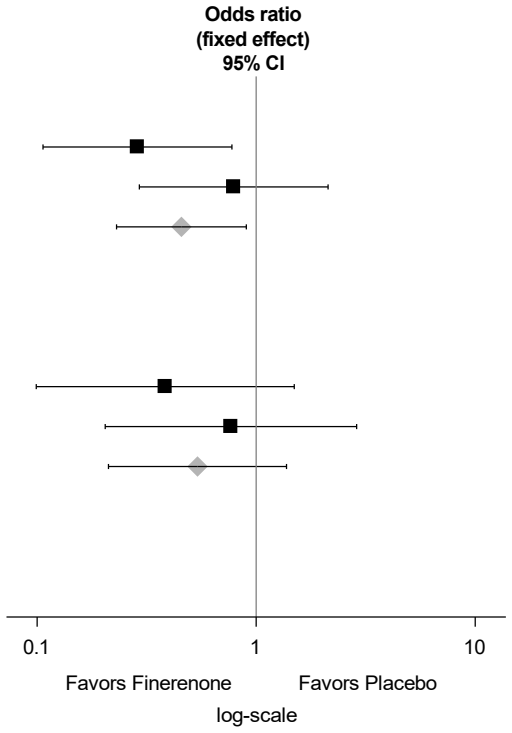
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	7 / 1634	21 / 1657	50.6	0.34 [0.14,0.79]	
FIGARO-DKD	9 / 1010	12 / 989	49.4	0.73 [0.31,1.75]	
Total	16 / 2644	33 / 2646		0.48 [0.26,0.88]	Z=-2.39, p=0.0168
Heterogeneity:	Q=1.58 (df=1)	p=0.2090	I^2=36.6%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	12E10 [12E10,12E10]	
FIGARO-DKD	0 / 43	1 / 71	0.0	0.00 [0.00,22E296]	
Total	1 / 172	1 / 186		1.21 [0.07,20.26]	Z=0.14, p=0.8922
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	0 / 678	4 / 677	0.0	0.00 [0.00,2E297]	
FIGARO-DKD	0 / 252	1 / 251	0.0	0.00 [0.00,1E297]	
Total	0 / 930	5 / 928		0.00 [0.00,22E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 176	0 / 161	0.0	-	
FIGARO-DKD	2 / 52	0 / 45	0.0	227E9 [227E9,227E9]	
Total	2 / 228	0 / 206		264E9 [264E9,264E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.40 (df=3)	p=0.9407	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.16.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

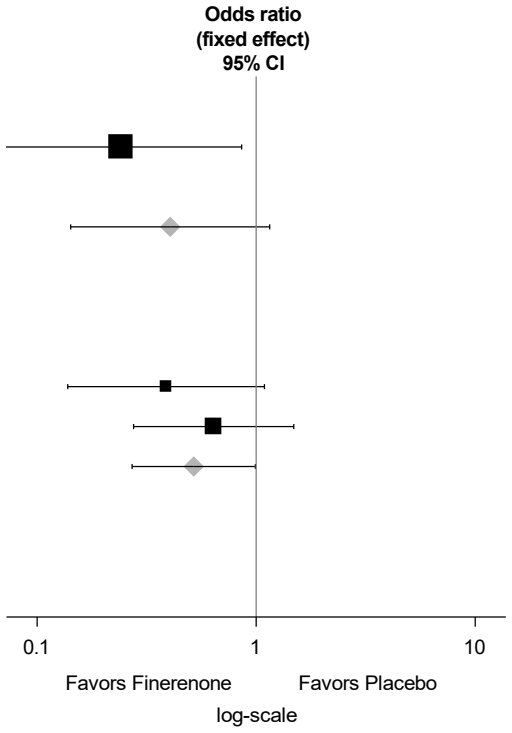
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	5 / 1797	18 / 1870	50.0	0.29 [0.11,0.77]	
FIGARO-DKD	7 / 917	9 / 933	50.0	0.79 [0.29,2.13]	
Total	12 / 2714	27 / 2803		0.46 [0.23,0.90]	Z=-2.26, p=0.0240
Heterogeneity:	Q=2.01 (df=1)	p=0.1560	I^2=50.3%		
Female					
FIDELIO-DKD	3 / 820	7 / 740	48.7	0.38 [0.10,1.49]	
FIGARO-DKD	4 / 440	5 / 423	51.3	0.77 [0.20,2.88]	
Total	7 / 1260	12 / 1163		0.54 [0.21,1.38]	Z=-1.29, p=0.1964
Heterogeneity:	Q=0.51 (df=1)	p=0.4744	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7749	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.16.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

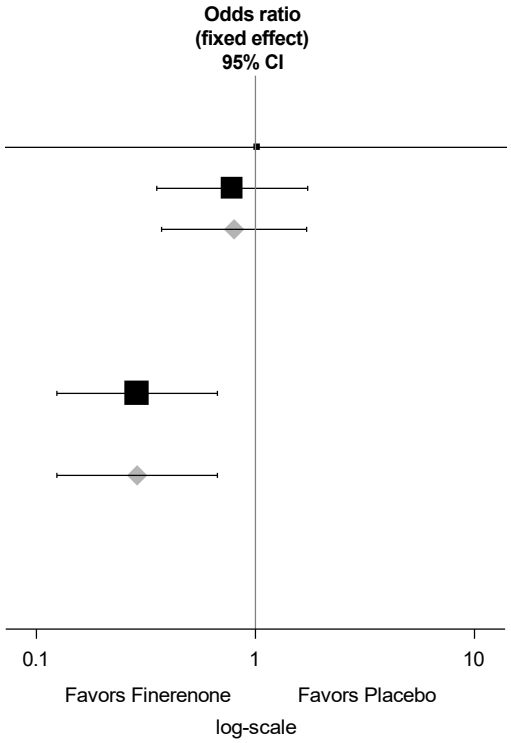
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 1103	12 / 1075	100.0	0.24 [0.07,0.86]	
FIGARO-DKD	2 / 336	0 / 335	0.0	922E8 [922E8,922E8]	
Total	5 / 1439	12 / 1410		0.40 [0.14,1.15]	Z=-1.69, p=0.0903
Heterogeneity:	Q=0.64 (df=1)	p=0.4246	I^2=0.0%		
>= 65					
FIDELIO-DKD	5 / 1514	13 / 1535	39.9	0.39 [0.14,1.09]	
FIGARO-DKD	9 / 1021	14 / 1021	60.1	0.64 [0.28,1.48]	
Total	14 / 2535	27 / 2556		0.52 [0.27,0.99]	Z=-1.99, p=0.0471
Heterogeneity:	Q=0.54 (df=1)	p=0.4618	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.16 (df=1)	p=0.6933	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.16.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

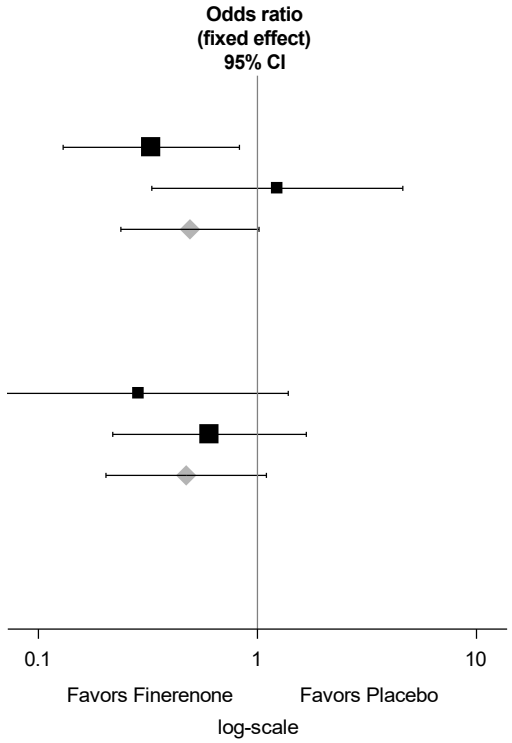
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	1 / 213	7.5	1.02 [0.06,16.40]	
FIGARO-DKD	11 / 1357	14 / 1356	92.5	0.78 [0.35,1.73]	
Total	12 / 1566	15 / 1569		0.80 [0.37,1.71]	Z=-0.58, p=0.5640
Heterogeneity:	Q=0.03 (df=1)	p=0.8583	I^2=0.0%		
Very High					
FIDELIO-DKD	7 / 2408	24 / 2397	100.0	0.29 [0.12,0.67]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	7 / 2408	24 / 2397		0.29 [0.12,0.67]	Z=-2.89, p=0.0039
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.09 (df=1)	p=0.0789	I^2=67.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.16.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac failure chronic (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

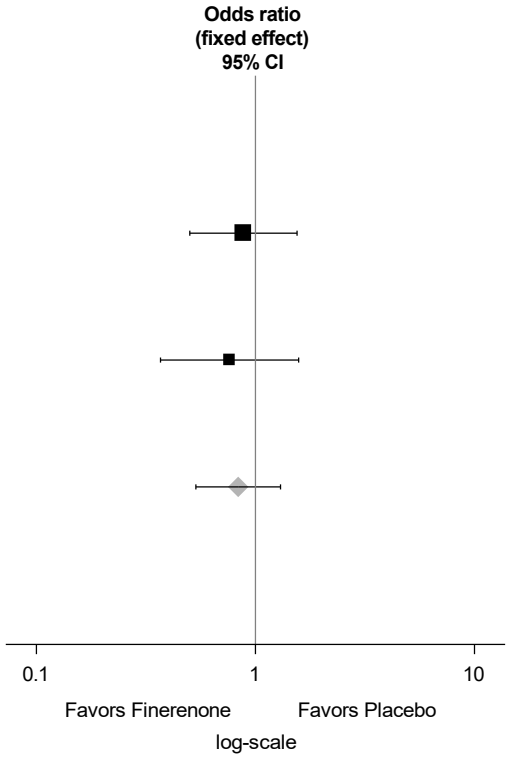
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	6 / 1556	18 / 1541	67.0	0.33 [0.13,0.83]	
FIGARO-DKD	5 / 637	4 / 627	33.0	1.23 [0.33,4.61]	
Total	11 / 2193	22 / 2168		0.49 [0.24,1.02]	Z=-1.92, p=0.0554
Heterogeneity:	Q=2.60 (df=1)	p=0.1068	I^2=61.5%		
45 - < 60					
FIDELIO-DKD	2 / 1061	7 / 1069	29.5	0.29 [0.06,1.38]	
FIGARO-DKD	6 / 720	10 / 729	70.5	0.60 [0.22,1.67]	
Total	8 / 1781	17 / 1798		0.47 [0.20,1.10]	Z=-1.74, p=0.0817
Heterogeneity:	Q=0.61 (df=1)	p=0.4339	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9444	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.17: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Coronary artery disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

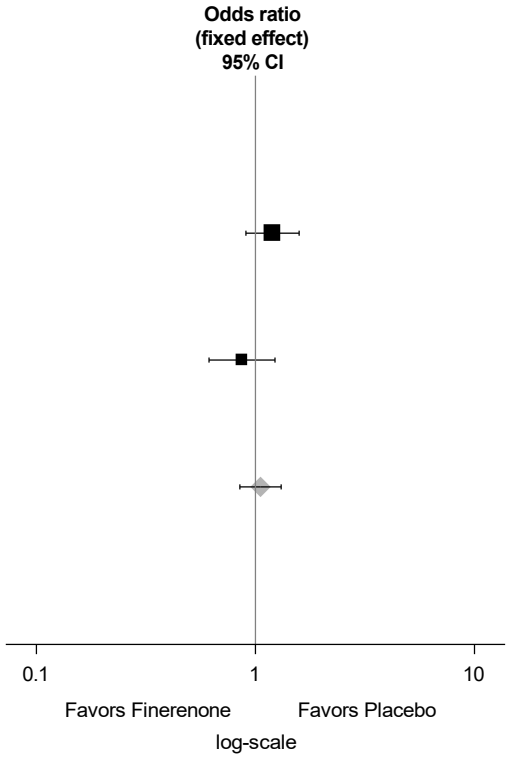
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	26 / 2610	62.4	0.88 [0.50,1.55]	
FIGARO-DKD	13 / 1357	17 / 1356	37.6	0.76 [0.37,1.57]	
Total	36 / 3974	43 / 3966		0.83 [0.53,1.30]	Z=-0.80, p=0.4242
Heterogeneity:	Q=0.10 (df=1)	p=0.7563	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.18: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ear And Labyrinth Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

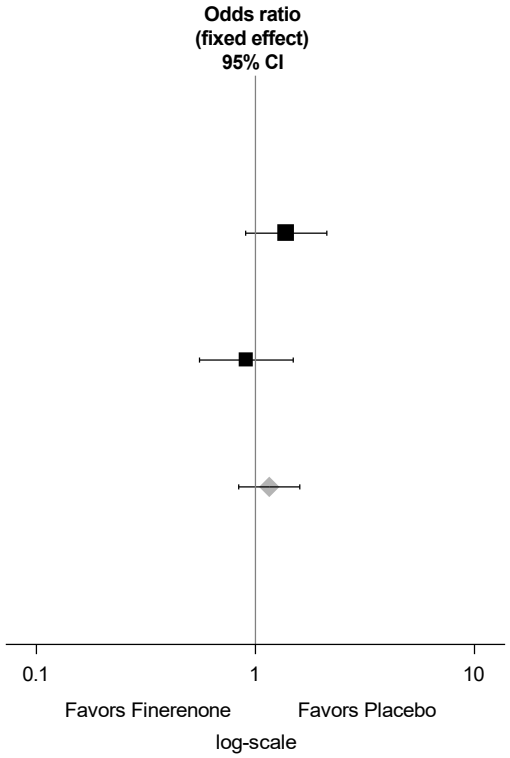
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	112 / 2617	94 / 2610	60.6	1.20 [0.90,1.58]	
FIGARO-DKD	63 / 1357	72 / 1356	39.4	0.87 [0.61,1.23]	
Total	175 / 3974	166 / 3966		1.05 [0.85,1.31]	Z=0.48, p=0.6310
Heterogeneity:	Q=1.99 (df=1)	p=0.1581	I^2=49.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.19: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vertigo (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

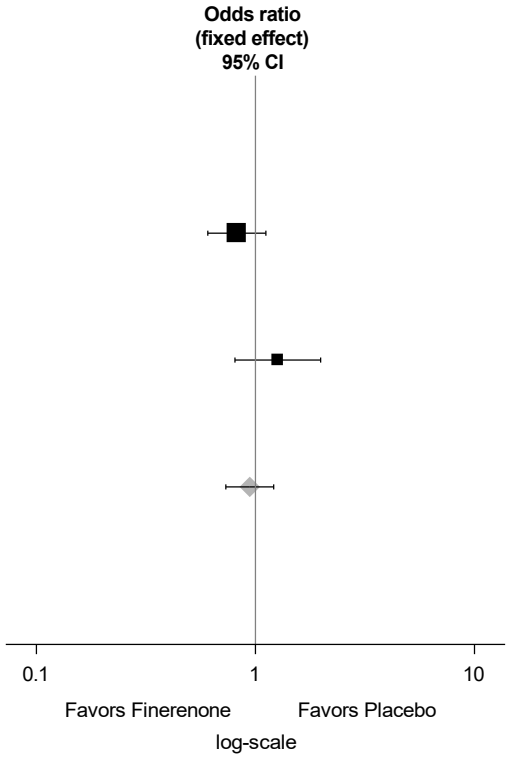
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2617	37 / 2610	57.1	1.38 [0.90,2.12]	
FIGARO-DKD	31 / 1357	34 / 1356	42.9	0.91 [0.56,1.49]	
Total	82 / 3974	71 / 3966		1.16 [0.84,1.59]	Z=0.89, p=0.3756
Heterogeneity:	Q=1.59 (df=1)	p=0.2077	I^2=37.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.20: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Endocrine Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

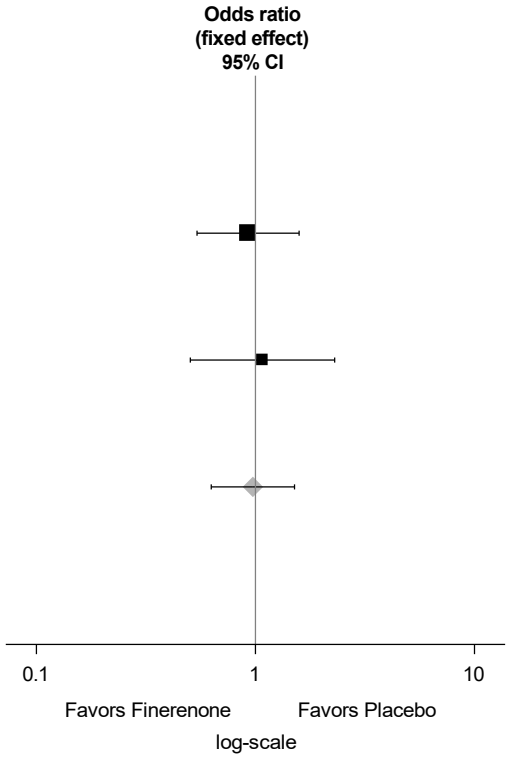
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	78 / 2617	94 / 2610	68.5	0.82 [0.61,1.12]	
FIGARO-DKD	44 / 1357	35 / 1356	31.5	1.26 [0.81,1.98]	
Total	122 / 3974	129 / 3966		0.94 [0.73,1.21]	Z=-0.47, p=0.6415
Heterogeneity:	Q=2.41 (df=1)	p=0.1209	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.21: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypothyroidism (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

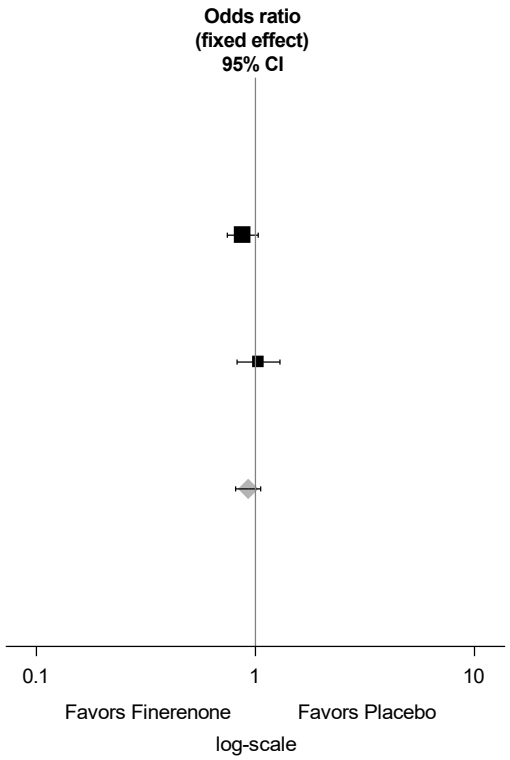
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	28 / 2610	66.7	0.93 [0.54,1.58]	
FIGARO-DKD	14 / 1357	13 / 1356	33.3	1.08 [0.50,2.30]	
Total	40 / 3974	41 / 3966		0.97 [0.63,1.51]	Z=-0.12, p=0.9038
Heterogeneity:	Q=0.10 (df=1)	p=0.7490	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.22: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

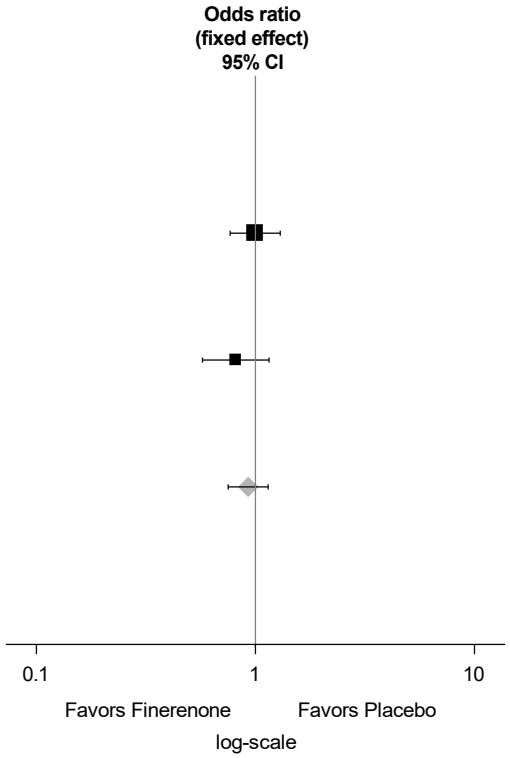
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	316 / 2617	354 / 2610	65.8	0.88 [0.74,1.03]	
FIGARO-DKD	176 / 1357	171 / 1356	34.2	1.03 [0.82,1.29]	
Total	492 / 3974	525 / 3966		0.93 [0.81,1.06]	Z=-1.14, p=0.2533
Heterogeneity:	Q=1.36 (df=1)	p=0.2429	I^2=26.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.23: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

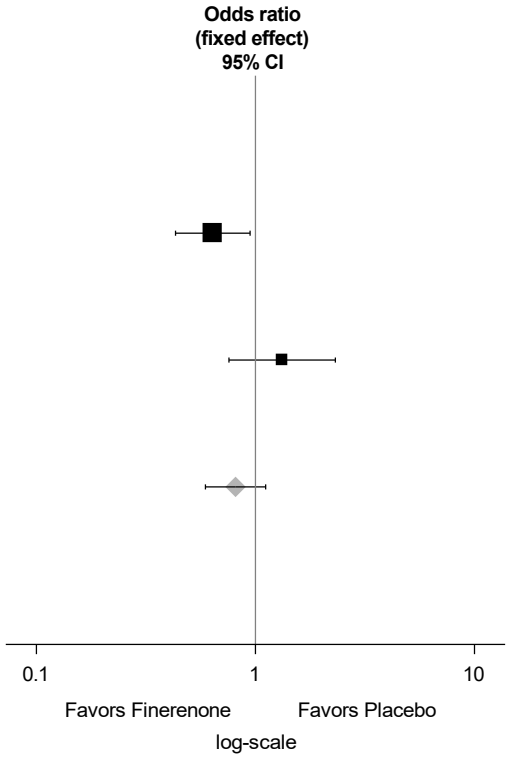
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	116 / 2617	116 / 2610	63.9	1.00 [0.77,1.30]	
FIGARO-DKD	60 / 1357	73 / 1356	36.1	0.81 [0.57,1.15]	
Total	176 / 3974	189 / 3966		0.93 [0.75,1.14]	Z=-0.72, p=0.4741
Heterogeneity:	Q=0.83 (df=1)	p=0.3610	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.24: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic retinopathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

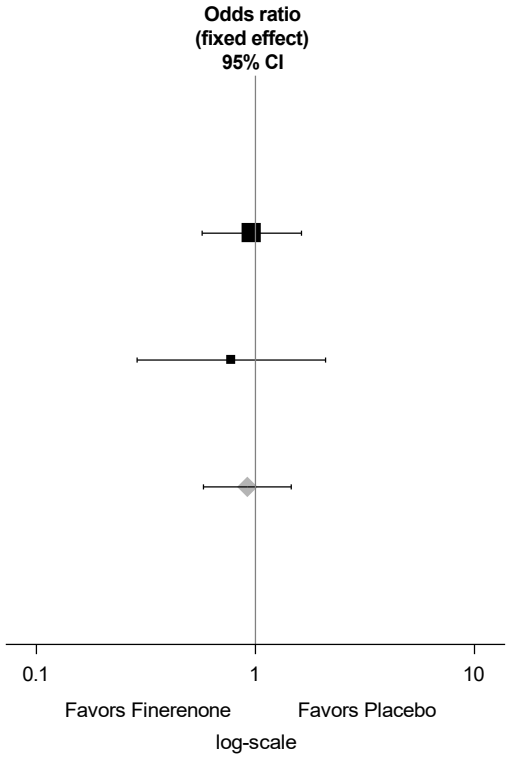
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2617	65 / 2610	67.1	0.64 [0.43,0.95]	
FIGARO-DKD	29 / 1357	22 / 1356	32.9	1.32 [0.76,2.32]	
Total	71 / 3974	87 / 3966		0.81 [0.59,1.11]	Z=-1.30, p=0.1948
Heterogeneity:	Q=4.38 (df=1)	p=0.0364	I^2=77.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.25: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitreous haemorrhage (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

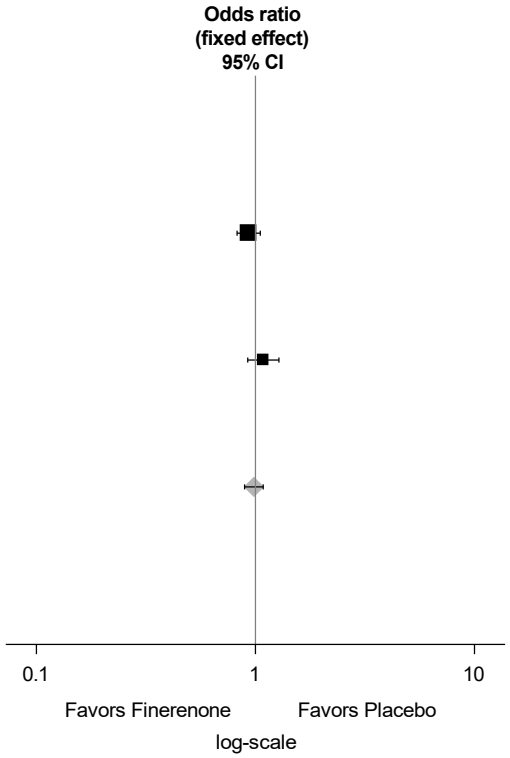
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	29 / 2610	78.3	0.96 [0.57,1.62]	
FIGARO-DKD	7 / 1357	9 / 1356	21.7	0.78 [0.29,2.09]	
Total	35 / 3974	38 / 3966		0.92 [0.58,1.46]	Z=-0.36, p=0.7170
Heterogeneity:	Q=0.14 (df=1)	p=0.7062	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.26: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

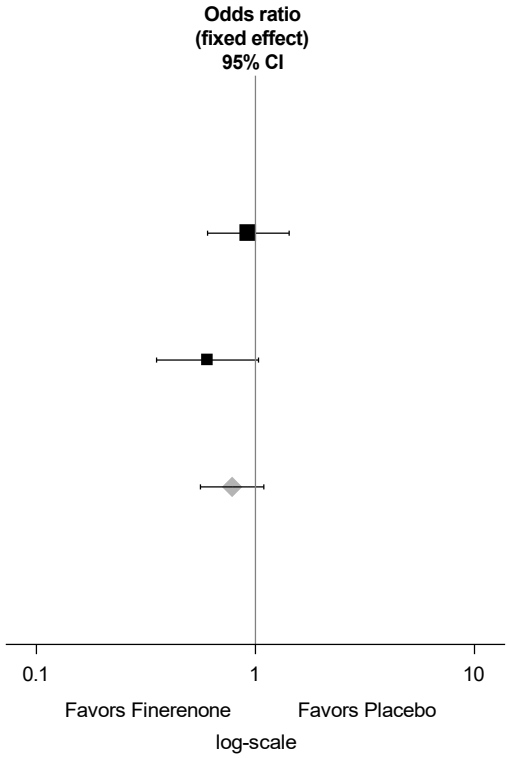
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	693 / 2617	728 / 2610	64.4	0.93 [0.82,1.05]	
FIGARO-DKD	423 / 1357	399 / 1356	35.6	1.09 [0.92,1.28]	
Total	1116 / 3974	1127 / 3966		0.98 [0.89,1.08]	Z=-0.33, p=0.7419
Heterogeneity:	Q=2.19 (df=1)	p=0.1391	I^2=54.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.27: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

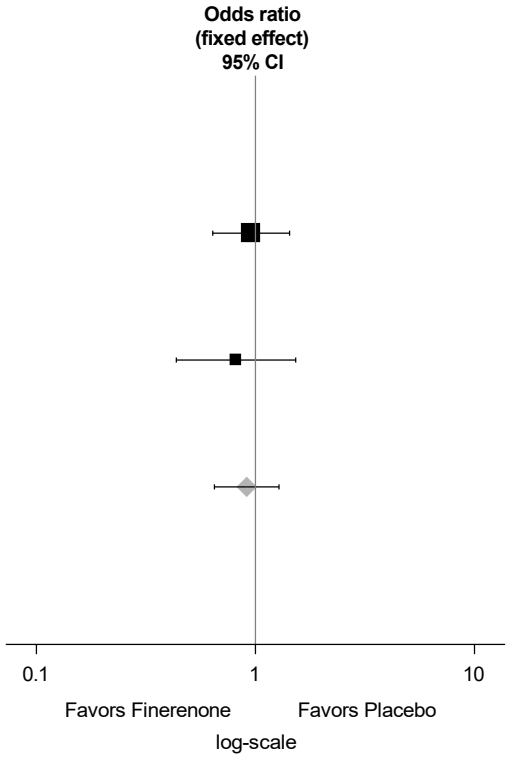
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2617	44 / 2610	60.9	0.93 [0.60,1.43]	
FIGARO-DKD	22 / 1357	36 / 1356	39.1	0.60 [0.35,1.03]	
Total	63 / 3974	80 / 3966		0.78 [0.56,1.09]	Z=-1.44, p=0.1491
Heterogeneity:	Q=1.50 (df=1)	p=0.2202	I^2=33.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.28: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Abdominal pain upper (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

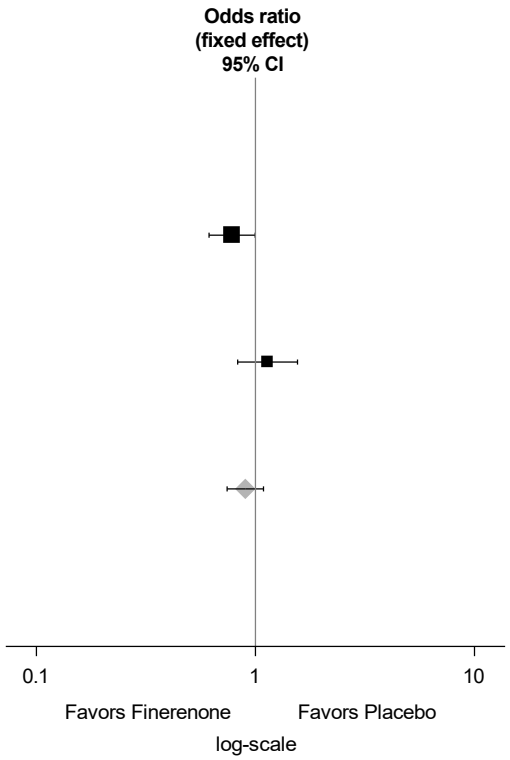
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2617	49 / 2610	70.7	0.96 [0.64,1.43]	
FIGARO-DKD	18 / 1357	22 / 1356	29.3	0.82 [0.44,1.53]	
Total	65 / 3974	71 / 3966		0.91 [0.65,1.28]	Z=-0.53, p=0.5953
Heterogeneity:	Q=0.17 (df=1)	p=0.6758	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.29: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Constipation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

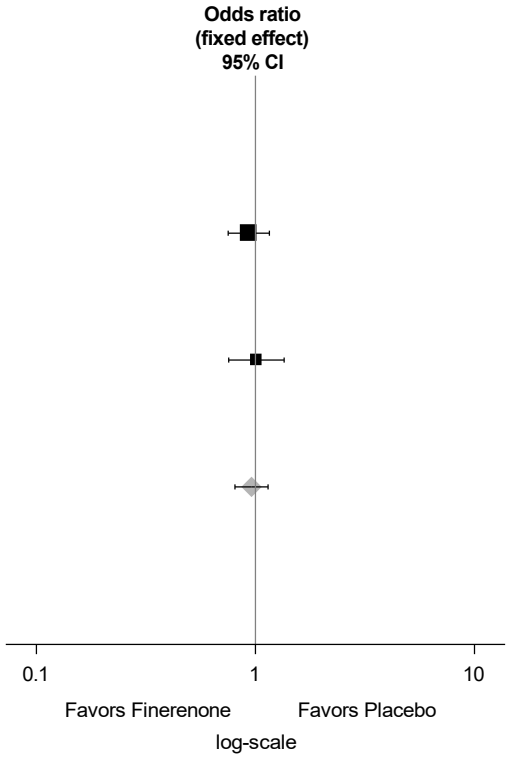
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	124 / 2617	156 / 2610	62.8	0.78 [0.61,1.00]	
FIGARO-DKD	88 / 1357	78 / 1356	37.2	1.14 [0.83,1.56]	
Total	212 / 3974	234 / 3966		0.90 [0.74,1.09]	Z=-1.09, p=0.2743
Heterogeneity:	Q=3.39 (df=1)	p=0.0656	I^2=70.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.30: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diarrhoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

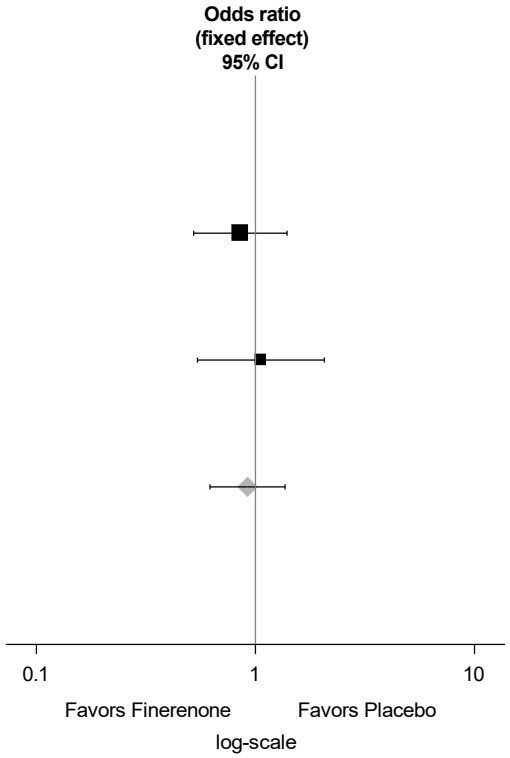
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	170 / 2617	181 / 2610	64.4	0.93 [0.75,1.16]	
FIGARO-DKD	98 / 1357	97 / 1356	35.6	1.01 [0.75,1.35]	
Total	268 / 3974	278 / 3966		0.96 [0.81,1.14]	Z=-0.47, p=0.6401
Heterogeneity:	Q=0.19 (df=1)	p=0.6646	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.31: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspepsia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

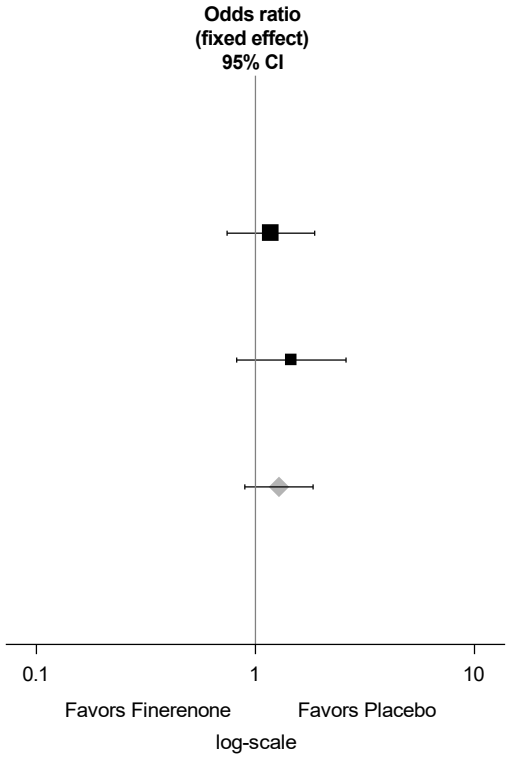
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	35 / 2610	64.9	0.85 [0.52,1.39]	
FIGARO-DKD	18 / 1357	17 / 1356	35.1	1.06 [0.54,2.06]	
Total	48 / 3974	52 / 3966		0.92 [0.62,1.37]	Z=-0.41, p=0.6800
Heterogeneity:	Q=0.26 (df=1)	p=0.6093	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.32: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

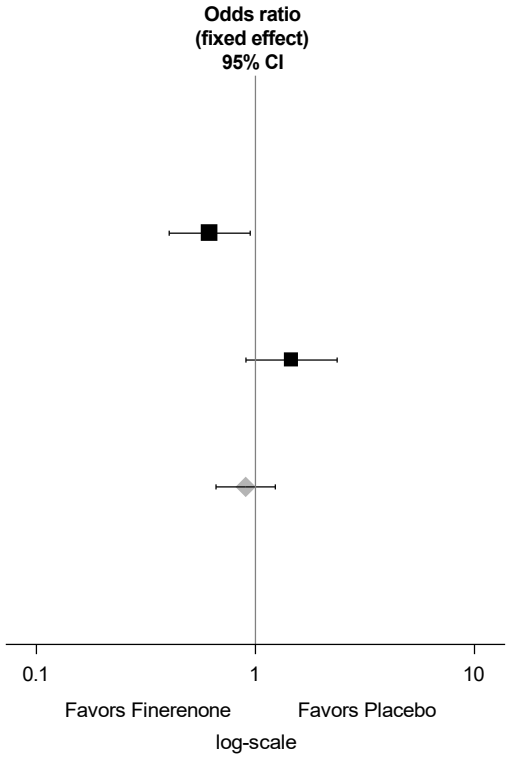
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2617	34 / 2610	60.9	1.18 [0.74,1.86]	
FIGARO-DKD	29 / 1357	20 / 1356	39.1	1.46 [0.82,2.59]	
Total	69 / 3974	54 / 3966		1.28 [0.89,1.83]	Z=1.35, p=0.1772
Heterogeneity:	Q=0.33 (df=1)	p=0.5664	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.33: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastrooesophageal reflux disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

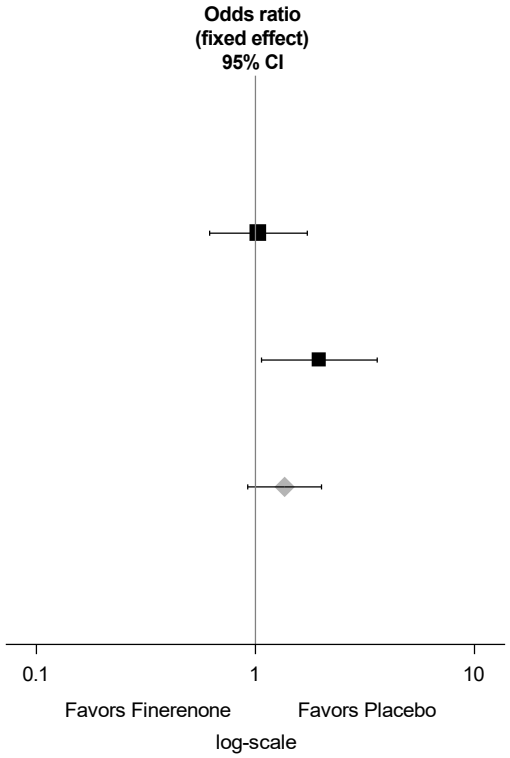
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	56 / 2610	55.9	0.62 [0.40,0.95]	
FIGARO-DKD	42 / 1357	29 / 1356	44.1	1.46 [0.90,2.36]	
Total	77 / 3974	85 / 3966		0.90 [0.66,1.23]	Z=-0.65, p=0.5178
Heterogeneity:	Q=6.92 (df=1)	p=0.0085	I^2=85.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.34: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haemorrhoids (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

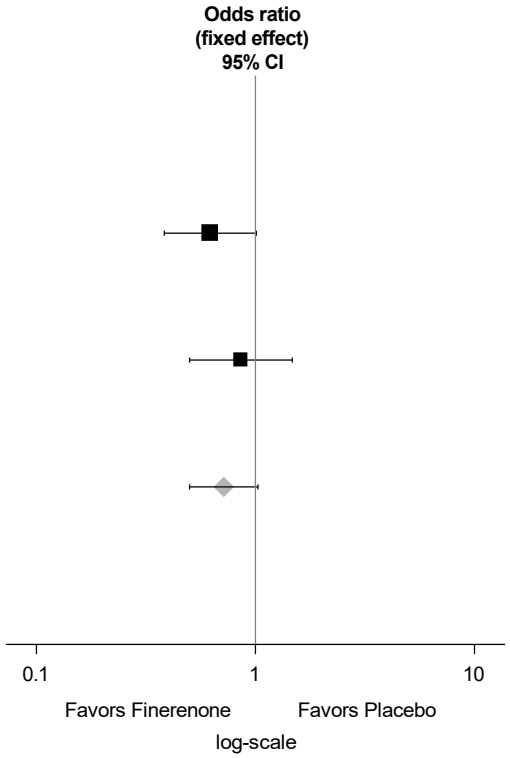
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	29 / 2610	58.4	1.03 [0.62,1.72]	
FIGARO-DKD	31 / 1357	16 / 1356	41.6	1.96 [1.07,3.60]	
Total	61 / 3974	45 / 3966		1.36 [0.92,2.00]	Z=1.55, p=0.1212
Heterogeneity:	Q=2.49 (df=1)	p=0.1146	I^2=59.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.35: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Large intestine polyp (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

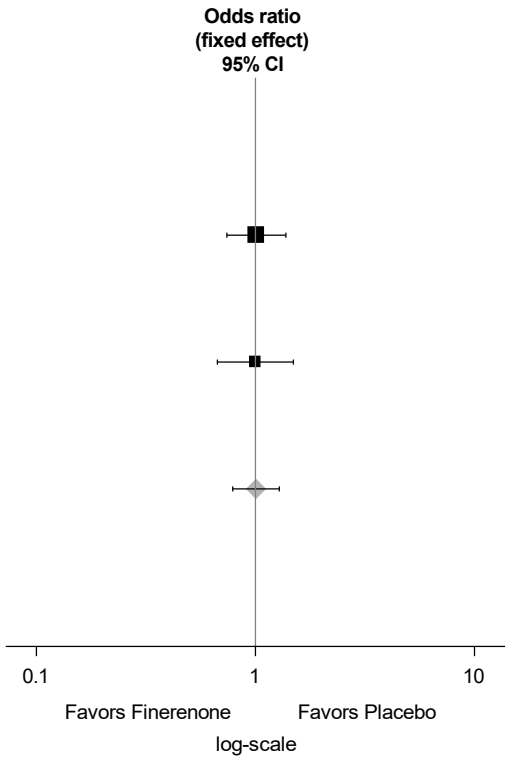
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	43 / 2610	55.4	0.62 [0.38,1.01]	
FIGARO-DKD	25 / 1357	29 / 1356	44.6	0.86 [0.50,1.47]	
Total	52 / 3974	72 / 3966		0.72 [0.50,1.03]	Z=-1.81, p=0.0698
Heterogeneity:	Q=0.76 (df=1)	p=0.3842	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.36: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nausea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

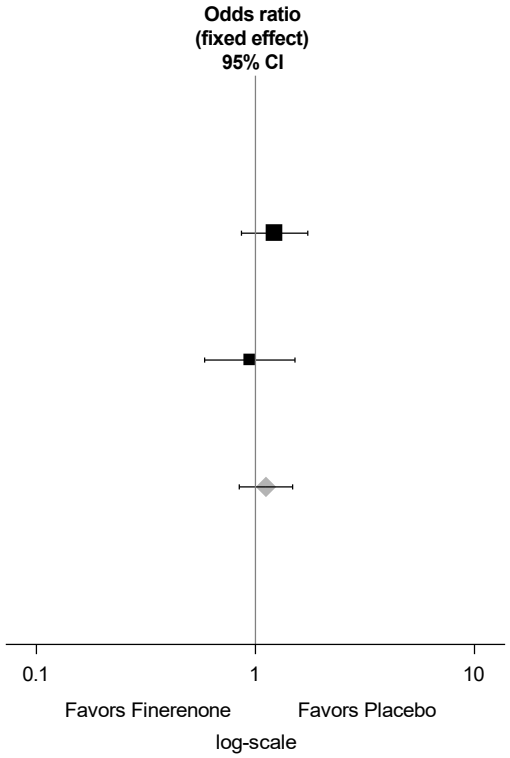
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	83 / 2617	82 / 2610	62.4	1.01 [0.74,1.38]	
FIGARO-DKD	50 / 1357	50 / 1356	37.6	1.00 [0.67,1.49]	
Total	133 / 3974	132 / 3966		1.01 [0.79,1.28]	Z=0.05, p=0.9630
Heterogeneity:	Q=0.00 (df=1)	p=0.9675	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.37: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vomiting (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

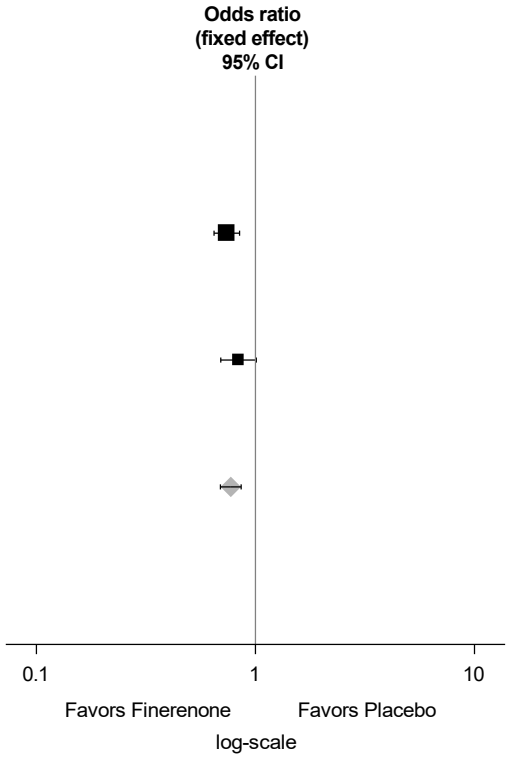
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	72 / 2617	59 / 2610	65.0	1.22 [0.86,1.73]	
FIGARO-DKD	34 / 1357	36 / 1356	35.0	0.94 [0.59,1.52]	
Total	106 / 3974	95 / 3966		1.12 [0.84,1.48]	Z=0.77, p=0.4406
Heterogeneity:	Q=0.75 (df=1)	p=0.3853	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.38: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

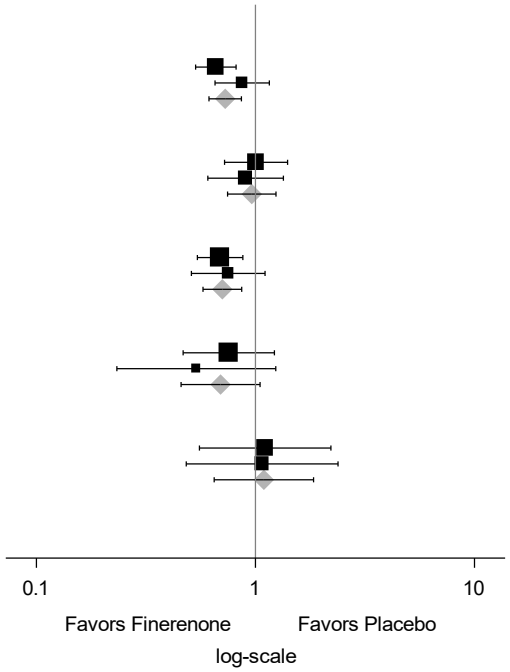
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	481 / 2617	609 / 2610	66.0	0.74 [0.65,0.85]	
FIGARO-DKD	258 / 1357	297 / 1356	34.0	0.84 [0.69,1.01]	
Total	739 / 3974	906 / 3966		0.77 [0.69,0.86]	Z=-4.66, p=<.0001
Heterogeneity:	Q=1.10 (df=1)	p=0.2933	I^2=9.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.38.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

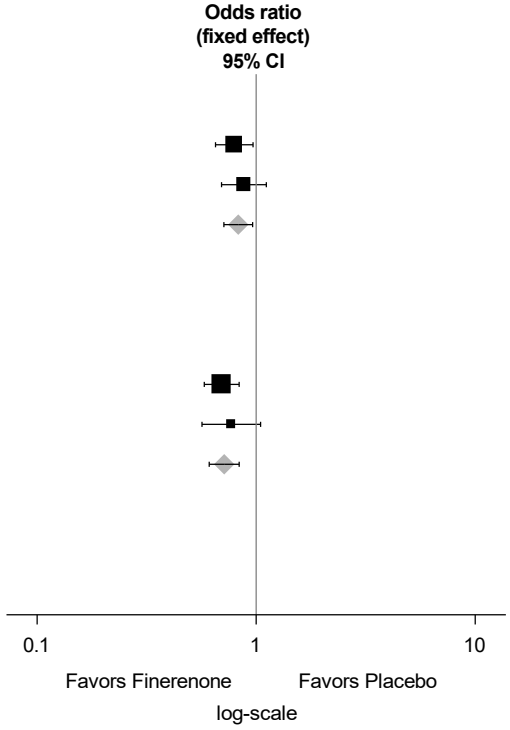
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	183 / 1075	252 / 1062	64.3	0.66 [0.53,0.82]	
FIGARO-DKD	109 / 638	122 / 637	35.7	0.87 [0.65,1.16]	
Total	292 / 1713	374 / 1699		0.73 [0.61,0.86]	Z=-3.66, p=0.0003
Heterogeneity:	Q=2.32 (df=1)	p=0.1274	I^2=57.0%		
North America					
FIDELIO-DKD	87 / 424	89 / 436	59.0	1.01 [0.72,1.40]	
FIGARO-DKD	61 / 267	67 / 271	41.0	0.90 [0.61,1.34]	
Total	148 / 691	156 / 707		0.96 [0.75,1.24]	Z=-0.30, p=0.7657
Heterogeneity:	Q=0.17 (df=1)	p=0.6766	I^2=0.0%		
Asia					
FIDELIO-DKD	155 / 751	204 / 745	72.4	0.69 [0.54,0.88]	
FIGARO-DKD	60 / 289	75 / 290	27.6	0.75 [0.51,1.11]	
Total	215 / 1040	279 / 1035		0.71 [0.58,0.87]	Z=-3.35, p=0.0008
Heterogeneity:	Q=0.13 (df=1)	p=0.7133	I^2=0.0%		
Latin America					
FIDELIO-DKD	35 / 273	44 / 270	75.2	0.76 [0.47,1.22]	
FIGARO-DKD	10 / 102	17 / 101	24.8	0.54 [0.23,1.24]	
Total	45 / 375	61 / 371		0.69 [0.46,1.05]	Z=-1.73, p=0.0833
Heterogeneity:	Q=0.48 (df=1)	p=0.4877	I^2=0.0%		
Others					
FIDELIO-DKD	21 / 94	20 / 97	57.1	1.11 [0.55,2.21]	
FIGARO-DKD	18 / 61	16 / 57	42.9	1.07 [0.48,2.38]	
Total	39 / 155	36 / 154		1.09 [0.65,1.84]	Z=0.33, p=0.7400
Heterogeneity:	Q=0.00 (df=1)	p=0.9526	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.04 (df=4)	p=0.1965	I^2=33.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.38.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

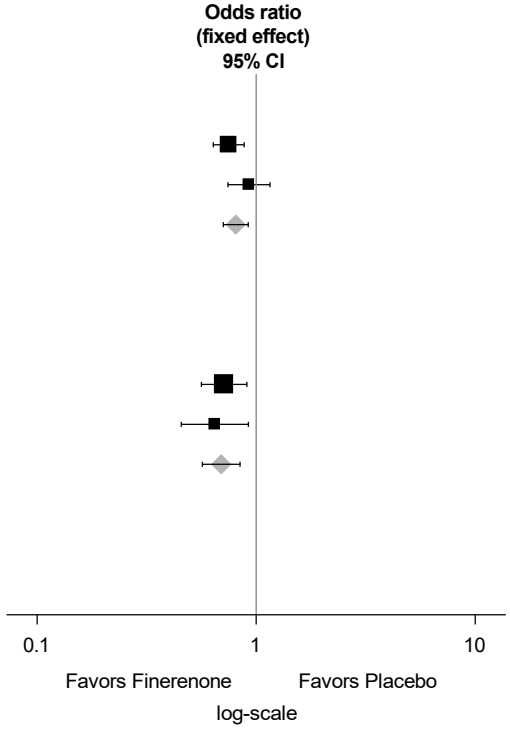
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	228 / 1213	273 / 1210	58.7	0.79 [0.65,0.97]	
FIGARO-DKD	167 / 862	182 / 848	41.3	0.88 [0.69,1.11]	
Total	395 / 2075	455 / 2058		0.83 [0.71,0.96]	Z=-2.44, p=0.0146
Heterogeneity:	Q=0.42 (df=1)	p=0.5174	I^2=0.0%		
Absent					
FIDELIO-DKD	253 / 1404	336 / 1400	73.9	0.70 [0.58,0.84]	
FIGARO-DKD	91 / 495	115 / 508	26.1	0.77 [0.57,1.05]	
Total	344 / 1899	451 / 1908		0.71 [0.61,0.84]	Z=-4.18, p=<.0001
Heterogeneity:	Q=0.30 (df=1)	p=0.5821	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.76 (df=1)	p=0.1844	I^2=43.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.38.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

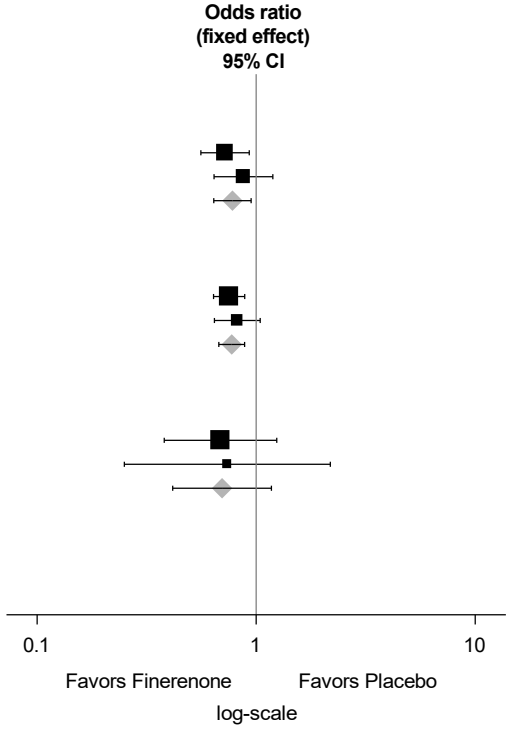
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	338 / 1735	415 / 1700	65.0	0.75 [0.64,0.88]	
FIGARO-DKD	194 / 924	207 / 929	35.0	0.93 [0.74,1.16]	
Total	532 / 2659	622 / 2629		0.81 [0.71,0.92]	Z=-3.21, p=0.0013
Heterogeneity:	Q=2.31 (df=1)	p=0.1283	I^2=56.8%		
> 4.5					
FIDELIO-DKD	143 / 882	194 / 910	68.5	0.71 [0.56,0.91]	
FIGARO-DKD	64 / 433	90 / 426	31.5	0.65 [0.45,0.92]	
Total	207 / 1315	284 / 1336		0.69 [0.57,0.84]	Z=-3.64, p=0.0003
Heterogeneity:	Q=0.20 (df=1)	p=0.6524	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2061	I^2=37.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.38.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

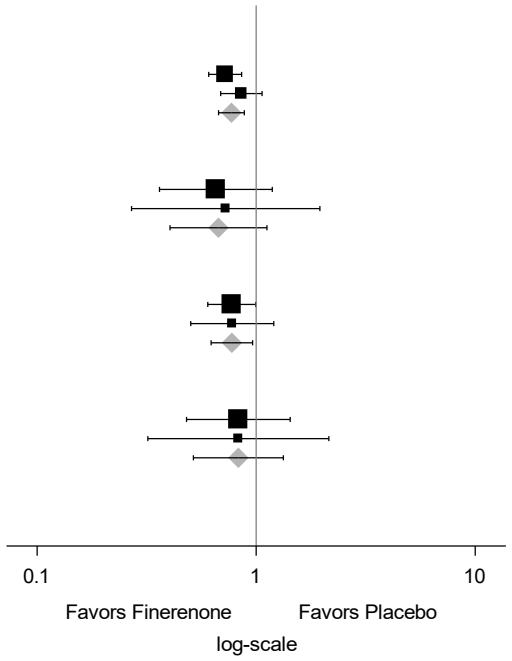
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	133 / 724	172 / 723	59.6	0.72 [0.56,0.93]	
FIGARO-DKD	96 / 494	107 / 495	40.4	0.87 [0.64,1.19]	
Total	229 / 1218	279 / 1218		0.78 [0.64,0.95]	Z=-2.49, p=0.0128
Heterogeneity:	Q=0.90 (df=1)	p=0.3438	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	323 / 1759	405 / 1760	68.3	0.75 [0.64,0.89]	
FIGARO-DKD	154 / 829	180 / 827	31.7	0.82 [0.64,1.04]	
Total	477 / 2588	585 / 2587		0.77 [0.68,0.89]	Z=-3.72, p=0.0002
Heterogeneity:	Q=0.33 (df=1)	p=0.5631	I^2=0.0%		
>= 160					
FIDELIO-DKD	25 / 133	32 / 127	77.0	0.69 [0.38,1.24]	
FIGARO-DKD	8 / 34	10 / 34	23.0	0.74 [0.25,2.18]	
Total	33 / 167	42 / 161		0.70 [0.42,1.17]	Z=-1.35, p=0.1756
Heterogeneity:	Q=0.01 (df=1)	p=0.9090	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=2)	p=0.9271	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.38.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

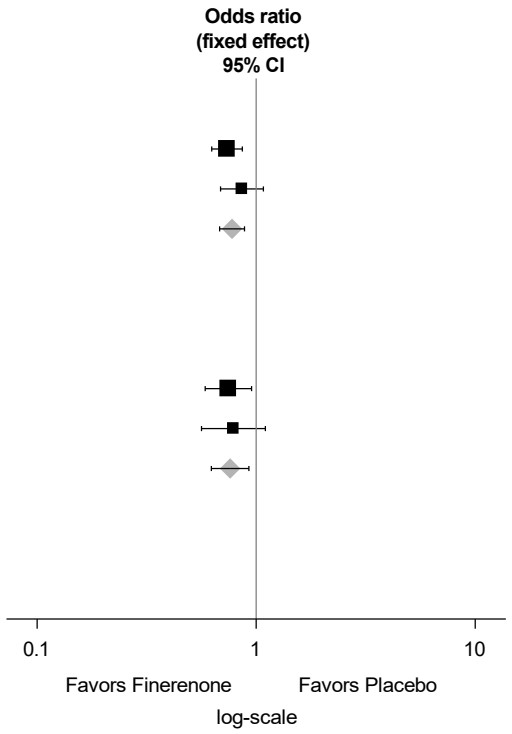
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	280 / 1634	369 / 1657	61.2	0.72 [0.61,0.86]	
FIGARO-DKD	194 / 1010	215 / 989	38.8	0.86 [0.69,1.06]	
Total	474 / 2644	584 / 2646		0.77 [0.67,0.88]	Z=-3.77, p=0.0002
Heterogeneity:	Q=1.44 (df=1)	p=0.2297	I^2=30.7%		
Black					
FIDELIO-DKD	26 / 129	32 / 115	73.6	0.65 [0.36,1.18]	
FIGARO-DKD	7 / 43	15 / 71	26.4	0.73 [0.27,1.95]	
Total	33 / 172	47 / 186		0.67 [0.40,1.12]	Z=-1.53, p=0.1272
Heterogeneity:	Q=0.03 (df=1)	p=0.8608	I^2=0.0%		
Asian					
FIDELIO-DKD	144 / 678	175 / 677	75.0	0.77 [0.60,1.00]	
FIGARO-DKD	46 / 252	56 / 251	25.0	0.78 [0.50,1.20]	
Total	190 / 930	231 / 928		0.77 [0.62,0.96]	Z=-2.29, p=0.0217
Heterogeneity:	Q=0.00 (df=1)	p=0.9839	I^2=0.0%		
Others					
FIDELIO-DKD	31 / 176	33 / 161	75.3	0.83 [0.48,1.43]	
FIGARO-DKD	11 / 52	11 / 45	24.7	0.83 [0.32,2.15]	
Total	42 / 228	44 / 206		0.83 [0.52,1.33]	Z=-0.78, p=0.4377
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.37 (df=3)	p=0.9468	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.38.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	327 / 1797	434 / 1870	66.2	0.74 [0.63,0.86]	
FIGARO-DKD	179 / 917	205 / 933	33.8	0.86 [0.69,1.08]	
Total	506 / 2714	639 / 2803		0.78 [0.68,0.88]	Z=-3.80, p=0.0001
Heterogeneity:	Q=1.24 (df=1)	p=0.2655	I^2=19.4%		
Female					
FIDELIO-DKD	154 / 820	175 / 740	65.4	0.75 [0.58,0.95]	
FIGARO-DKD	79 / 440	92 / 423	34.6	0.79 [0.56,1.10]	
Total	233 / 1260	267 / 1163		0.76 [0.62,0.93]	Z=-2.72, p=0.0065
Heterogeneity:	Q=0.06 (df=1)	p=0.8016	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8657	I^2=0.0%		

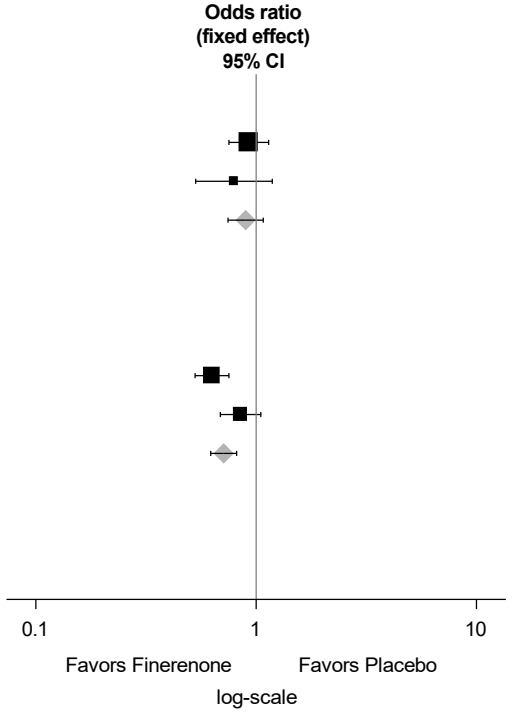


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.38.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	221 / 1103	229 / 1075	78.8	0.93 [0.75,1.14]	
FIGARO-DKD	53 / 336	64 / 335	21.2	0.79 [0.53,1.18]	
Total	274 / 1439	293 / 1410		0.90 [0.75,1.08]	Z=-1.17, p=0.2413
Heterogeneity:	Q=0.45 (df=1)	p=0.5013	I^2=0.0%		
>= 65					
FIDELIO-DKD	260 / 1514	380 / 1535	58.9	0.63 [0.53,0.75]	
FIGARO-DKD	205 / 1021	233 / 1021	41.1	0.85 [0.69,1.05]	
Total	465 / 2535	613 / 2556		0.71 [0.62,0.82]	Z=-4.91, p=<.0001
Heterogeneity:	Q=4.51 (df=1)	p=0.0337	I^2=77.8%		
Subgroup Heterogeneity:	Q=3.88 (df=1)	p=0.0490	I^2=74.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.

Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.

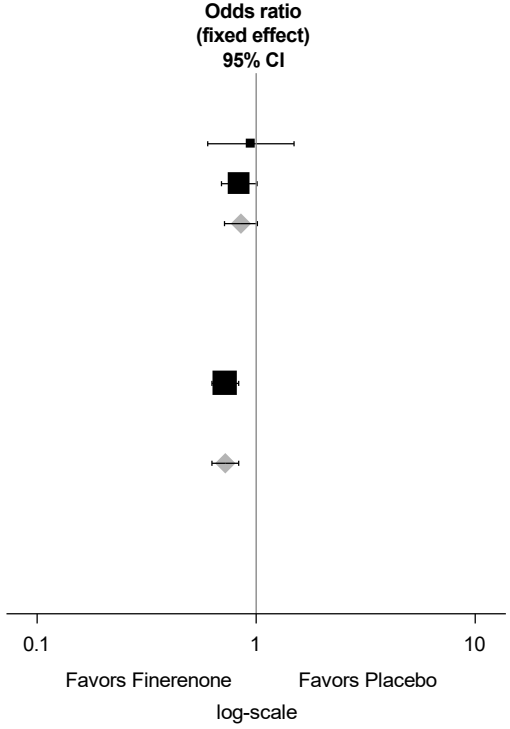
For 'Total' the same model as for single studies including study as additional factor was applied.

The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Category 'Missing' was excluded from meta-analysis.

Figure A2.2.38.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

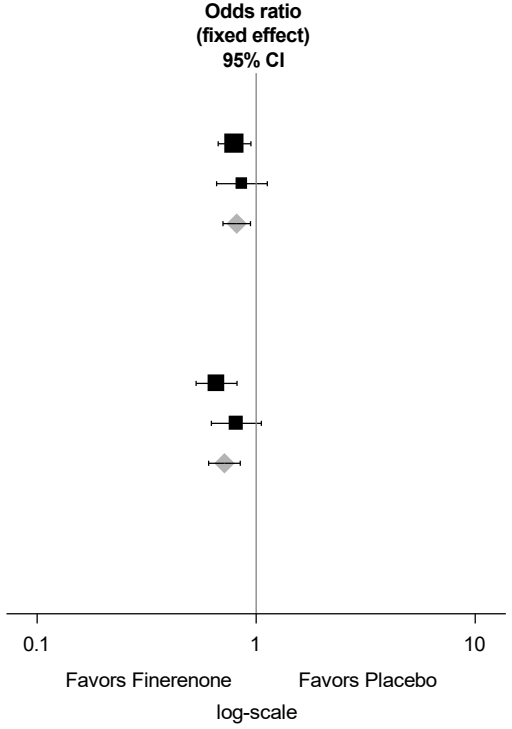
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	47 / 209	50 / 213	14.5	0.95 [0.60,1.49]	
FIGARO-DKD	258 / 1357	297 / 1356	85.5	0.84 [0.69,1.01]	
Total	305 / 1566	347 / 1569		0.85 [0.72,1.01]	Z=-1.82, p=0.0693
Heterogeneity:	Q=0.24 (df=1)	p=0.6257	I^2=0.0%		
Very High					
FIDELIO-DKD	434 / 2408	559 / 2397	100.0	0.72 [0.63,0.83]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	434 / 2408	559 / 2397		0.72 [0.63,0.83]	Z=-4.52, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.09 (df=1)	p=0.1482	I^2=52.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.38.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

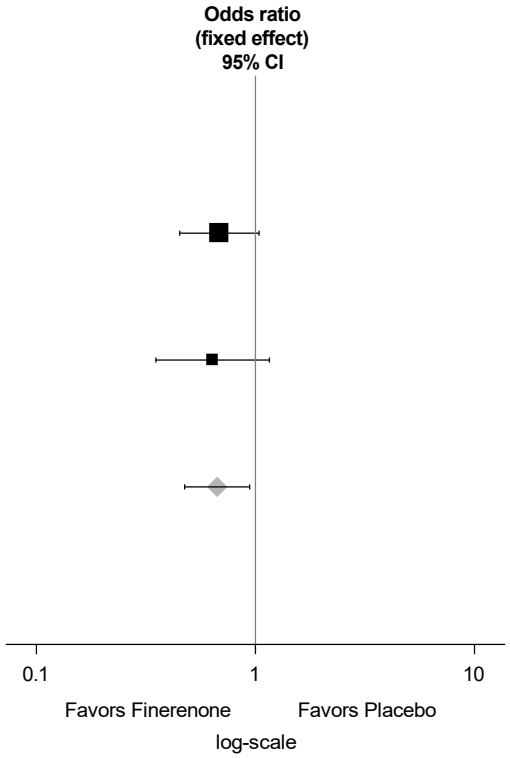
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	304 / 1556	360 / 1541	70.6	0.80 [0.67,0.95]	
FIGARO-DKD	132 / 637	146 / 627	29.4	0.86 [0.66,1.12]	
Total	436 / 2193	506 / 2168		0.82 [0.71,0.94]	Z=-2.77, p=0.0056
Heterogeneity:	Q=0.23 (df=1)	p=0.6300	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	177 / 1061	249 / 1069	59.9	0.66 [0.53,0.82]	
FIGARO-DKD	126 / 720	151 / 729	40.1	0.81 [0.62,1.06]	
Total	303 / 1781	400 / 1798		0.72 [0.61,0.85]	Z=-3.93, p=<.0001
Heterogeneity:	Q=1.44 (df=1)	p=0.2294	I^2=30.8%		
Subgroup Heterogeneity:	Q=1.32 (df=1)	p=0.2513	I^2=24.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

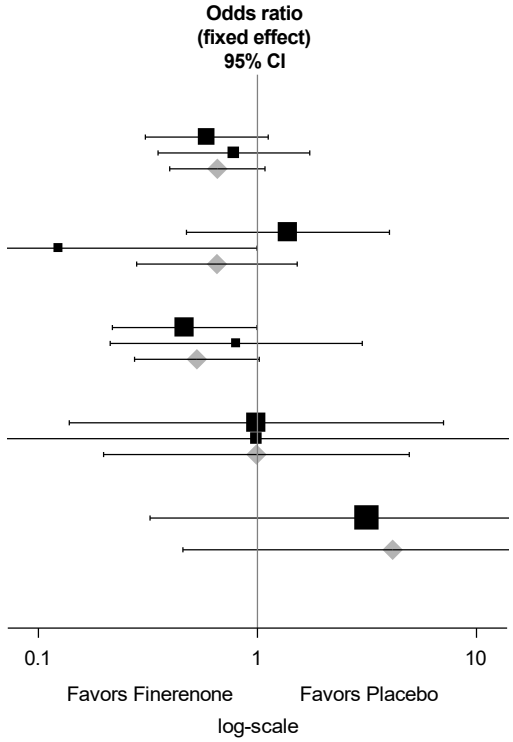
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	55 / 2610	67.2	0.68 [0.45,1.04]	
FIGARO-DKD	18 / 1357	28 / 1356	32.8	0.64 [0.35,1.16]	
Total	56 / 3974	83 / 3966		0.67 [0.48,0.94]	Z=-2.31, p=0.0210
Heterogeneity:	Q=0.04 (df=1)	p=0.8485	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.39.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

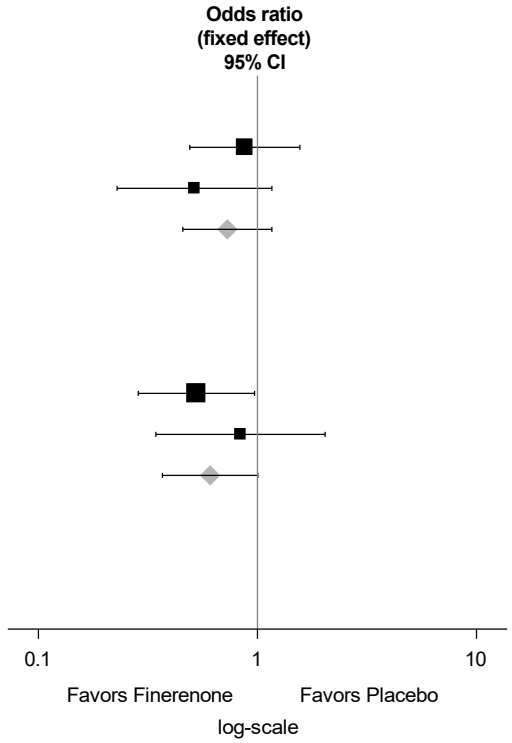
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	25 / 1062	60.4	0.59 [0.31,1.12]	
FIGARO-DKD	11 / 638	14 / 637	39.6	0.78 [0.35,1.73]	
Total	26 / 1713	39 / 1699		0.66 [0.40,1.08]	Z=-1.65, p=0.0991
Heterogeneity:	Q=0.30 (df=1)	p=0.5859	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	6 / 436	79.3	1.38 [0.47,4.01]	
FIGARO-DKD	1 / 267	8 / 271	20.7	0.12 [0.02,1.00]	
Total	9 / 691	14 / 707		0.65 [0.28,1.52]	Z=-0.99, p=0.3226
Heterogeneity:	Q=4.33 (df=1)	p=0.0375	I^2=76.9%		
Asia					
FIDELIO-DKD	10 / 751	21 / 745	75.2	0.47 [0.22,0.99]	
FIGARO-DKD	4 / 289	5 / 290	24.8	0.80 [0.21,3.01]	
Total	14 / 1040	26 / 1035		0.53 [0.27,1.02]	Z=-1.90, p=0.0570
Heterogeneity:	Q=0.48 (df=1)	p=0.4866	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	2 / 270	66.7	0.99 [0.14,7.07]	
FIGARO-DKD	1 / 102	1 / 101	33.3	0.99 [0.06,16.05]	
Total	3 / 375	3 / 371		0.99 [0.20,4.93]	Z=-0.01, p=0.9895
Heterogeneity:	Q=0.00 (df=1)	p=0.9995	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 94	1 / 97	100.0	3.16 [0.32,30.98]	
FIGARO-DKD	1 / 61	0 / 57	0.0	944E8 [944E8,944E8]	
Total	4 / 155	1 / 154		4.14 [0.46,37.58]	Z=1.26, p=0.2064
Heterogeneity:	Q=0.05 (df=1)	p=0.8170	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.35 (df=4)	p=0.5015	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

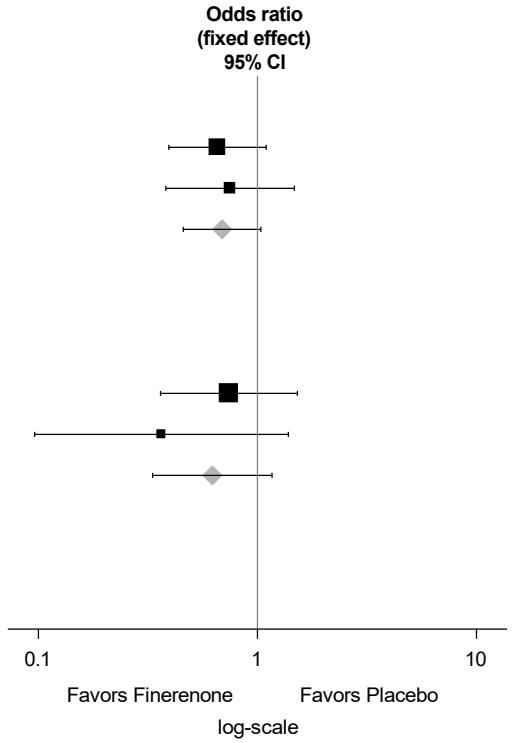
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	22 / 1213	25 / 1210	66.4	0.88 [0.49,1.56]	
FIGARO-DKD	9 / 862	17 / 848	33.6	0.52 [0.23,1.16]	
Total	31 / 2075	42 / 2058		0.73 [0.46,1.16]	Z=-1.33, p=0.1849
Heterogeneity:	Q=1.08 (df=1)	p=0.2987	I^2=7.4%		
Absent					
FIDELIO-DKD	16 / 1404	30 / 1400	67.9	0.53 [0.29,0.97]	
FIGARO-DKD	9 / 495	11 / 508	32.1	0.84 [0.34,2.04]	
Total	25 / 1899	41 / 1908		0.61 [0.37,1.00]	Z=-1.94, p=0.0519
Heterogeneity:	Q=0.71 (df=1)	p=0.4001	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6059	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

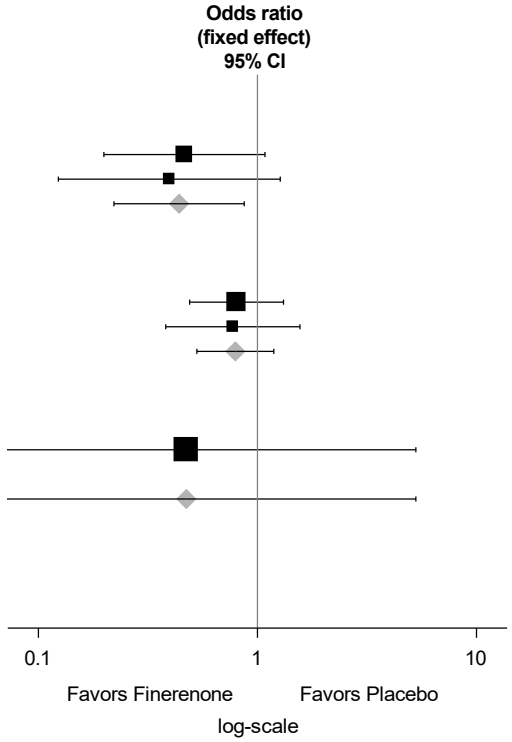
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1735	37 / 1700	63.5	0.66 [0.39,1.10]	
FIGARO-DKD	15 / 924	20 / 929	36.5	0.75 [0.38,1.47]	
Total	40 / 2659	57 / 2629		0.69 [0.46,1.04]	Z=-1.79, p=0.0739
Heterogeneity:	Q=0.09 (df=1)	p=0.7598	I^2=0.0%		
> 4.5					
FIDELIO-DKD	13 / 882	18 / 910	77.5	0.74 [0.36,1.52]	
FIGARO-DKD	3 / 433	8 / 426	22.5	0.36 [0.10,1.38]	
Total	16 / 1315	26 / 1336		0.62 [0.33,1.17]	Z=-1.48, p=0.1386
Heterogeneity:	Q=0.85 (df=1)	p=0.3580	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7889	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

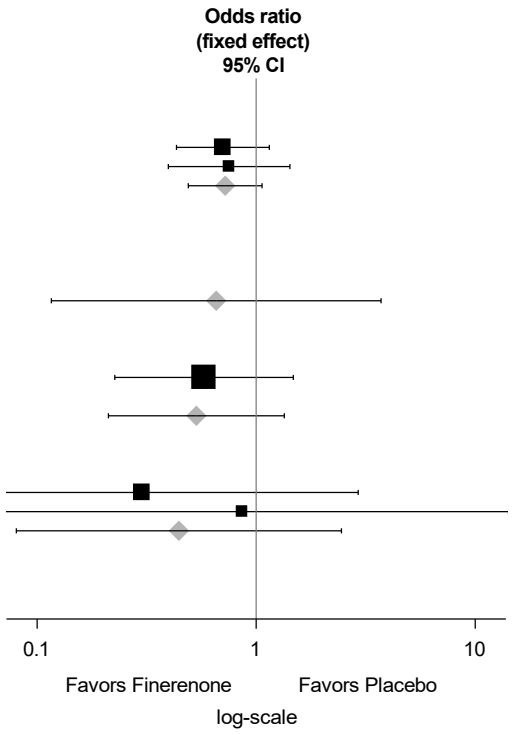
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	8 / 724	17 / 723	65.5	0.46 [0.20,1.08]	
FIGARO-DKD	4 / 494	10 / 495	34.5	0.40 [0.12,1.27]	
Total	12 / 1218	27 / 1218		0.44 [0.22,0.87]	Z=-2.36, p=0.0184
Heterogeneity:	Q=0.05 (df=1)	p=0.8291	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	29 / 1759	36 / 1760	67.1	0.80 [0.49,1.32]	
FIGARO-DKD	14 / 829	18 / 827	32.9	0.77 [0.38,1.56]	
Total	43 / 2588	54 / 2587		0.79 [0.53,1.19]	Z=-1.13, p=0.2597
Heterogeneity:	Q=0.01 (df=1)	p=0.9292	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	2 / 127	100.0	0.47 [0.04,5.29]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	1 / 167	2 / 161		0.47 [0.04,5.29]	Z=-0.61, p=0.5437
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.21 (df=2)	p=0.3316	I^2=9.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

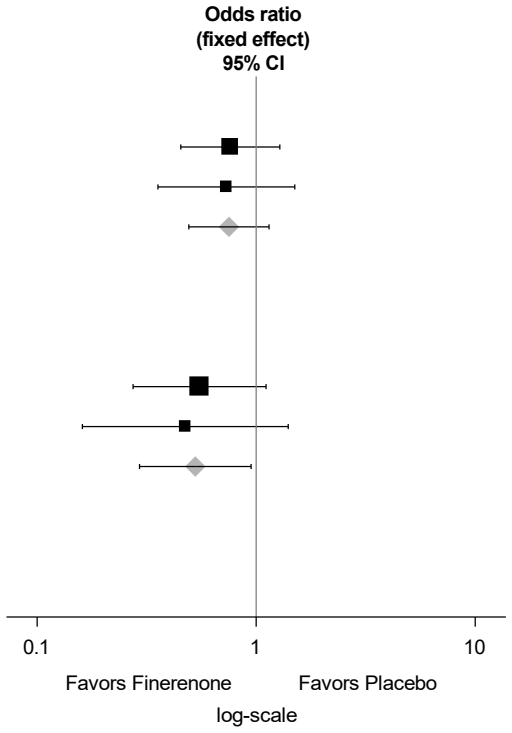
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	28 / 1634	40 / 1657	63.2	0.70 [0.43,1.15]	
FIGARO-DKD	17 / 1010	22 / 989	36.8	0.75 [0.40,1.43]	
Total	45 / 2644	62 / 2646		0.72 [0.49,1.06]	Z=-1.65, p=0.0995
Heterogeneity:	Q=0.03 (df=1)	p=0.8732	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	0 / 115	0.0	892E8 [892E8,892E8]	
FIGARO-DKD	0 / 43	4 / 71	0.0	0.00 [0.00,14E296]	
Total	2 / 172	4 / 186		0.66 [0.12,3.72]	Z=-0.48, p=0.6346
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	7 / 678	12 / 677	100.0	0.58 [0.23,1.48]	
FIGARO-DKD	0 / 252	1 / 251	0.0	0.00 [0.00,1E297]	
Total	7 / 930	13 / 928		0.53 [0.21,1.34]	Z=-1.33, p=0.1825
Heterogeneity:	Q=0.03 (df=1)	p=0.8659	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	3 / 161	60.3	0.30 [0.03,2.92]	
FIGARO-DKD	1 / 52	1 / 45	39.7	0.86 [0.05,14.20]	
Total	2 / 228	4 / 206		0.44 [0.08,2.45]	Z=-0.93, p=0.3514
Heterogeneity:	Q=0.33 (df=1)	p=0.5665	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.60 (df=3)	p=0.8970	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.39.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

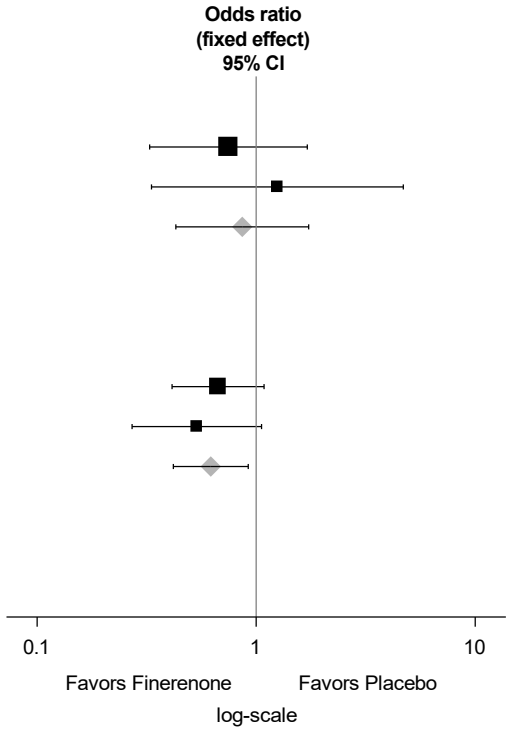
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1797	34 / 1870	65.6	0.76 [0.45,1.28]	
FIGARO-DKD	13 / 917	18 / 933	34.4	0.73 [0.36,1.50]	
Total	38 / 2714	52 / 2803		0.75 [0.49,1.15]	Z=-1.33, p=0.1834
Heterogeneity:	Q=0.01 (df=1)	p=0.9273	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 820	21 / 740	70.6	0.55 [0.27,1.11]	
FIGARO-DKD	5 / 440	10 / 423	29.4	0.47 [0.16,1.40]	
Total	18 / 1260	31 / 1163		0.53 [0.29,0.95]	Z=-2.14, p=0.0325
Heterogeneity:	Q=0.05 (df=1)	p=0.8194	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3373	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.39.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

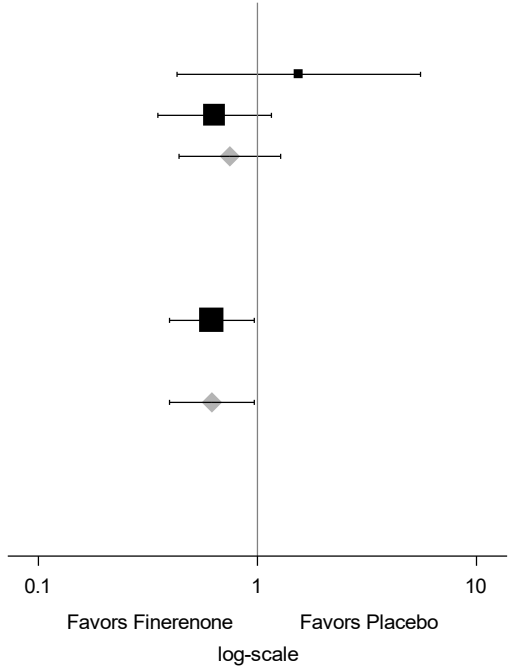
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1103	13 / 1075	71.8	0.75 [0.33,1.71]	
FIGARO-DKD	5 / 336	4 / 335	28.2	1.25 [0.33,4.70]	
Total	15 / 1439	17 / 1410		0.86 [0.43,1.74]	Z=-0.41, p=0.6817
Heterogeneity:	Q=0.42 (df=1)	p=0.5186	I^2=0.0%		
>= 65					
FIDELIO-DKD	28 / 1514	42 / 1535	66.5	0.67 [0.41,1.09]	
FIGARO-DKD	13 / 1021	24 / 1021	33.5	0.54 [0.27,1.06]	
Total	41 / 2535	66 / 2556		0.62 [0.42,0.92]	Z=-2.37, p=0.0176
Heterogeneity:	Q=0.27 (df=1)	p=0.6001	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=1)	p=0.4185	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.39.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

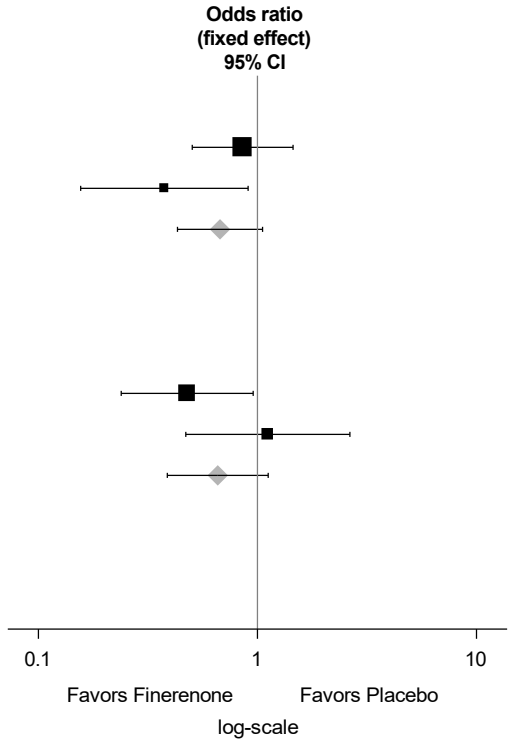
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	6 / 209	4 / 213	17.9	1.54 [0.43,5.55]	
FIGARO-DKD	18 / 1357	28 / 1356	82.1	0.64 [0.35,1.16]	
Total	24 / 1566	32 / 1569		0.75 [0.44,1.28]	Z=-1.06, p=0.2869
Heterogeneity:	Q=1.51 (df=1)	p=0.2195	I^2=33.7%		
Very High					
FIDELIO-DKD	32 / 2408	51 / 2397	100.0	0.62 [0.40,0.97]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	32 / 2408	51 / 2397		0.62 [0.40,0.97]	Z=-2.11, p=0.0352
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5950	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.39.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Asthenia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

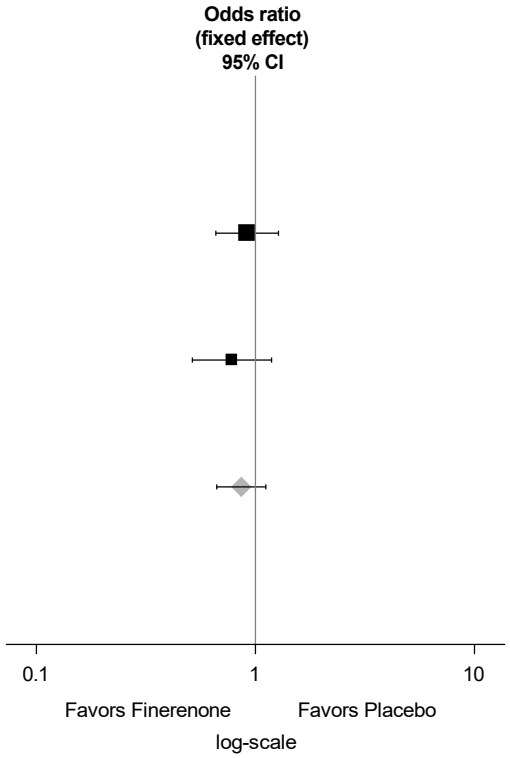
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	26 / 1556	30 / 1541	73.4	0.86 [0.50,1.45]	
FIGARO-DKD	7 / 637	18 / 627	26.6	0.38 [0.16,0.91]	
Total	33 / 2193	48 / 2168		0.67 [0.43,1.06]	Z=-1.72, p=0.0846
Heterogeneity:	Q=2.47 (df=1)	p=0.1160	I^2=59.5%		
45 - < 60					
FIDELIO-DKD	12 / 1061	25 / 1069	60.7	0.48 [0.24,0.96]	
FIGARO-DKD	11 / 720	10 / 729	39.3	1.12 [0.47,2.64]	
Total	23 / 1781	35 / 1798		0.66 [0.39,1.12]	Z=-1.54, p=0.1230
Heterogeneity:	Q=2.26 (df=1)	p=0.1330	I^2=55.7%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9465	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.40: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chest pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

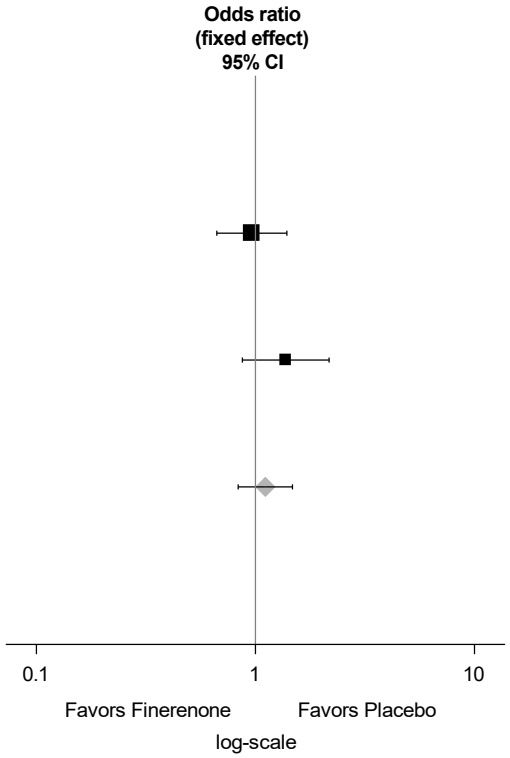
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2617	76 / 2610	61.5	0.92 [0.66,1.27]	
FIGARO-DKD	41 / 1357	52 / 1356	38.5	0.78 [0.52,1.18]	
Total	111 / 3974	128 / 3966		0.86 [0.67,1.12]	Z=-1.13, p=0.2581
Heterogeneity:	Q=0.35 (df=1)	p=0.5560	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.41: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fatigue (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

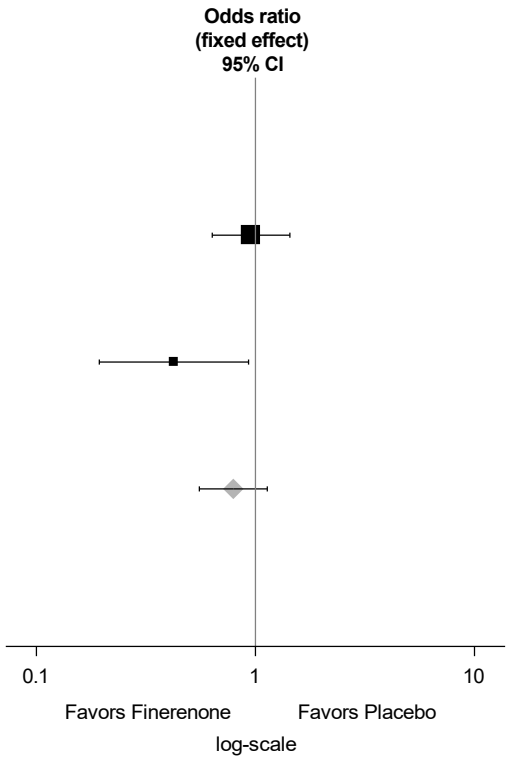
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	57 / 2617	59 / 2610	60.5	0.96 [0.67,1.39]	
FIGARO-DKD	45 / 1357	33 / 1356	39.5	1.38 [0.87,2.17]	
Total	102 / 3974	92 / 3966		1.11 [0.83,1.48]	Z=0.71, p=0.4756
Heterogeneity:	Q=1.42 (df=1)	p=0.2329	I^2=29.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.42: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

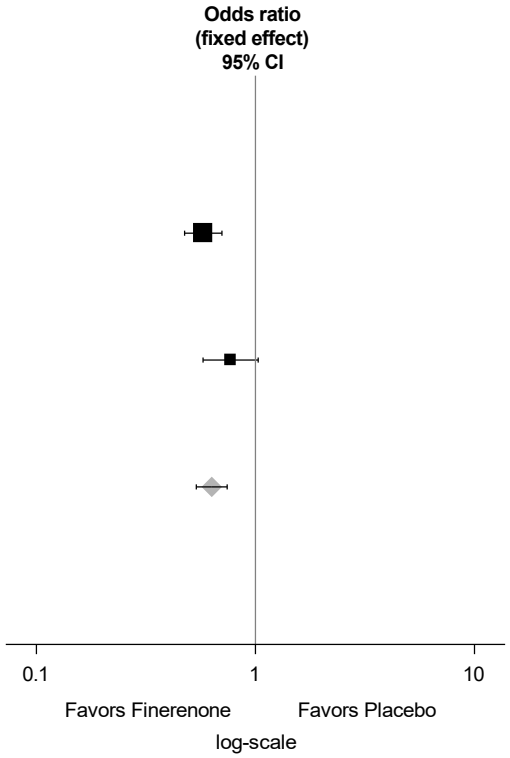
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	48 / 2610	78.7	0.95 [0.63,1.44]	
FIGARO-DKD	9 / 1357	21 / 1356	21.3	0.42 [0.19,0.93]	
Total	55 / 3974	69 / 3966		0.79 [0.55,1.13]	Z=-1.28, p=0.2015
Heterogeneity:	Q=3.24 (df=1)	p=0.0720	I^2=69.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.43: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

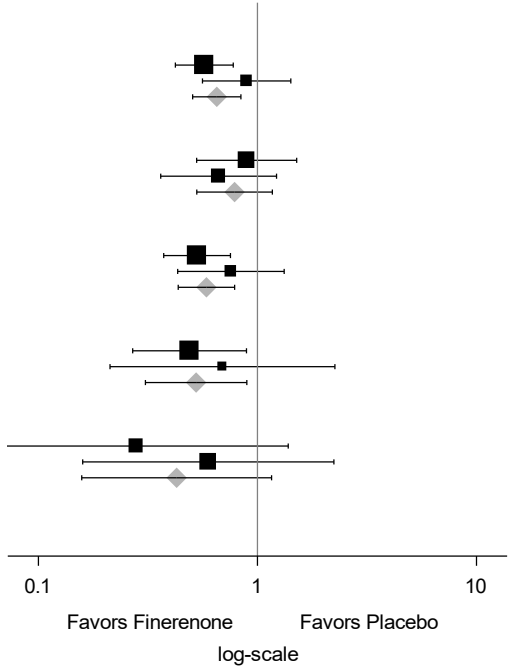
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	175 / 2617	288 / 2610	68.6	0.58 [0.47,0.70]	
FIGARO-DKD	88 / 1357	112 / 1356	31.4	0.77 [0.58,1.03]	
Total	263 / 3974	400 / 3966		0.63 [0.54,0.74]	Z=-5.55, p=<.0001
Heterogeneity:	Q=2.59 (df=1)	p=0.1075	I^2=61.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.43.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

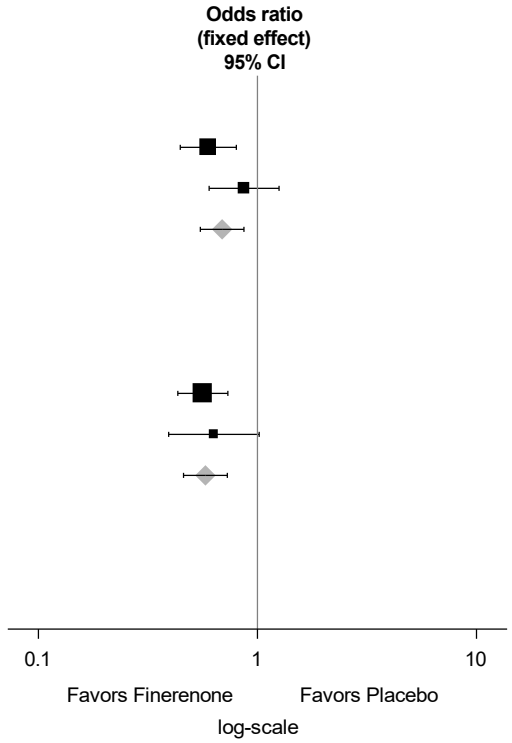
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	73 / 1075	120 / 1062	70.0	0.57 [0.42,0.78]	
FIGARO-DKD	36 / 638	40 / 637	30.0	0.89 [0.56,1.42]	
Total	109 / 1713	160 / 1699		0.65 [0.51,0.84]	Z=-3.30, p=0.0010
Heterogeneity:	Q=2.47 (df=1)	p=0.1160	I^2=59.5%		
North America					
FIDELIO-DKD	28 / 424	32 / 436	57.3	0.89 [0.53,1.51]	
FIGARO-DKD	19 / 267	28 / 271	42.7	0.66 [0.36,1.22]	
Total	47 / 691	60 / 707		0.79 [0.53,1.17]	Z=-1.19, p=0.2353
Heterogeneity:	Q=0.52 (df=1)	p=0.4729	I^2=0.0%		
Asia					
FIDELIO-DKD	54 / 751	95 / 745	71.8	0.53 [0.37,0.75]	
FIGARO-DKD	24 / 289	31 / 290	28.2	0.76 [0.43,1.32]	
Total	78 / 1040	126 / 1035		0.58 [0.43,0.79]	Z=-3.54, p=0.0004
Heterogeneity:	Q=1.12 (df=1)	p=0.2909	I^2=10.3%		
Latin America					
FIDELIO-DKD	18 / 273	34 / 270	79.6	0.49 [0.27,0.89]	
FIGARO-DKD	5 / 102	7 / 101	20.4	0.69 [0.21,2.26]	
Total	23 / 375	41 / 371		0.52 [0.31,0.89]	Z=-2.37, p=0.0177
Heterogeneity:	Q=0.26 (df=1)	p=0.6092	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	7 / 97	40.6	0.28 [0.06,1.38]	
FIGARO-DKD	4 / 61	6 / 57	59.4	0.60 [0.16,2.23]	
Total	6 / 155	13 / 154		0.43 [0.16,1.16]	Z=-1.67, p=0.0952
Heterogeneity:	Q=0.52 (df=1)	p=0.4725	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.54 (df=4)	p=0.6381	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.43.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

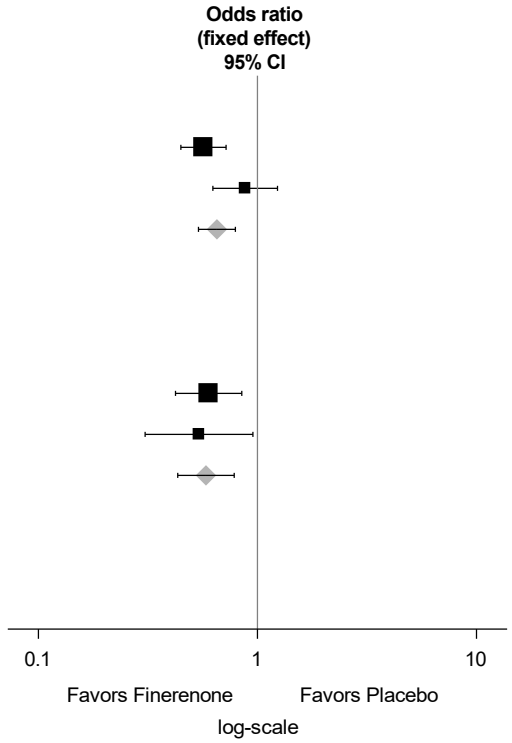
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	78 / 1213	125 / 1210	60.8	0.60 [0.44,0.80]	
FIGARO-DKD	58 / 862	65 / 848	39.2	0.87 [0.60,1.25]	
Total	136 / 2075	190 / 2058		0.69 [0.55,0.87]	Z=-3.18, p=0.0015
Heterogeneity:	Q=2.45 (df=1)	p=0.1175	I^2=59.2%		
Absent					
FIDELIO-DKD	97 / 1404	163 / 1400	76.6	0.56 [0.43,0.73]	
FIGARO-DKD	30 / 495	47 / 508	23.4	0.63 [0.39,1.02]	
Total	127 / 1899	210 / 1908		0.58 [0.46,0.73]	Z=-4.66, p=<.0001
Heterogeneity:	Q=0.18 (df=1)	p=0.6745	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.12 (df=1)	p=0.2890	I^2=11.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.43.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	120 / 1735	197 / 1700	67.1	0.57 [0.45,0.72]	
FIGARO-DKD	68 / 924	77 / 929	32.9	0.88 [0.63,1.23]	
Total	188 / 2659	274 / 2629		0.65 [0.54,0.79]	Z=-4.30, p=<.0001
Heterogeneity:	Q=4.30 (df=1)	p=0.0381	I^2=76.8%		
> 4.5					
FIDELIO-DKD	55 / 882	91 / 910	72.6	0.60 [0.42,0.85]	
FIGARO-DKD	20 / 433	35 / 426	27.4	0.54 [0.31,0.95]	
Total	75 / 1315	126 / 1336		0.58 [0.43,0.78]	Z=-3.57, p=0.0004
Heterogeneity:	Q=0.09 (df=1)	p=0.7657	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.41 (df=1)	p=0.5244	I^2=0.0%		

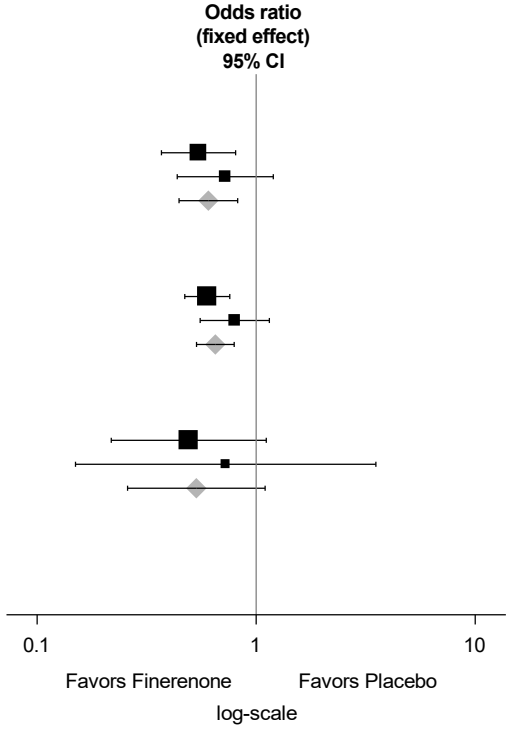


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.43.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Oedema peripheral (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

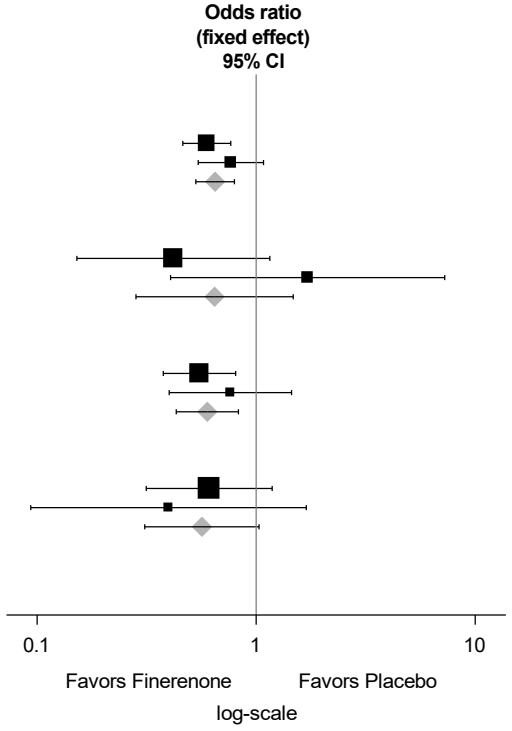
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	43 / 724	75 / 723	62.6	0.55 [0.37,0.81]	
FIGARO-DKD	28 / 494	38 / 495	37.4	0.72 [0.44,1.20]	
Total	71 / 1218	113 / 1218		0.60 [0.44,0.82]	Z=-3.20, p=0.0014
Heterogeneity:	Q=0.75 (df=1)	p=0.3878	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	122 / 1759	195 / 1760	70.3	0.60 [0.47,0.76]	
FIGARO-DKD	57 / 829	70 / 827	29.7	0.80 [0.55,1.15]	
Total	179 / 2588	265 / 2587		0.65 [0.53,0.79]	Z=-4.25, p=<.0001
Heterogeneity:	Q=1.70 (df=1)	p=0.1919	I^2=41.3%		
>= 160					
FIDELIO-DKD	10 / 133	18 / 127	79.0	0.49 [0.22,1.11]	
FIGARO-DKD	3 / 34	4 / 34	21.0	0.73 [0.15,3.52]	
Total	13 / 167	22 / 161		0.53 [0.26,1.10]	Z=-1.71, p=0.0882
Heterogeneity:	Q=0.18 (df=1)	p=0.6685	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.38 (df=2)	p=0.8286	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.43.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

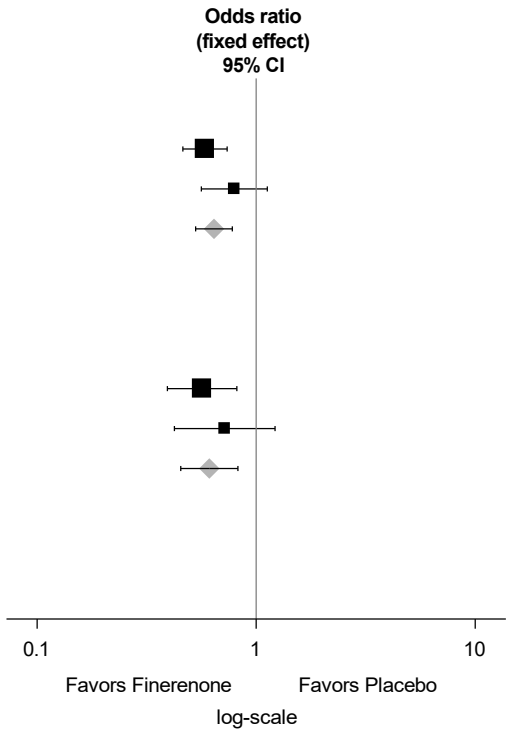
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	106 / 1634	173 / 1657	65.0	0.60 [0.46,0.77]	
FIGARO-DKD	63 / 1010	79 / 989	35.0	0.77 [0.54,1.08]	
Total	169 / 2644	252 / 2646		0.65 [0.53,0.80]	Z=-4.17, p=<.0001
Heterogeneity:	Q=1.35 (df=1)	p=0.2445	I^2=26.2%		
Black					
FIDELIO-DKD	6 / 129	12 / 115	66.9	0.42 [0.15,1.15]	
FIGARO-DKD	4 / 43	4 / 71	33.1	1.72 [0.41,7.26]	
Total	10 / 172	16 / 186		0.65 [0.28,1.48]	Z=-1.04, p=0.2999
Heterogeneity:	Q=2.47 (df=1)	p=0.1159	I^2=59.5%		
Asian					
FIDELIO-DKD	46 / 678	79 / 677	74.1	0.55 [0.38,0.81]	
FIGARO-DKD	18 / 252	23 / 251	25.9	0.76 [0.40,1.45]	
Total	64 / 930	102 / 928		0.60 [0.43,0.83]	Z=-3.08, p=0.0021
Heterogeneity:	Q=0.73 (df=1)	p=0.3939	I^2=0.0%		
Others					
FIDELIO-DKD	17 / 176	24 / 161	82.7	0.61 [0.31,1.18]	
FIGARO-DKD	3 / 52	6 / 45	17.3	0.40 [0.09,1.69]	
Total	20 / 228	30 / 206		0.57 [0.31,1.03]	Z=-1.86, p=0.0627
Heterogeneity:	Q=0.28 (df=1)	p=0.5986	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.31 (df=3)	p=0.9580	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.43.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

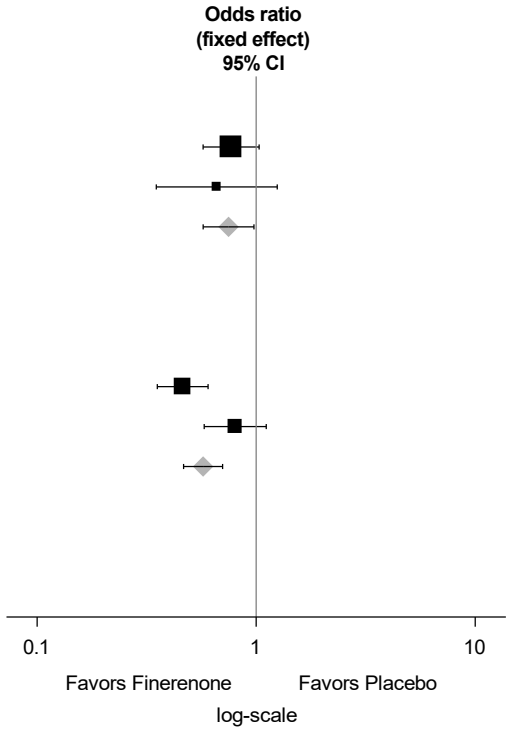
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	123 / 1797	209 / 1870	68.9	0.58 [0.46,0.74]	
FIGARO-DKD	62 / 917	78 / 933	31.1	0.79 [0.56,1.12]	
Total	185 / 2714	287 / 2803		0.64 [0.53,0.78]	Z=-4.51, p=<.0001
Heterogeneity:	Q=2.09 (df=1)	p=0.1478	I^2=52.3%		
Female					
FIDELIO-DKD	52 / 820	79 / 740	67.7	0.57 [0.39,0.82]	
FIGARO-DKD	26 / 440	34 / 423	32.3	0.72 [0.42,1.22]	
Total	78 / 1260	113 / 1163		0.61 [0.45,0.83]	Z=-3.21, p=0.0013
Heterogeneity:	Q=0.53 (df=1)	p=0.4686	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7886	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.43.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

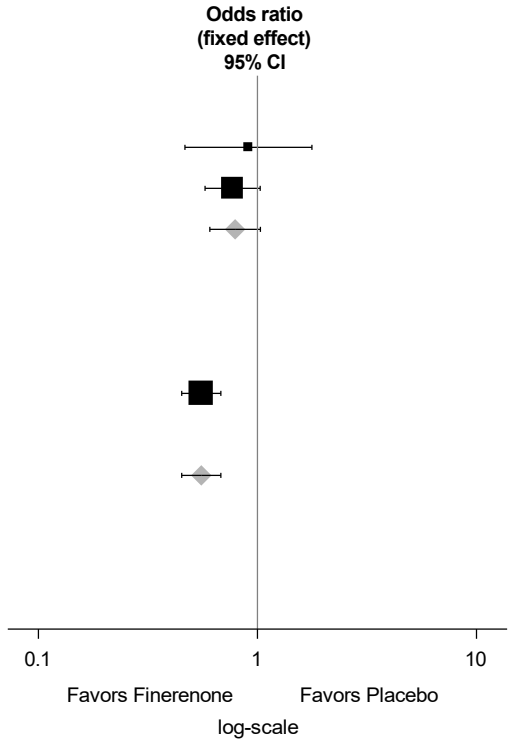
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	88 / 1103	109 / 1075	82.3	0.77 [0.57,1.03]	
FIGARO-DKD	17 / 336	25 / 335	17.7	0.66 [0.35,1.25]	
Total	105 / 1439	134 / 1410		0.75 [0.57,0.98]	Z=-2.13, p=0.0330
Heterogeneity:	Q=0.18 (df=1)	p=0.6731	I^2=0.0%		
>= 65					
FIDELIO-DKD	87 / 1514	179 / 1535	59.9	0.46 [0.35,0.60]	
FIGARO-DKD	71 / 1021	87 / 1021	40.1	0.80 [0.58,1.11]	
Total	158 / 2535	266 / 2556		0.57 [0.47,0.70]	Z=-5.33, p=<.0001
Heterogeneity:	Q=6.60 (df=1)	p=0.0102	I^2=84.9%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1193	I^2=58.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.43.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

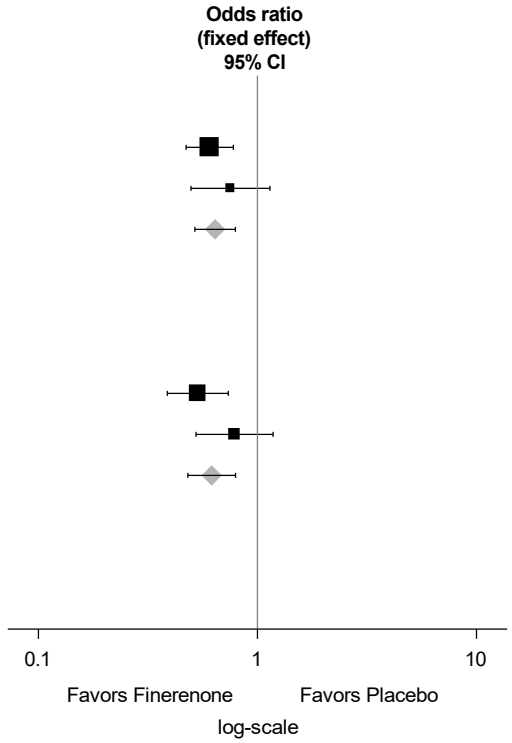
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	18 / 209	20 / 213	15.9	0.91 [0.47,1.77]	
FIGARO-DKD	88 / 1357	112 / 1356	84.1	0.77 [0.58,1.03]	
Total	106 / 1566	132 / 1569		0.79 [0.61,1.03]	Z=-1.73, p=0.0834
Heterogeneity:	Q=0.20 (df=1)	p=0.6546	I^2=0.0%		
Very High					
FIDELIO-DKD	157 / 2408	268 / 2397	100.0	0.55 [0.45,0.68]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	157 / 2408	268 / 2397		0.55 [0.45,0.68]	Z=-5.63, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.30 (df=1)	p=0.0381	I^2=76.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.43.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Oedema peripheral (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

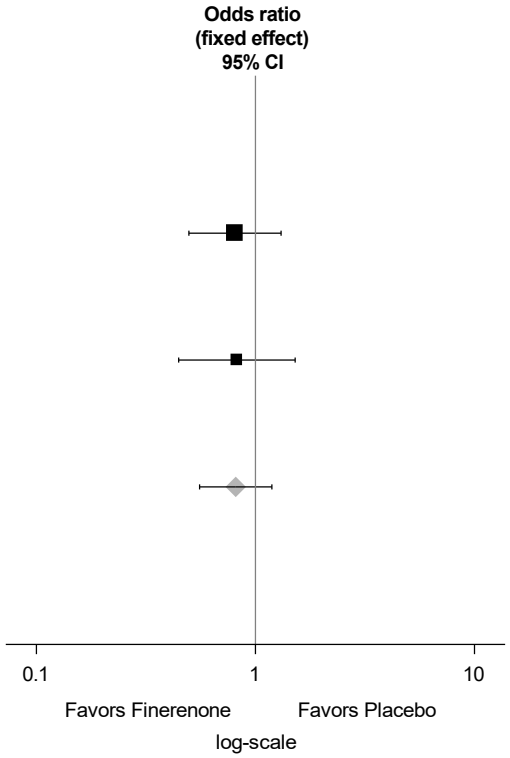
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	112 / 1556	175 / 1541	73.6	0.61 [0.47,0.78]	
FIGARO-DKD	43 / 637	55 / 627	26.4	0.75 [0.50,1.14]	
Total	155 / 2193	230 / 2168		0.64 [0.52,0.79]	Z=-4.09, p=<.0001
Heterogeneity:	Q=0.78 (df=1)	p=0.3773	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	63 / 1061	113 / 1069	61.5	0.53 [0.39,0.74]	
FIGARO-DKD	45 / 720	57 / 729	38.5	0.79 [0.52,1.18]	
Total	108 / 1781	170 / 1798		0.62 [0.48,0.79]	Z=-3.76, p=0.0002
Heterogeneity:	Q=2.15 (df=1)	p=0.1427	I^2=53.5%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8284	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.44: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral swelling (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

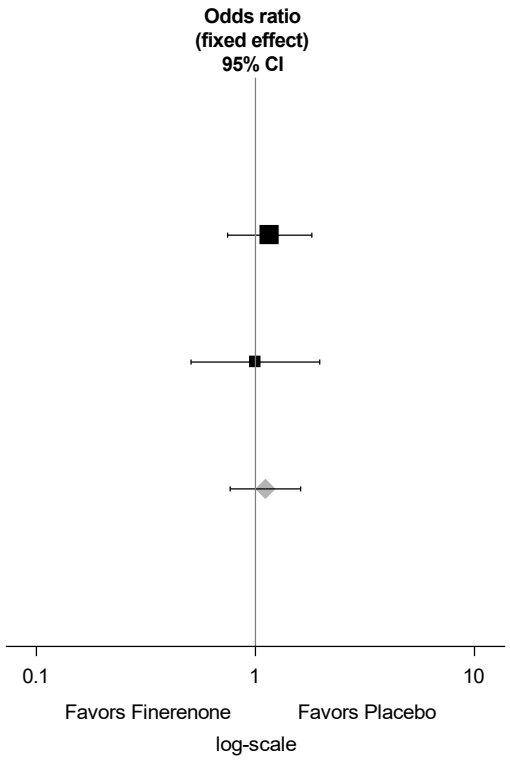
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	37 / 2610	61.5	0.81 [0.50,1.31]	
FIGARO-DKD	19 / 1357	23 / 1356	38.5	0.82 [0.45,1.52]	
Total	49 / 3974	60 / 3966		0.81 [0.56,1.19]	Z=-1.07, p=0.2849
Heterogeneity:	Q=0.00 (df=1)	p=0.9593	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.45: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pyrexia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

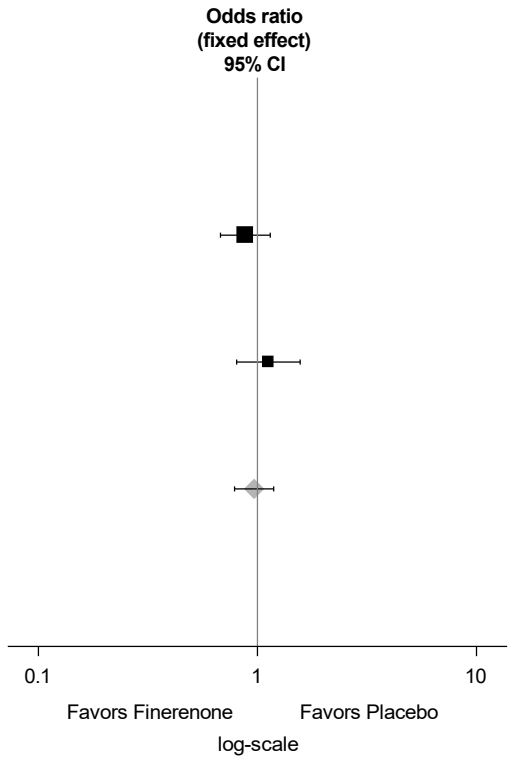
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	37 / 2610	70.0	1.16 [0.75,1.81]	
FIGARO-DKD	17 / 1357	17 / 1356	30.0	1.00 [0.51,1.97]	
Total	60 / 3974	54 / 3966		1.11 [0.77,1.61]	Z=0.55, p=0.5792
Heterogeneity:	Q=0.13 (df=1)	p=0.7150	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.46: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

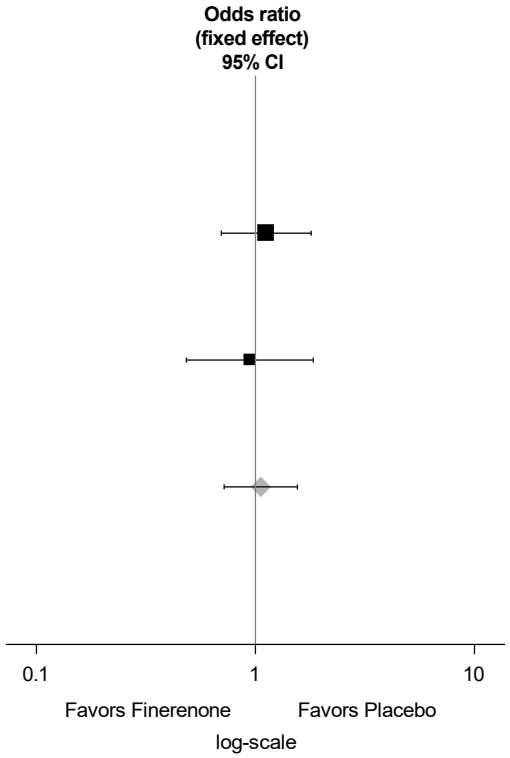
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2617	125 / 2610	62.0	0.88 [0.68,1.14]	
FIGARO-DKD	77 / 1357	69 / 1356	38.0	1.12 [0.80,1.57]	
Total	188 / 3974	194 / 3966		0.97 [0.79,1.19]	Z=-0.33, p=0.7383
Heterogeneity:	Q=1.25 (df=1)	p=0.2628	I^2=20.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.47: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cholelithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

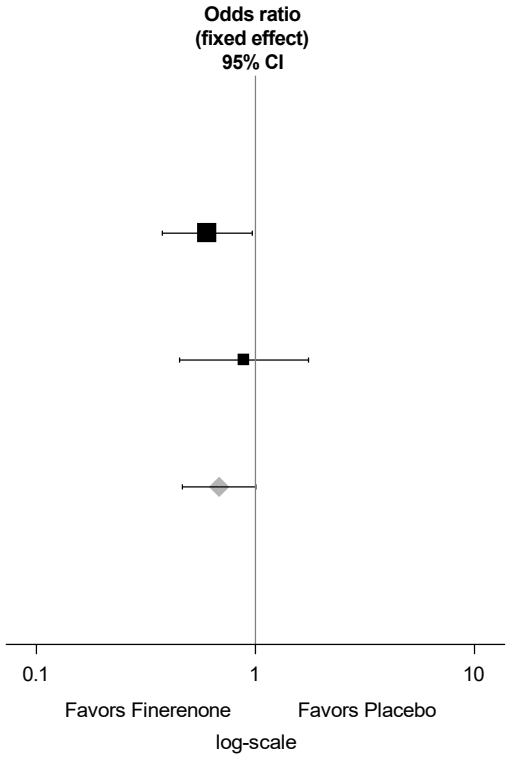
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	33 / 2610	66.6	1.12 [0.70,1.80]	
FIGARO-DKD	17 / 1357	18 / 1356	33.4	0.94 [0.48,1.84]	
Total	54 / 3974	51 / 3966		1.06 [0.72,1.55]	Z=0.28, p=0.7762
Heterogeneity:	Q=0.17 (df=1)	p=0.6803	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.48: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hepatic steatosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

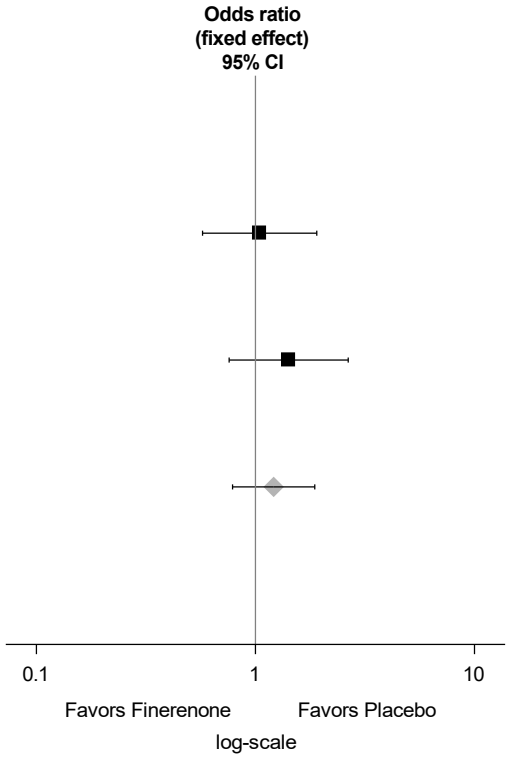
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	46 / 2610	67.2	0.60 [0.38,0.97]	
FIGARO-DKD	16 / 1357	18 / 1356	32.8	0.89 [0.45,1.75]	
Total	44 / 3974	64 / 3966		0.68 [0.46,1.00]	Z=-1.94, p=0.0527
Heterogeneity:	Q=0.84 (df=1)	p=0.3598	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.49: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Immune System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

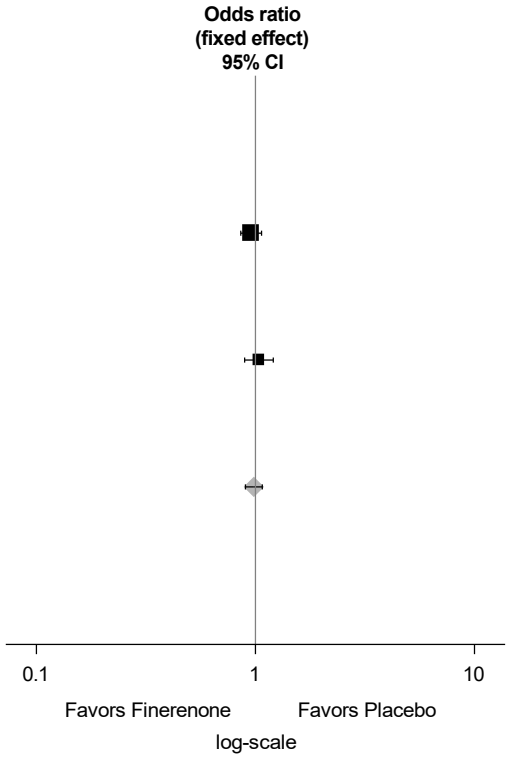
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	22 / 2617	21 / 2610	52.1	1.05 [0.57,1.91]	
FIGARO-DKD	24 / 1357	17 / 1356	47.9	1.42 [0.76,2.65]	
Total	46 / 3974	38 / 3966		1.21 [0.79,1.87]	Z=0.87, p=0.3850
Heterogeneity:	Q=0.48 (df=1)	p=0.4905	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.50: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

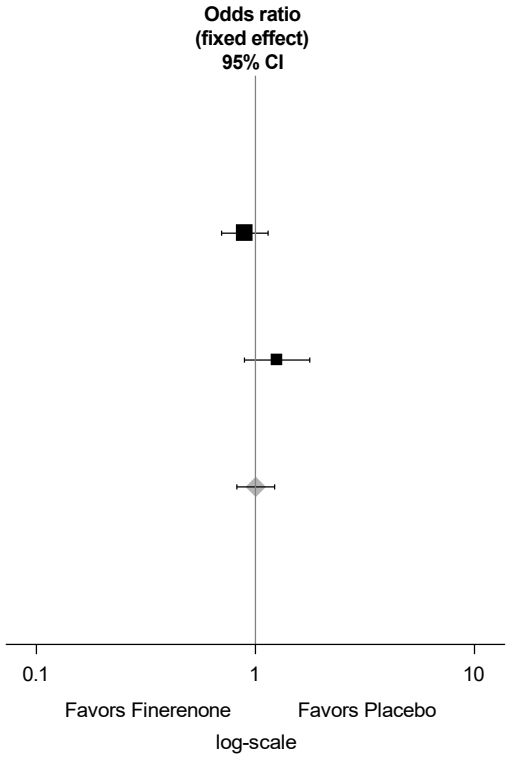
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	1139 / 2617	1165 / 2610	65.5	0.96 [0.86,1.07]	
FIGARO-DKD	664 / 1357	651 / 1356	34.5	1.04 [0.89,1.21]	
Total	1803 / 3974	1816 / 3966		0.98 [0.90,1.07]	Z=-0.37, p=0.7086
Heterogeneity:	Q=0.75 (df=1)	p=0.3871	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.51: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Bronchitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

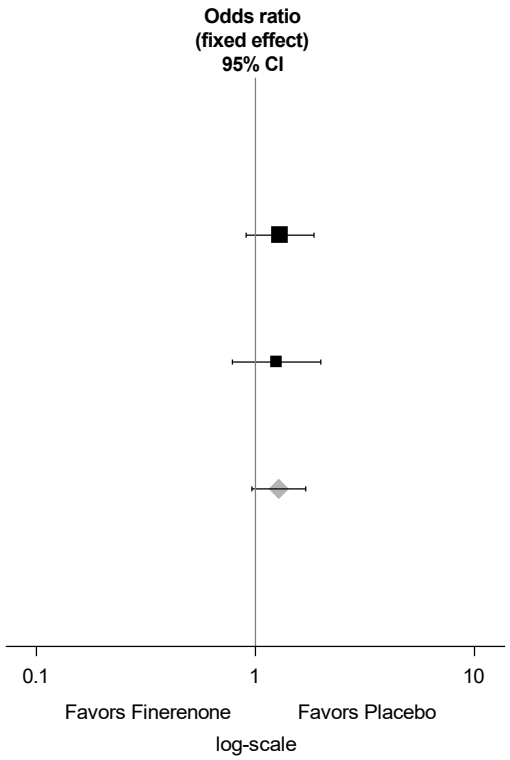
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	129 / 2617	143 / 2610	66.4	0.89 [0.70,1.14]	
FIGARO-DKD	77 / 1357	62 / 1356	33.6	1.26 [0.89,1.77]	
Total	206 / 3974	205 / 3966		1.00 [0.82,1.22]	Z=0.03, p=0.9764
Heterogeneity:	Q=2.49 (df=1)	p=0.1148	I^2=59.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.52: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

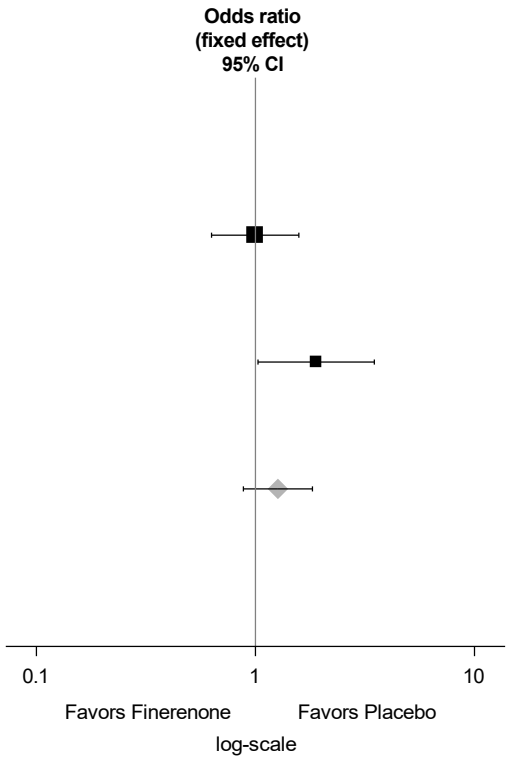
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	71 / 2617	55 / 2610	63.0	1.30 [0.91,1.85]	
FIGARO-DKD	41 / 1357	33 / 1356	37.0	1.25 [0.78,1.99]	
Total	112 / 3974	88 / 3966		1.28 [0.96,1.70]	Z=1.70, p=0.0890
Heterogeneity:	Q=0.01 (df=1)	p=0.9027	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.53: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Conjunctivitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

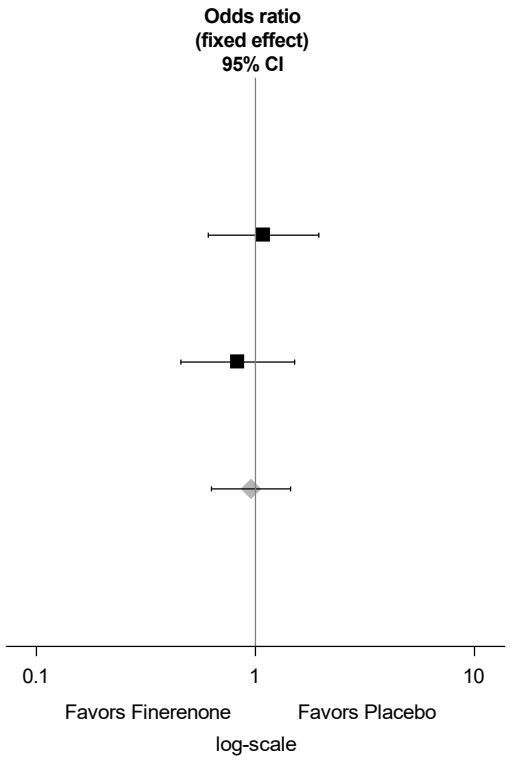
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	37 / 2610	64.0	1.00 [0.63,1.58]	
FIGARO-DKD	30 / 1357	16 / 1356	36.0	1.89 [1.03,3.49]	
Total	67 / 3974	53 / 3966		1.27 [0.88,1.82]	Z=1.27, p=0.2025
Heterogeneity:	Q=2.70 (df=1)	p=0.1002	I^2=63.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.54: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cystitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

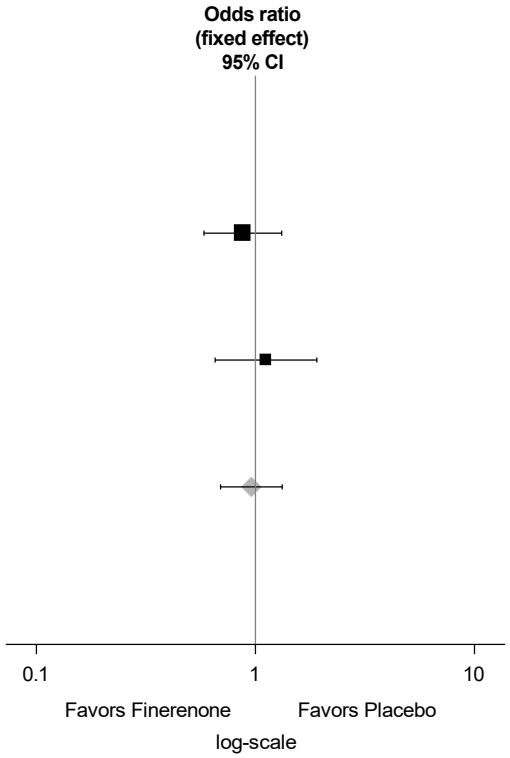
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2617	22 / 2610	51.5	1.09 [0.61,1.95]	
FIGARO-DKD	20 / 1357	24 / 1356	48.5	0.83 [0.46,1.51]	
Total	44 / 3974	46 / 3966		0.95 [0.63,1.45]	Z=-0.22, p=0.8256
Heterogeneity:	Q=0.41 (df=1)	p=0.5240	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.55: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gastroenteritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

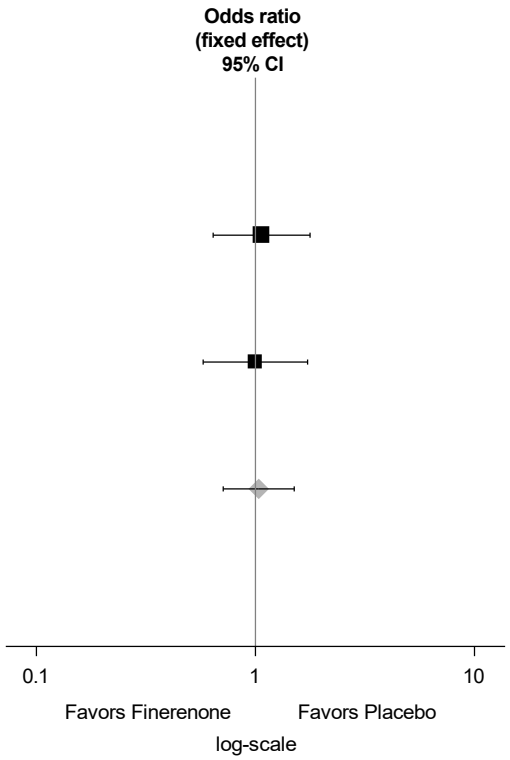
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2617	50 / 2610	63.1	0.88 [0.58,1.32]	
FIGARO-DKD	29 / 1357	26 / 1356	36.9	1.12 [0.65,1.91]	
Total	73 / 3974	76 / 3966		0.96 [0.69,1.32]	Z=-0.26, p=0.7947
Heterogeneity:	Q=0.50 (df=1)	p=0.4781	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.56: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Herpes zoster (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

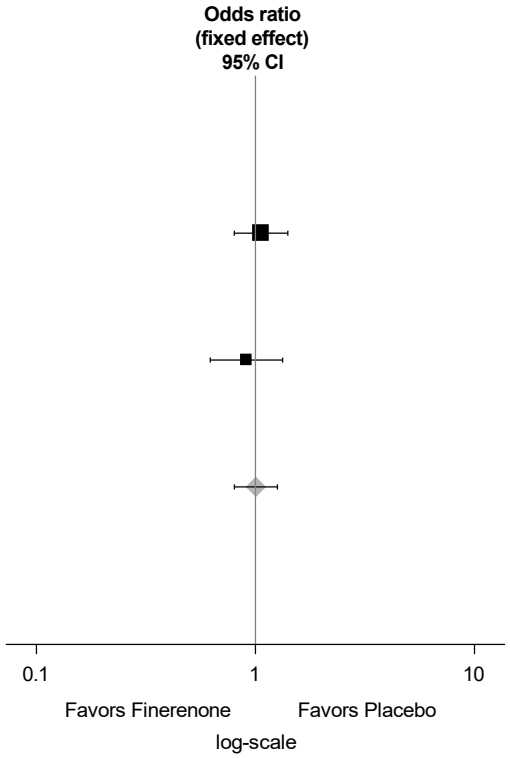
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	29 / 2610	53.7	1.07 [0.64,1.78]	
FIGARO-DKD	26 / 1357	26 / 1356	46.3	1.00 [0.58,1.73]	
Total	57 / 3974	55 / 3966		1.04 [0.71,1.50]	Z=0.18, p=0.8564
Heterogeneity:	Q=0.03 (df=1)	p=0.8638	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.57: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Influenza (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

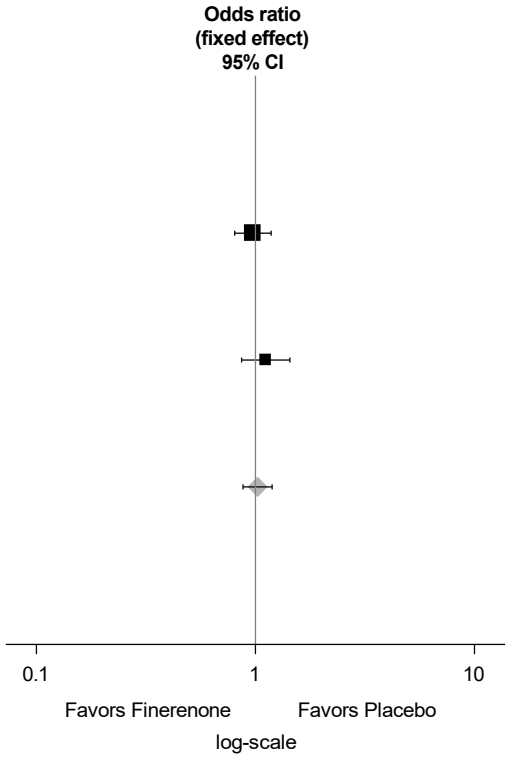
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	104 / 2617	98 / 2610	64.6	1.06 [0.80,1.41]	
FIGARO-DKD	53 / 1357	58 / 1356	35.4	0.91 [0.62,1.33]	
Total	157 / 3974	156 / 3966		1.00 [0.80,1.26]	Z=0.04, p=0.9683
Heterogeneity:	Q=0.41 (df=1)	p=0.5240	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.58: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nasopharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

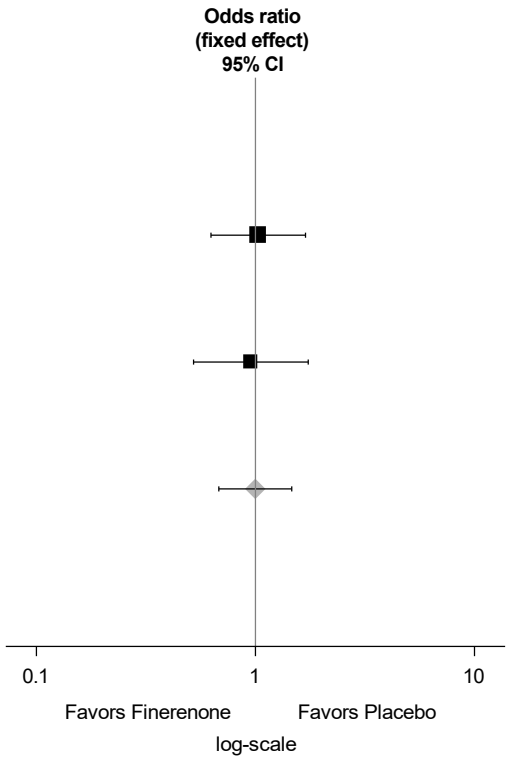
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	227 / 2617	232 / 2610	63.7	0.97 [0.80,1.18]	
FIGARO-DKD	139 / 1357	126 / 1356	36.3	1.11 [0.86,1.44]	
Total	366 / 3974	358 / 3966		1.02 [0.88,1.19]	Z=0.28, p=0.7763
Heterogeneity:	Q=0.69 (df=1)	p=0.4060	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.59: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pharyngitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

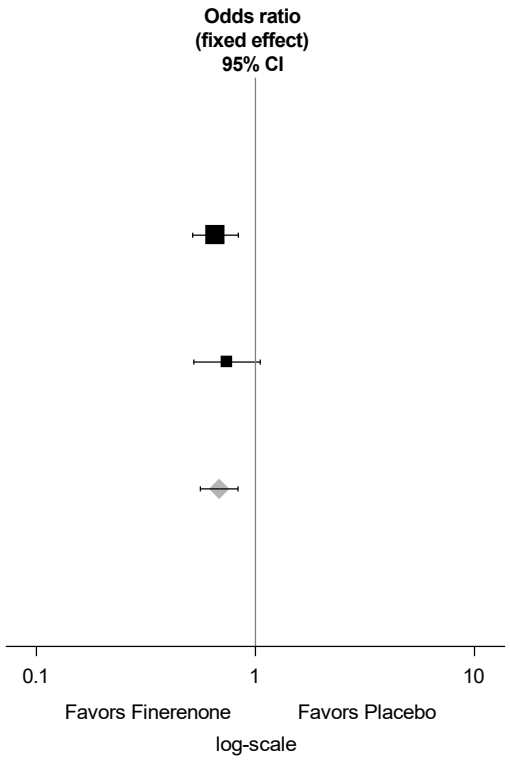
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	31 / 2610	59.5	1.03 [0.63,1.69]	
FIGARO-DKD	21 / 1357	22 / 1356	40.5	0.95 [0.52,1.74]	
Total	53 / 3974	53 / 3966		1.00 [0.68,1.46]	Z=-0.01, p=0.9922
Heterogeneity:	Q=0.04 (df=1)	p=0.8459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.60: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

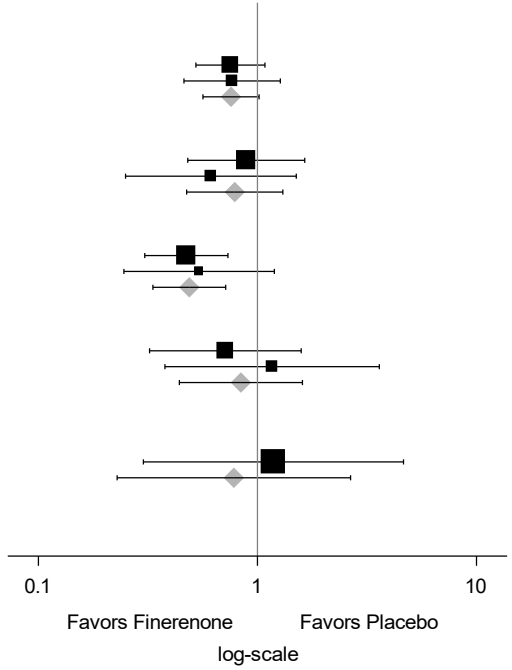
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	118 / 2617	175 / 2610	67.9	0.66 [0.52,0.84]	
FIGARO-DKD	58 / 1357	77 / 1356	32.1	0.74 [0.52,1.05]	
Total	176 / 3974	252 / 3966		0.68 [0.56,0.83]	Z=-3.78, p=0.0002
Heterogeneity:	Q=0.31 (df=1)	p=0.5753	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.60.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

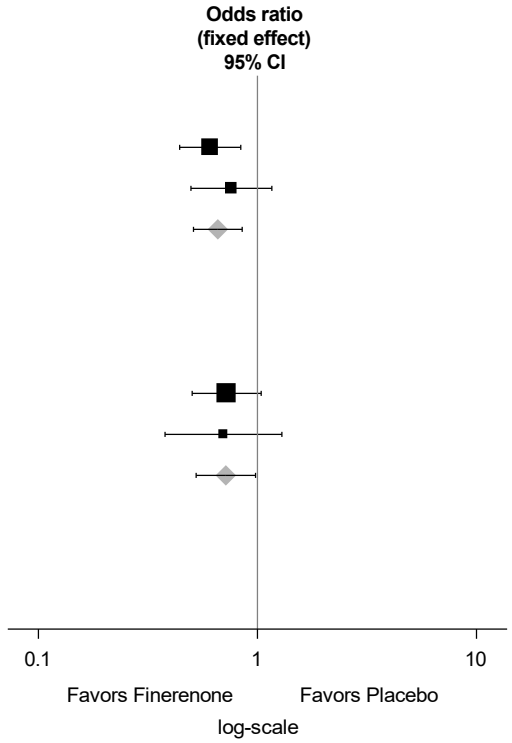
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	55 / 1075	71 / 1062	66.1	0.75 [0.52,1.08]	
FIGARO-DKD	28 / 638	36 / 637	33.9	0.77 [0.46,1.27]	
Total	83 / 1713	107 / 1699		0.76 [0.56,1.02]	Z=-1.85, p=0.0646
Heterogeneity:	Q=0.00 (df=1)	p=0.9548	I^2=0.0%		
North America					
FIDELIO-DKD	20 / 424	23 / 436	68.1	0.89 [0.48,1.64]	
FIGARO-DKD	8 / 267	13 / 271	31.9	0.61 [0.25,1.50]	
Total	28 / 691	36 / 707		0.79 [0.48,1.31]	Z=-0.93, p=0.3548
Heterogeneity:	Q=0.45 (df=1)	p=0.5031	I^2=0.0%		
Asia					
FIDELIO-DKD	32 / 751	64 / 745	76.6	0.47 [0.31,0.73]	
FIGARO-DKD	10 / 289	18 / 290	23.4	0.54 [0.25,1.19]	
Total	42 / 1040	82 / 1035		0.49 [0.33,0.72]	Z=-3.67, p=0.0002
Heterogeneity:	Q=0.08 (df=1)	p=0.7709	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 273	15 / 270	66.7	0.71 [0.32,1.58]	
FIGARO-DKD	7 / 102	6 / 101	33.3	1.17 [0.38,3.60]	
Total	18 / 375	21 / 371		0.84 [0.44,1.60]	Z=-0.53, p=0.5980
Heterogeneity:	Q=0.49 (df=1)	p=0.4853	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	5 / 61	4 / 57	100.0	1.18 [0.30,4.64]	
Total	5 / 155	6 / 154		0.78 [0.23,2.66]	Z=-0.40, p=0.6918
Heterogeneity:	Q=0.36 (df=1)	p=0.5508	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.16 (df=4)	p=0.3842	I^2=4.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.60.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

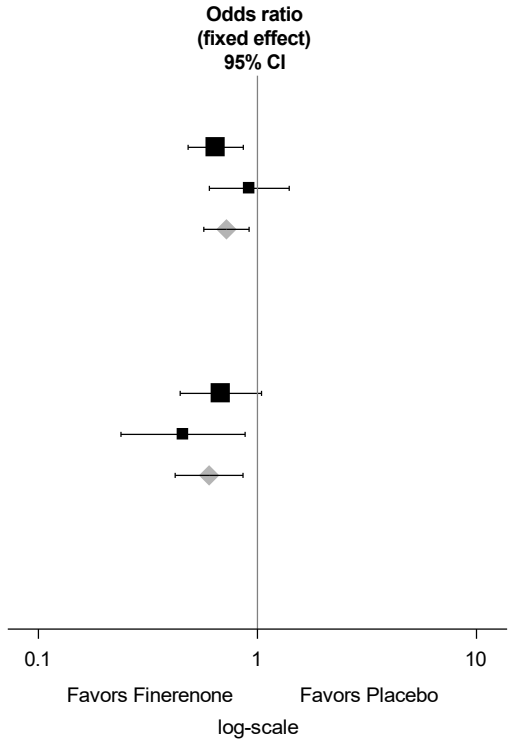
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	65 / 1213	103 / 1210	63.7	0.61 [0.44,0.84]	
FIGARO-DKD	40 / 862	51 / 848	36.3	0.76 [0.50,1.16]	
Total	105 / 2075	154 / 2058		0.66 [0.51,0.85]	Z=-3.19, p=0.0014
Heterogeneity:	Q=0.67 (df=1)	p=0.4124	I^2=0.0%		
Absent					
FIDELIO-DKD	53 / 1404	72 / 1400	74.1	0.72 [0.50,1.04]	
FIGARO-DKD	18 / 495	26 / 508	25.9	0.70 [0.38,1.29]	
Total	71 / 1899	98 / 1908		0.72 [0.52,0.98]	Z=-2.09, p=0.0370
Heterogeneity:	Q=0.01 (df=1)	p=0.9261	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.17 (df=1)	p=0.6825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.60.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

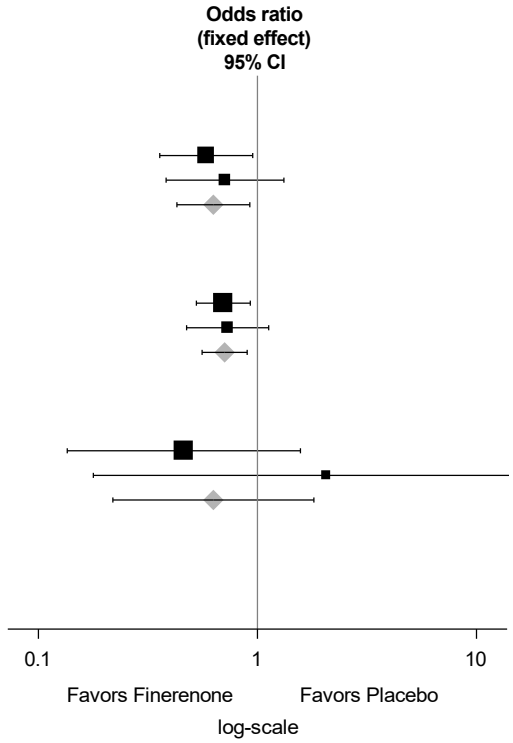
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	81 / 1735	120 / 1700	67.7	0.64 [0.48,0.86]	
FIGARO-DKD	44 / 924	48 / 929	32.3	0.92 [0.60,1.40]	
Total	125 / 2659	168 / 2629		0.72 [0.57,0.92]	Z=-2.68, p=0.0073
Heterogeneity:	Q=1.84 (df=1)	p=0.1751	I^2=45.6%		
> 4.5					
FIDELIO-DKD	37 / 882	55 / 910	70.0	0.68 [0.44,1.04]	
FIGARO-DKD	14 / 433	29 / 426	30.0	0.46 [0.24,0.88]	
Total	51 / 1315	84 / 1336		0.60 [0.42,0.86]	Z=-2.79, p=0.0052
Heterogeneity:	Q=1.00 (df=1)	p=0.3177	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.69 (df=1)	p=0.4047	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.60.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

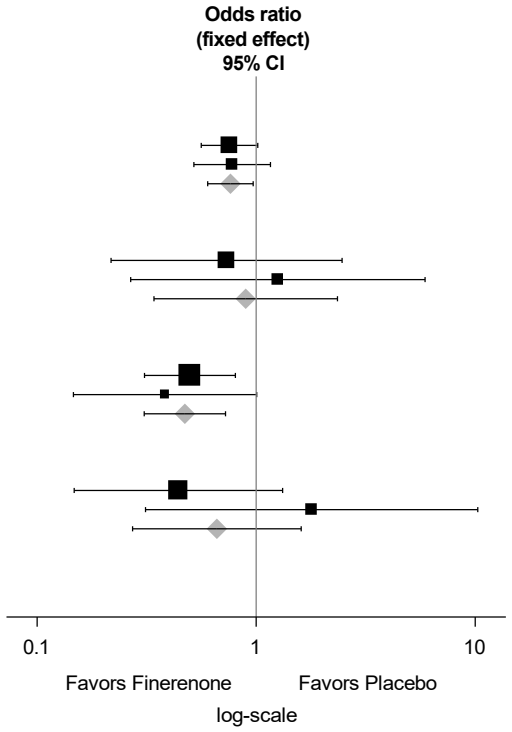
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	27 / 724	45 / 723	61.6	0.58 [0.36,0.95]	
FIGARO-DKD	18 / 494	25 / 495	38.4	0.71 [0.38,1.32]	
Total	45 / 1218	70 / 1218		0.63 [0.43,0.92]	Z=-2.37, p=0.0178
Heterogeneity:	Q=0.24 (df=1)	p=0.6240	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	87 / 1759	122 / 1760	69.9	0.70 [0.53,0.93]	
FIGARO-DKD	38 / 829	51 / 827	30.1	0.73 [0.47,1.13]	
Total	125 / 2588	173 / 2587		0.71 [0.56,0.90]	Z=-2.86, p=0.0043
Heterogeneity:	Q=0.03 (df=1)	p=0.8635	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	8 / 127	80.0	0.46 [0.14,1.57]	
FIGARO-DKD	2 / 34	1 / 34	20.0	2.06 [0.18,23.88]	
Total	6 / 167	9 / 161		0.63 [0.22,1.81]	Z=-0.86, p=0.3900
Heterogeneity:	Q=1.15 (df=1)	p=0.2837	I^2=13.0%		
Subgroup Heterogeneity:	Q=0.29 (df=2)	p=0.8649	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.60.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

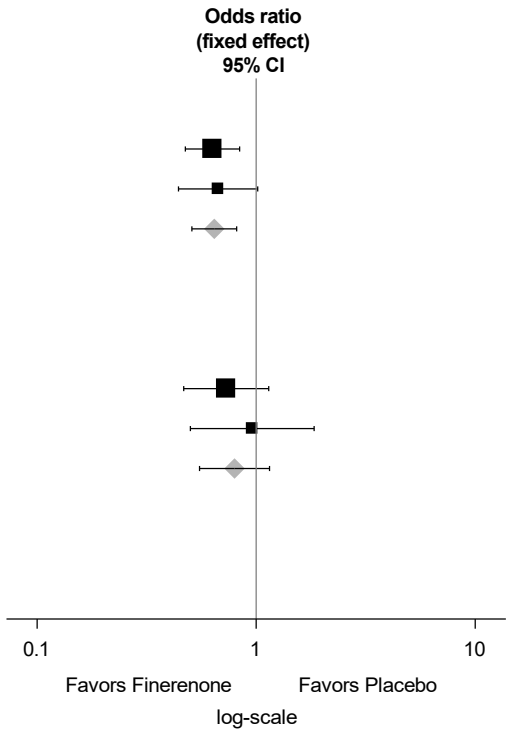
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	81 / 1634	107 / 1657	64.7	0.76 [0.56,1.02]	
FIGARO-DKD	45 / 1010	56 / 989	35.3	0.78 [0.52,1.16]	
Total	126 / 2644	163 / 2646		0.76 [0.60,0.97]	Z=-2.22, p=0.0266
Heterogeneity:	Q=0.01 (df=1)	p=0.9130	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	6 / 115	61.9	0.73 [0.22,2.47]	
FIGARO-DKD	3 / 43	4 / 71	38.1	1.26 [0.27,5.90]	
Total	8 / 172	10 / 186		0.90 [0.34,2.35]	Z=-0.22, p=0.8232
Heterogeneity:	Q=0.29 (df=1)	p=0.5909	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 678	52 / 677	80.3	0.50 [0.31,0.80]	
FIGARO-DKD	6 / 252	15 / 251	19.7	0.38 [0.15,1.01]	
Total	33 / 930	67 / 928		0.47 [0.31,0.72]	Z=-3.44, p=0.0006
Heterogeneity:	Q=0.23 (df=1)	p=0.6334	I^2=0.0%		
Others					
FIDELIO-DKD	5 / 176	10 / 161	71.8	0.44 [0.15,1.32]	
FIGARO-DKD	4 / 52	2 / 45	28.2	1.79 [0.31,10.27]	
Total	9 / 228	12 / 206		0.66 [0.27,1.61]	Z=-0.91, p=0.3610
Heterogeneity:	Q=1.77 (df=1)	p=0.1830	I^2=43.6%		
Subgroup Heterogeneity:	Q=3.99 (df=3)	p=0.2631	I^2=24.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.60.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

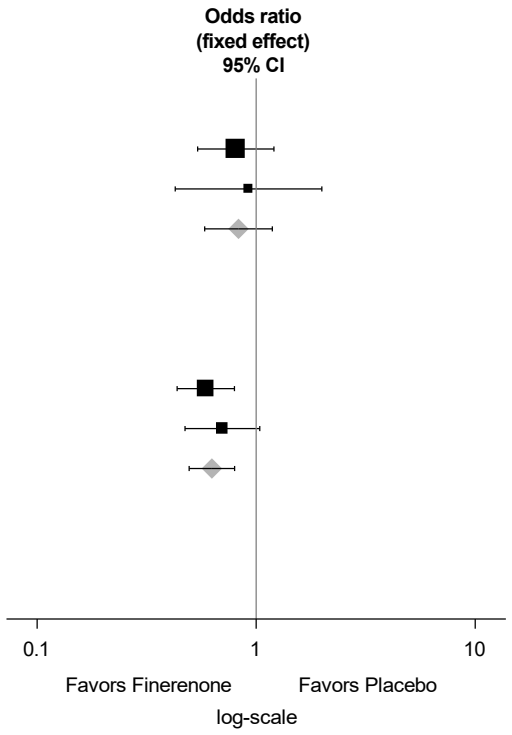
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	81 / 1797	130 / 1870	68.1	0.63 [0.47,0.84]	
FIGARO-DKD	39 / 917	58 / 933	31.9	0.67 [0.44,1.02]	
Total	120 / 2714	188 / 2803		0.64 [0.51,0.81]	Z=-3.67, p=0.0002
Heterogeneity:	Q=0.05 (df=1)	p=0.8192	I^2=0.0%		
Female					
FIDELIO-DKD	37 / 820	45 / 740	67.9	0.73 [0.47,1.14]	
FIGARO-DKD	19 / 440	19 / 423	32.1	0.96 [0.50,1.84]	
Total	56 / 1260	64 / 1163		0.80 [0.55,1.15]	Z=-1.21, p=0.2255
Heterogeneity:	Q=0.46 (df=1)	p=0.4965	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.91 (df=1)	p=0.3394	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.60.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

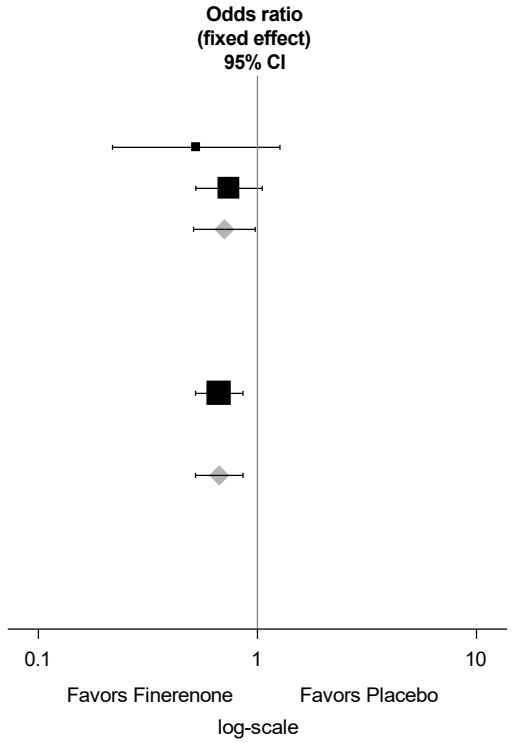
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	46 / 1103	55 / 1075	78.7	0.81 [0.54,1.21]	
FIGARO-DKD	13 / 336	14 / 335	21.3	0.92 [0.43,1.99]	
Total	59 / 1439	69 / 1410		0.83 [0.58,1.19]	Z=-1.02, p=0.3057
Heterogeneity:	Q=0.09 (df=1)	p=0.7624	I^2=0.0%		
>= 65					
FIDELIO-DKD	72 / 1514	120 / 1535	63.0	0.59 [0.44,0.80]	
FIGARO-DKD	45 / 1021	63 / 1021	37.0	0.70 [0.47,1.04]	
Total	117 / 2535	183 / 2556		0.63 [0.49,0.80]	Z=-3.82, p=0.0001
Heterogeneity:	Q=0.48 (df=1)	p=0.4892	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.64 (df=1)	p=0.2004	I^2=39.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.60.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

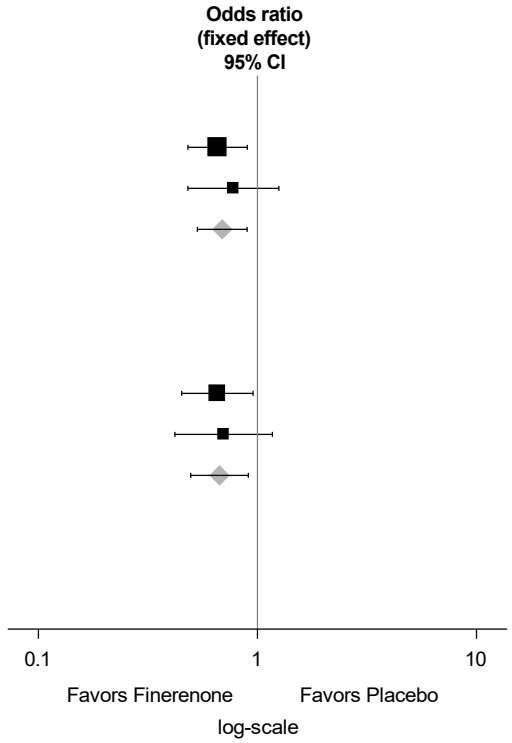
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	8 / 209	15 / 213	13.6	0.53 [0.22,1.27]	
FIGARO-DKD	58 / 1357	77 / 1356	86.4	0.74 [0.52,1.05]	
Total	66 / 1566	92 / 1569		0.71 [0.51,0.98]	Z=-2.10, p=0.0357
Heterogeneity:	Q=0.51 (df=1)	p=0.4755	I^2=0.0%		
Very High					
FIDELIO-DKD	110 / 2408	160 / 2397	100.0	0.67 [0.52,0.86]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	110 / 2408	160 / 2397		0.67 [0.52,0.86]	Z=-3.15, p=0.0016
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7951	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.60.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

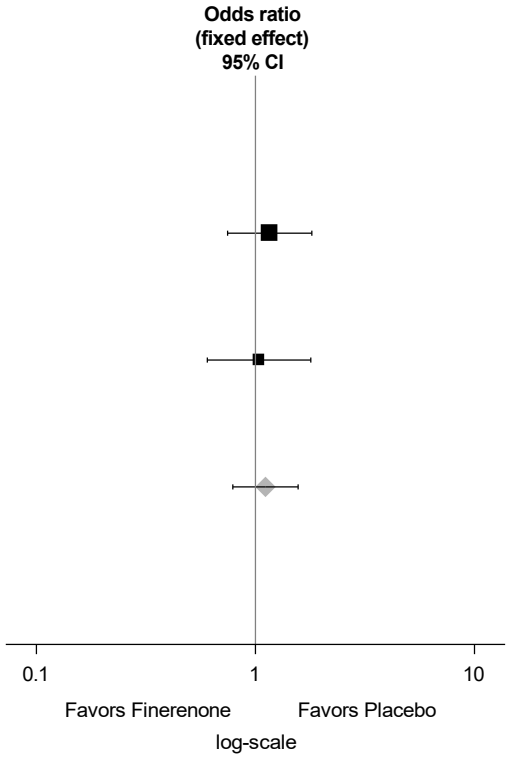
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	70 / 1556	103 / 1541	70.2	0.66 [0.48,0.90]	
FIGARO-DKD	32 / 637	40 / 627	29.8	0.78 [0.48,1.25]	
Total	102 / 2193	143 / 2168		0.69 [0.53,0.90]	Z=-2.78, p=0.0055
Heterogeneity:	Q=0.32 (df=1)	p=0.5697	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	48 / 1061	72 / 1069	65.1	0.66 [0.45,0.96]	
FIGARO-DKD	26 / 720	37 / 729	34.9	0.70 [0.42,1.17]	
Total	74 / 1781	109 / 1798		0.67 [0.50,0.91]	Z=-2.58, p=0.0099
Heterogeneity:	Q=0.04 (df=1)	p=0.8394	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8888	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.61: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

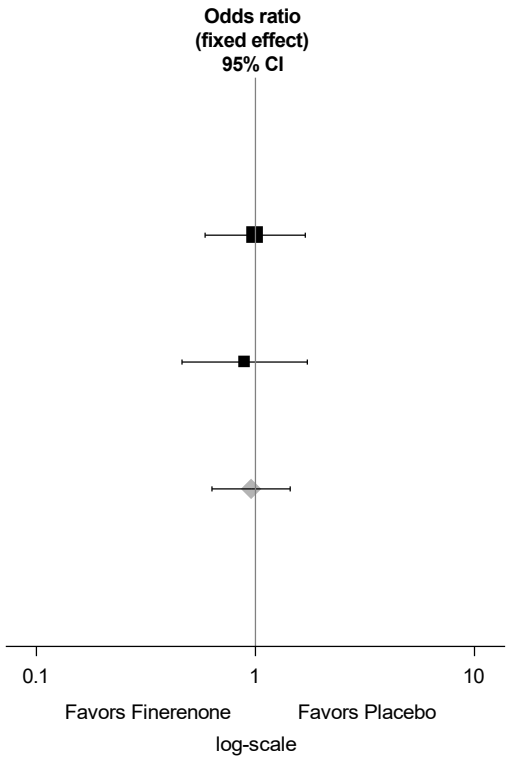
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	37 / 2610	60.1	1.16 [0.75,1.81]	
FIGARO-DKD	27 / 1357	26 / 1356	39.9	1.04 [0.60,1.79]	
Total	70 / 3974	63 / 3966		1.11 [0.79,1.57]	Z=0.60, p=0.5479
Heterogeneity:	Q=0.10 (df=1)	p=0.7540	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.62: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sinusitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

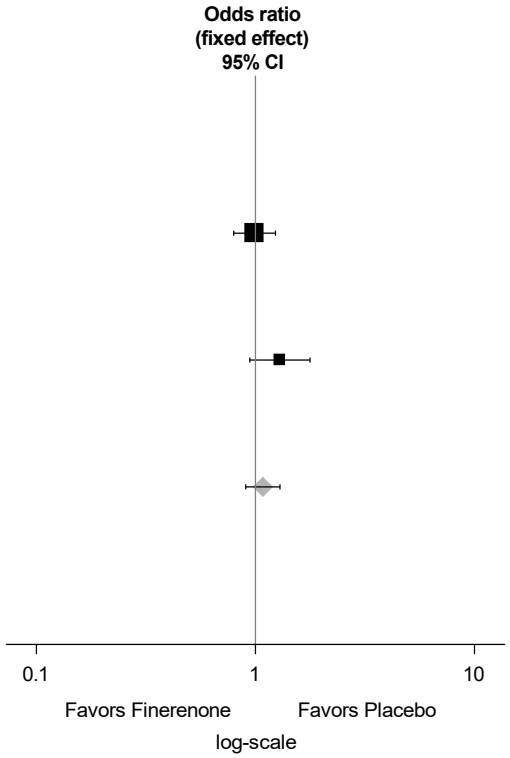
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	28 / 2610	61.0	1.00 [0.59,1.69]	
FIGARO-DKD	17 / 1357	19 / 1356	39.0	0.89 [0.46,1.73]	
Total	45 / 3974	47 / 3966		0.96 [0.63,1.44]	Z=-0.22, p=0.8267
Heterogeneity:	Q=0.07 (df=1)	p=0.7969	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.63: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Upper respiratory tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

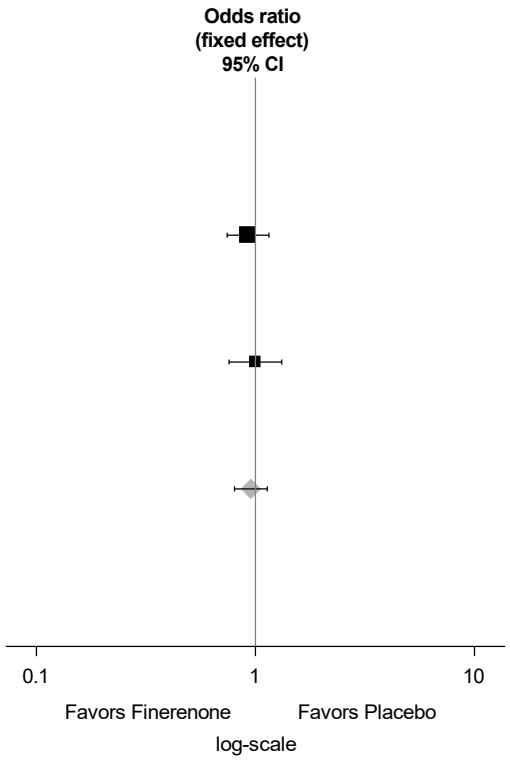
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	170 / 2617	171 / 2610	67.5	0.99 [0.80,1.23]	
FIGARO-DKD	93 / 1357	73 / 1356	32.5	1.29 [0.94,1.77]	
Total	263 / 3974	244 / 3966		1.08 [0.90,1.29]	Z=0.85, p=0.3963
Heterogeneity:	Q=1.84 (df=1)	p=0.1753	I^2=45.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.64: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

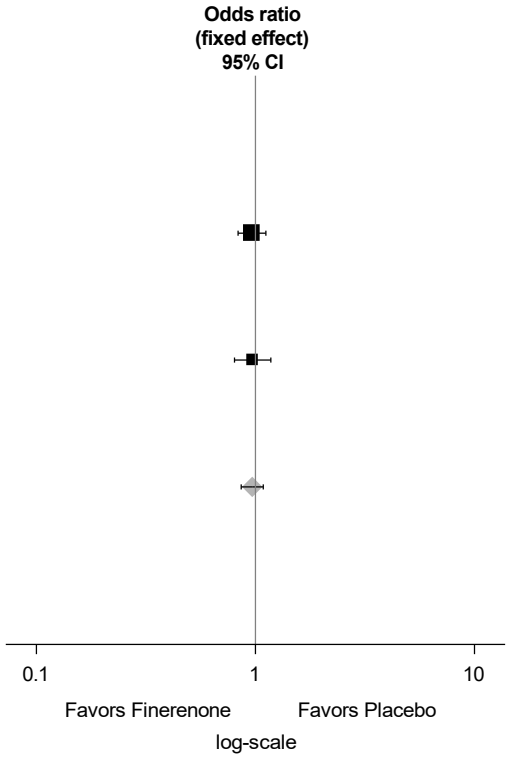
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	165 / 2617	177 / 2610	61.4	0.92 [0.74,1.15]	
FIGARO-DKD	109 / 1357	109 / 1356	38.6	1.00 [0.76,1.32]	
Total	274 / 3974	286 / 3966		0.95 [0.80,1.13]	Z=-0.55, p=0.5825
Heterogeneity:	Q=0.18 (df=1)	p=0.6685	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.65: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

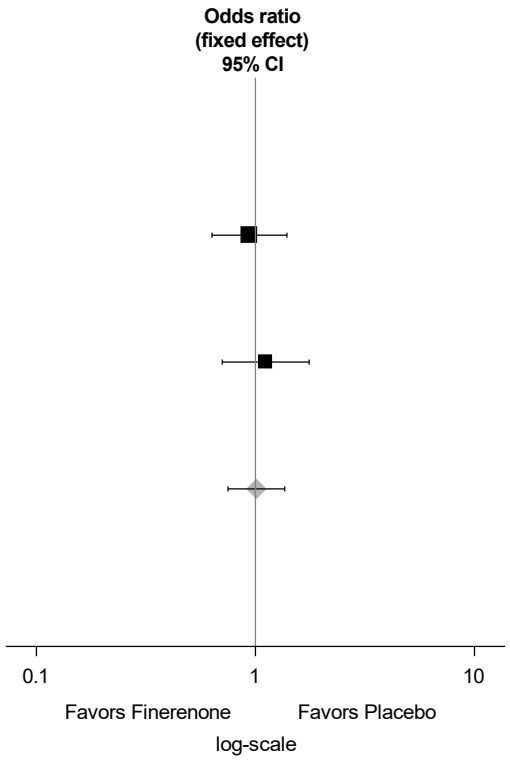
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	425 / 2617	437 / 2610	63.1	0.96 [0.83,1.12]	
FIGARO-DKD	258 / 1357	264 / 1356	36.9	0.97 [0.80,1.18]	
Total	683 / 3974	701 / 3966		0.97 [0.86,1.09]	Z=-0.57, p=0.5669
Heterogeneity:	Q=0.00 (df=1)	p=0.9534	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.66: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Contusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

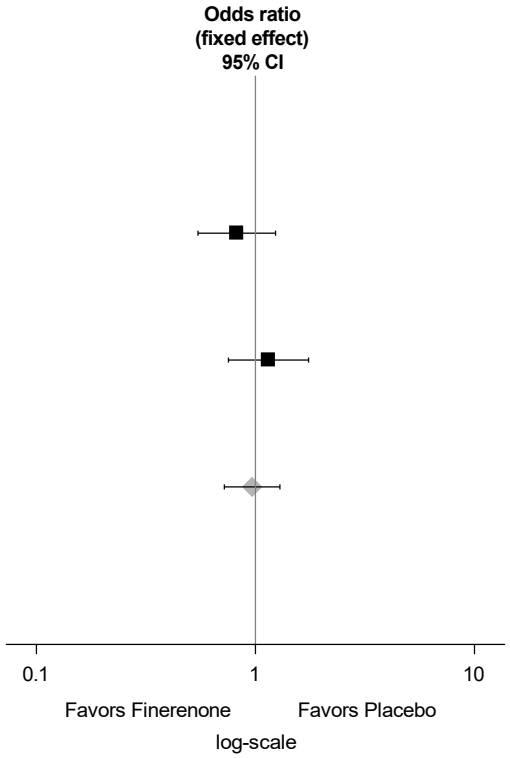
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2617	52 / 2610	57.3	0.94 [0.63,1.39]	
FIGARO-DKD	40 / 1357	36 / 1356	42.7	1.11 [0.71,1.76]	
Total	89 / 3974	88 / 3966		1.01 [0.75,1.36]	Z=0.06, p=0.9493
Heterogeneity:	Q=0.31 (df=1)	p=0.5785	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.67: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Fall (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

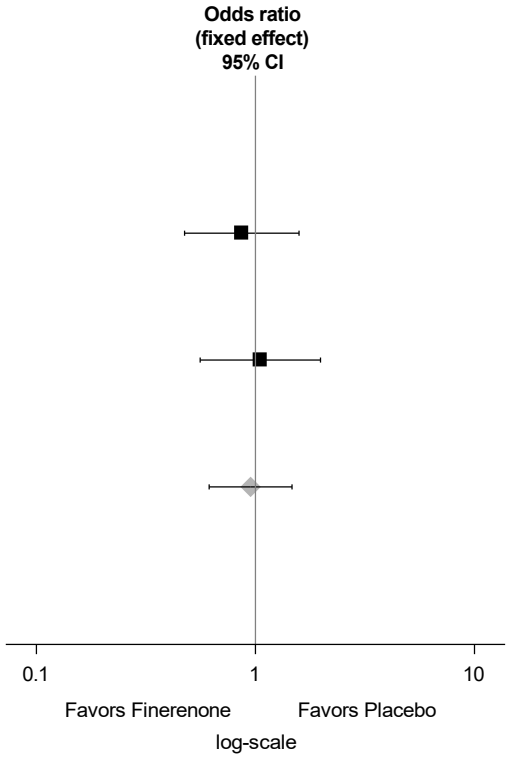
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	52 / 2610	51.6	0.82 [0.55,1.24]	
FIGARO-DKD	48 / 1357	42 / 1356	48.4	1.15 [0.75,1.75]	
Total	91 / 3974	94 / 3966		0.97 [0.72,1.29]	Z=-0.24, p=0.8139
Heterogeneity:	Q=1.24 (df=1)	p=0.2646	I^2=19.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.68: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Ligament sprain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

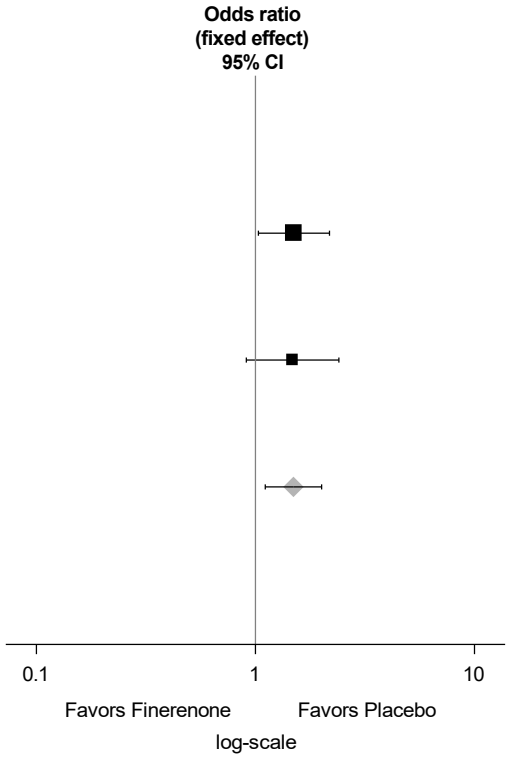
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	23 / 2610	52.5	0.87 [0.47,1.58]	
FIGARO-DKD	20 / 1357	19 / 1356	47.5	1.05 [0.56,1.98]	
Total	40 / 3974	42 / 3966		0.95 [0.61,1.47]	Z=-0.23, p=0.8180
Heterogeneity:	Q=0.19 (df=1)	p=0.6617	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.69: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

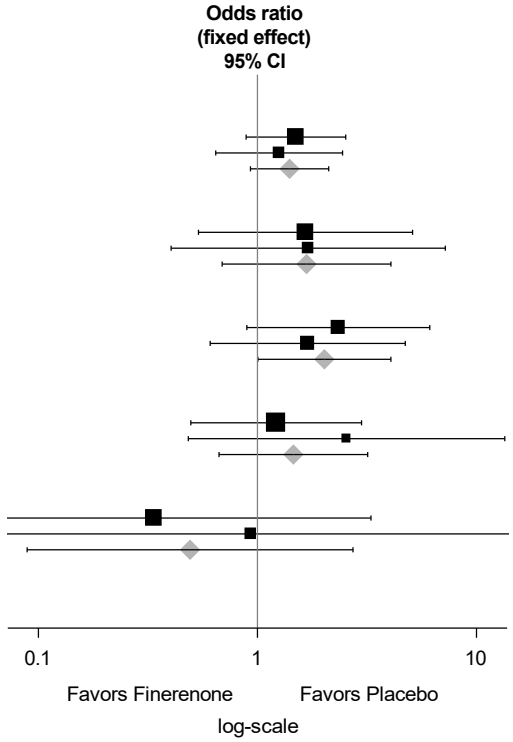
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	70 / 2617	47 / 2610	62.9	1.50 [1.03,2.18]	
FIGARO-DKD	41 / 1357	28 / 1356	37.1	1.48 [0.91,2.40]	
Total	111 / 3974	75 / 3966		1.49 [1.11,2.01]	Z=2.64, p=0.0083
Heterogeneity:	Q=0.00 (df=1)	p=0.9639	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.69.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

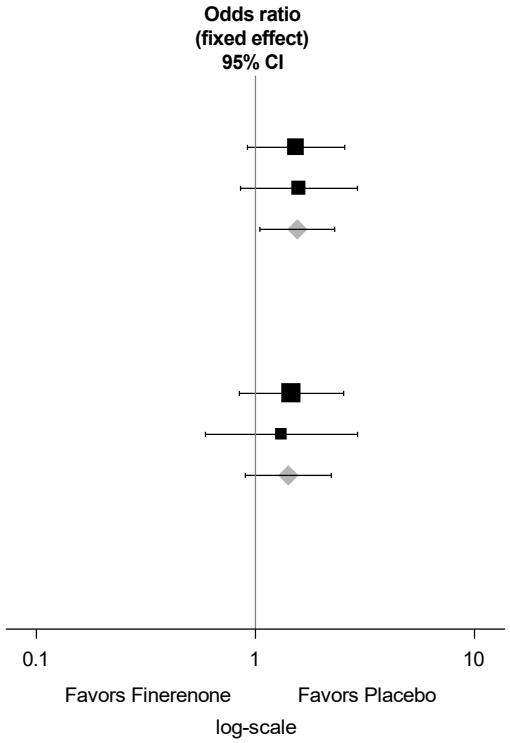
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	36 / 1075	24 / 1062	61.9	1.50 [0.89,2.53]	
FIGARO-DKD	20 / 638	16 / 637	38.1	1.26 [0.64,2.45]	
Total	56 / 1713	40 / 1699		1.40 [0.93,2.12]	Z=1.61, p=0.1077
Heterogeneity:	Q=0.17 (df=1)	p=0.6832	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	5 / 436	62.1	1.66 [0.54,5.11]	
FIGARO-DKD	5 / 267	3 / 271	37.9	1.70 [0.40,7.21]	
Total	13 / 691	8 / 707		1.68 [0.69,4.07]	Z=1.14, p=0.2542
Heterogeneity:	Q=0.00 (df=1)	p=0.9760	I^2=0.0%		
Asia					
FIDELIO-DKD	14 / 751	6 / 745	53.2	2.34 [0.89,6.12]	
FIGARO-DKD	10 / 289	6 / 290	46.8	1.70 [0.61,4.73]	
Total	24 / 1040	12 / 1035		2.02 [1.00,4.07]	Z=1.97, p=0.0486
Heterogeneity:	Q=0.20 (df=1)	p=0.6540	I^2=0.0%		
Latin America					
FIDELIO-DKD	11 / 273	9 / 270	77.5	1.22 [0.50,2.99]	
FIGARO-DKD	5 / 102	2 / 101	22.5	2.55 [0.48,13.47]	
Total	16 / 375	11 / 371		1.46 [0.67,3.19]	Z=0.95, p=0.3438
Heterogeneity:	Q=0.59 (df=1)	p=0.4425	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	60.0	0.34 [0.03,3.30]	
FIGARO-DKD	1 / 61	1 / 57	40.0	0.93 [0.06,15.28]	
Total	2 / 155	4 / 154		0.49 [0.09,2.73]	Z=-0.81, p=0.4175
Heterogeneity:	Q=0.31 (df=1)	p=0.5794	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.49 (df=4)	p=0.6463	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.69.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

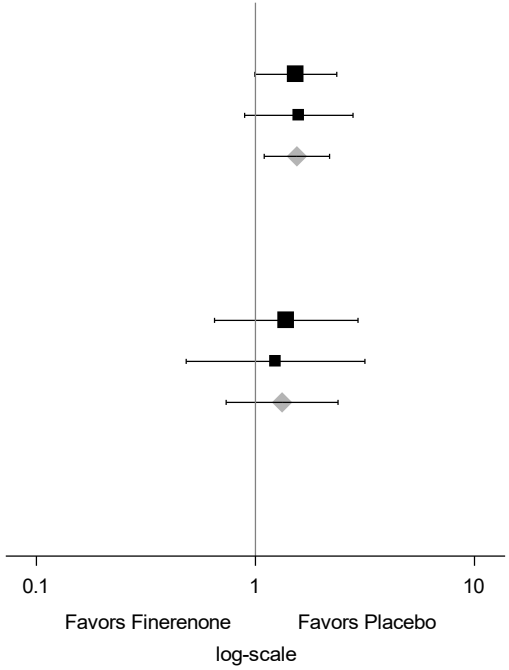
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	38 / 1213	25 / 1210	59.1	1.53 [0.92,2.56]	
FIGARO-DKD	27 / 862	17 / 848	40.9	1.58 [0.86,2.92]	
Total	65 / 2075	42 / 2058		1.55 [1.05,2.30]	Z=2.19, p=0.0283
Heterogeneity:	Q=0.01 (df=1)	p=0.9401	I^2=0.0%		
Absent					
FIDELIO-DKD	32 / 1404	22 / 1400	68.0	1.46 [0.84,2.53]	
FIGARO-DKD	14 / 495	11 / 508	32.0	1.32 [0.59,2.93]	
Total	46 / 1899	33 / 1908		1.41 [0.90,2.22]	Z=1.50, p=0.1338
Heterogeneity:	Q=0.05 (df=1)	p=0.8316	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.09 (df=1)	p=0.7580	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.69.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

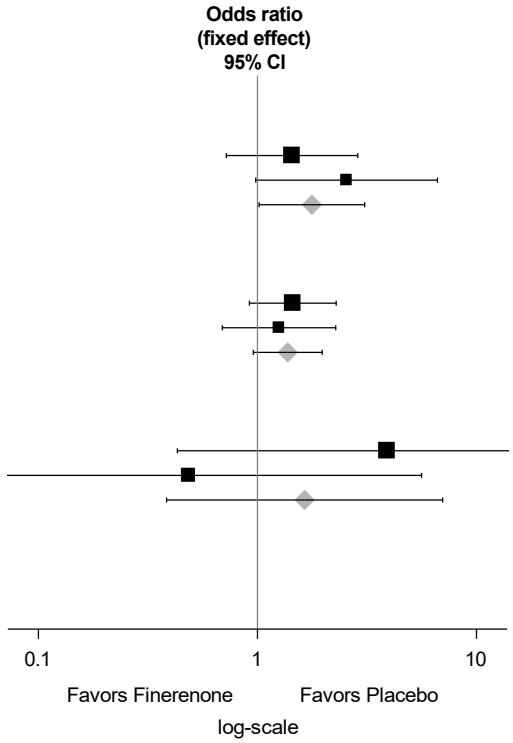
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	54 / 1735	35 / 1700	63.6	1.53 [0.99,2.35]	
FIGARO-DKD	31 / 924	20 / 929	36.4	1.58 [0.89,2.79]	
Total	85 / 2659	55 / 2629		1.55 [1.10,2.18]	Z=2.49, p=0.0129
Heterogeneity:	Q=0.01 (df=1)	p=0.9301	I^2=0.0%		
> 4.5					
FIDELIO-DKD	16 / 882	12 / 910	60.8	1.38 [0.65,2.94]	
FIGARO-DKD	10 / 433	8 / 426	39.2	1.24 [0.48,3.16]	
Total	26 / 1315	20 / 1336		1.32 [0.73,2.38]	Z=0.93, p=0.3508
Heterogeneity:	Q=0.03 (df=1)	p=0.8545	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6540	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.69.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

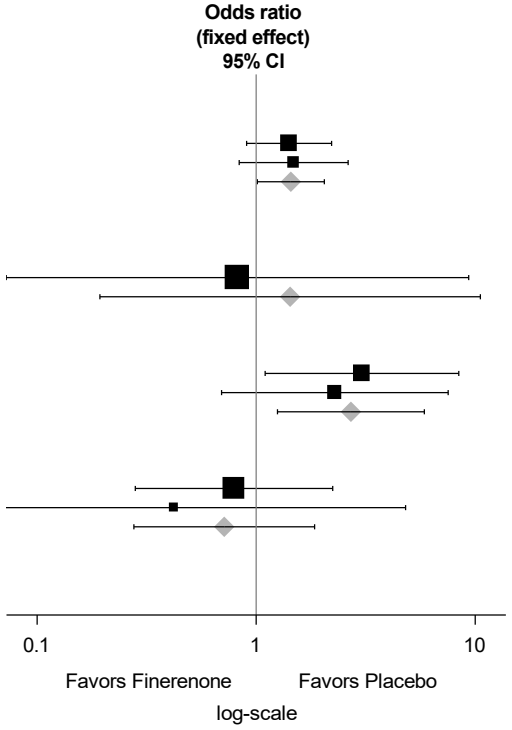
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	20 / 724	14 / 723	65.6	1.44 [0.72,2.87]	
FIGARO-DKD	15 / 494	6 / 495	34.4	2.55 [0.98,6.63]	
Total	35 / 1218	20 / 1218		1.77 [1.02,3.09]	Z=2.02, p=0.0434
Heterogeneity:	Q=0.91 (df=1)	p=0.3401	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	46 / 1759	32 / 1760	63.1	1.45 [0.92,2.29]	
FIGARO-DKD	25 / 829	20 / 827	36.9	1.25 [0.69,2.28]	
Total	71 / 2588	52 / 2587		1.38 [0.96,1.97]	Z=1.72, p=0.0846
Heterogeneity:	Q=0.14 (df=1)	p=0.7054	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	1 / 127	55.2	3.91 [0.43,35.44]	
FIGARO-DKD	1 / 34	2 / 34	44.8	0.48 [0.04,5.61]	
Total	5 / 167	3 / 161		1.64 [0.38,7.01]	Z=0.67, p=0.5030
Heterogeneity:	Q=1.55 (df=1)	p=0.2136	I^2=35.3%		
Subgroup Heterogeneity:	Q=0.58 (df=2)	p=0.7480	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.69.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

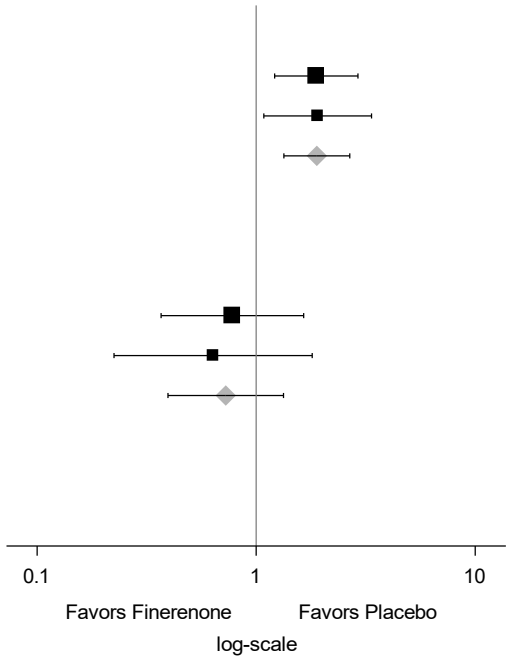
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	47 / 1634	34 / 1657	62.2	1.41 [0.90,2.21]	
FIGARO-DKD	30 / 1010	20 / 989	37.8	1.48 [0.84,2.63]	
Total	77 / 2644	54 / 2646		1.44 [1.01,2.05]	Z=2.03, p=0.0425
Heterogeneity:	Q=0.02 (df=1)	p=0.8970	I^2=0.0%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	12E10 [12E10,12E10]	
FIGARO-DKD	1 / 43	2 / 71	100.0	0.82 [0.07,9.34]	
Total	2 / 172	2 / 186		1.43 [0.19,10.56]	Z=0.35, p=0.7265
Heterogeneity:	Q=0.20 (df=1)	p=0.6553	I^2=0.0%		
Asian					
FIDELIO-DKD	15 / 678	5 / 677	57.8	3.04 [1.10,8.41]	
FIGARO-DKD	9 / 252	4 / 251	42.2	2.29 [0.70,7.53]	
Total	24 / 930	9 / 928		2.71 [1.25,5.86]	Z=2.53, p=0.0114
Heterogeneity:	Q=0.13 (df=1)	p=0.7215	I^2=0.0%		
Others					
FIDELIO-DKD	7 / 176	8 / 161	84.6	0.79 [0.28,2.24]	
FIGARO-DKD	1 / 52	2 / 45	15.4	0.42 [0.04,4.81]	
Total	8 / 228	10 / 206		0.71 [0.28,1.85]	Z=-0.69, p=0.4885
Heterogeneity:	Q=0.22 (df=1)	p=0.6403	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.63 (df=3)	p=0.2009	I^2=35.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.69.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

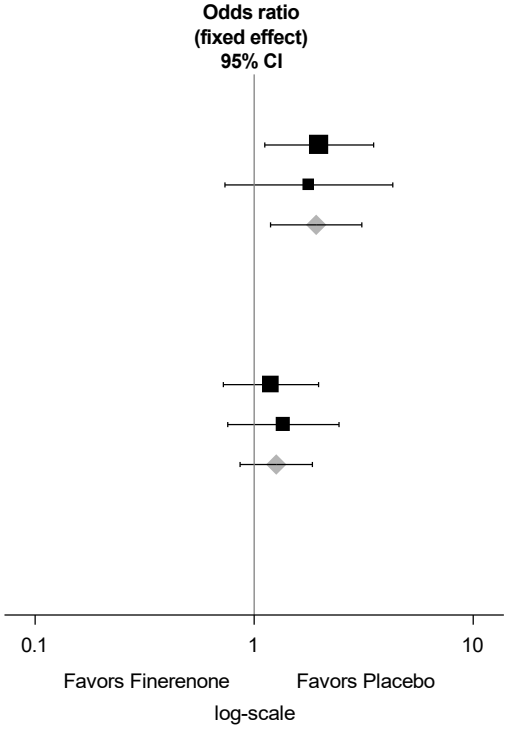
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	57 / 1797	32 / 1870	62.6	1.88 [1.21,2.92]	
FIGARO-DKD	35 / 917	19 / 933	37.4	1.91 [1.08,3.36]	
Total	92 / 2714	51 / 2803		1.89 [1.34,2.67]	Z=3.61, p=0.0003
Heterogeneity:	Q=0.00 (df=1)	p=0.9685	I^2=0.0%		
Female					
FIDELIO-DKD	13 / 820	15 / 740	65.9	0.78 [0.37,1.65]	
FIGARO-DKD	6 / 440	9 / 423	34.1	0.64 [0.22,1.80]	
Total	19 / 1260	24 / 1163		0.73 [0.40,1.33]	Z=-1.03, p=0.3018
Heterogeneity:	Q=0.10 (df=1)	p=0.7572	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.20 (df=1)	p=0.0073	I^2=86.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.69.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

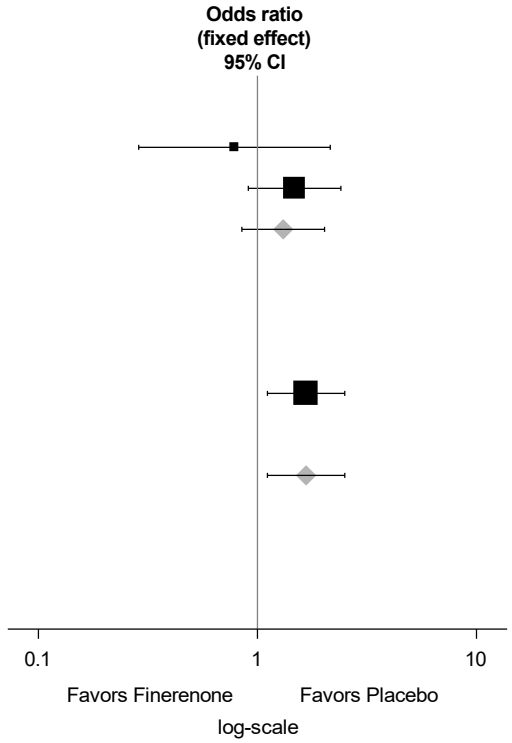
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	36 / 1103	18 / 1075	70.4	1.98 [1.12,3.51]	
FIGARO-DKD	14 / 336	8 / 335	29.6	1.78 [0.74,4.29]	
Total	50 / 1439	26 / 1410		1.92 [1.19,3.10]	Z=2.66, p=0.0077
Heterogeneity:	Q=0.04 (df=1)	p=0.8394	I^2=0.0%		
>= 65					
FIDELIO-DKD	34 / 1514	29 / 1535	57.7	1.19 [0.72,1.97]	
FIGARO-DKD	27 / 1021	20 / 1021	42.3	1.36 [0.76,2.44]	
Total	61 / 2535	49 / 2556		1.26 [0.86,1.84]	Z=1.20, p=0.2317
Heterogeneity:	Q=0.11 (df=1)	p=0.7394	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.81 (df=1)	p=0.1788	I^2=44.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.69.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

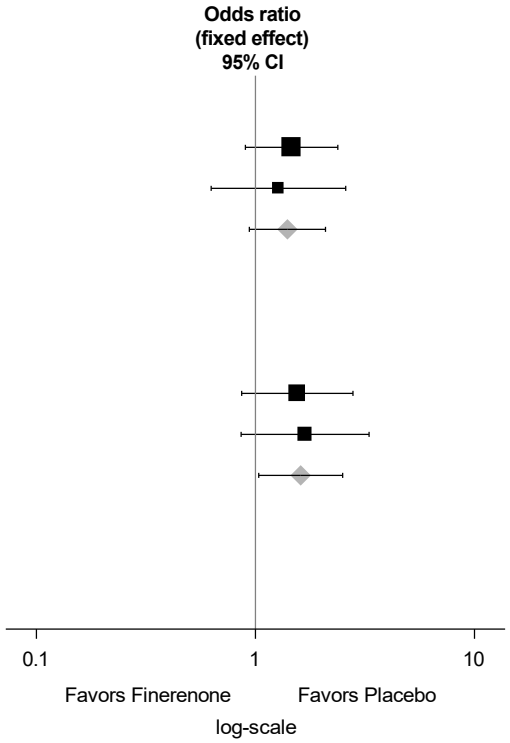
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	9 / 213	18.9	0.79 [0.29,2.15]	
FIGARO-DKD	41 / 1357	28 / 1356	81.1	1.48 [0.91,2.40]	
Total	48 / 1566	37 / 1569		1.31 [0.85,2.02]	Z=1.22, p=0.2223
Heterogeneity:	Q=1.23 (df=1)	p=0.2680	I^2=18.5%		
Very High					
FIDELIO-DKD	63 / 2408	38 / 2397	100.0	1.67 [1.11,2.50]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	63 / 2408	38 / 2397		1.67 [1.11,2.50]	Z=2.47, p=0.0137
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.63 (df=1)	p=0.4280	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.69.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Limb injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

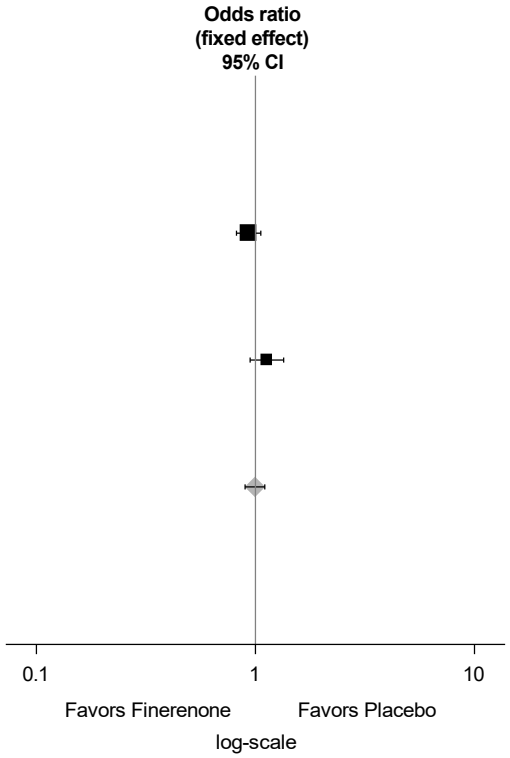
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	41 / 1556	28 / 1541	68.0	1.46 [0.90,2.38]	
FIGARO-DKD	18 / 637	14 / 627	32.0	1.27 [0.63,2.58]	
Total	59 / 2193	42 / 2168		1.40 [0.94,2.09]	Z=1.65, p=0.0999
Heterogeneity:	Q=0.10 (df=1)	p=0.7518	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	19 / 1069	56.9	1.55 [0.87,2.79]	
FIGARO-DKD	23 / 720	14 / 729	43.1	1.69 [0.86,3.30]	
Total	52 / 1781	33 / 1798		1.61 [1.03,2.50]	Z=2.11, p=0.0347
Heterogeneity:	Q=0.03 (df=1)	p=0.8573	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.21 (df=1)	p=0.6461	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.70: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

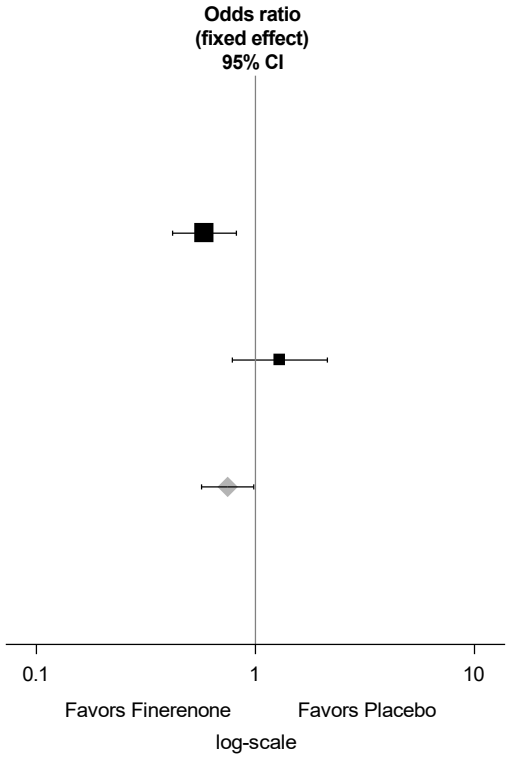
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	598 / 2617	630 / 2610	65.5	0.93 [0.82,1.06]	
FIGARO-DKD	341 / 1357	311 / 1356	34.5	1.13 [0.95,1.35]	
Total	939 / 3974	941 / 3966		0.99 [0.90,1.10]	Z=-0.10, p=0.9183
Heterogeneity:	Q=2.98 (df=1)	p=0.0842	I^2=66.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.71: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

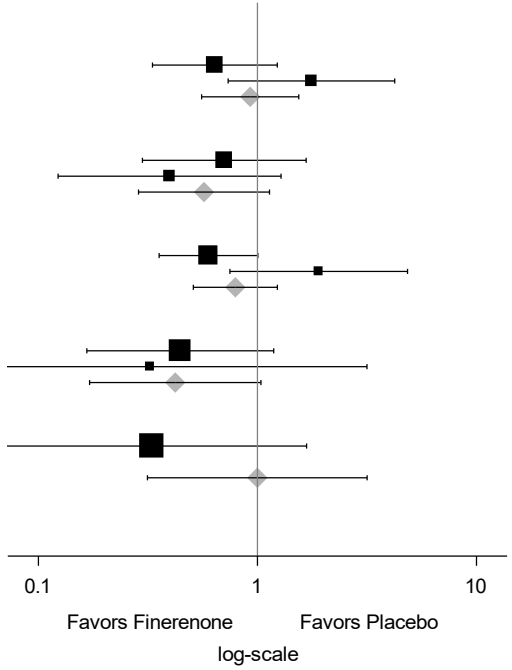
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	56 / 2617	94 / 2610	68.9	0.59 [0.42,0.82]	
FIGARO-DKD	36 / 1357	28 / 1356	31.1	1.29 [0.78,2.13]	
Total	92 / 3974	122 / 3966		0.75 [0.57,0.98]	Z=-2.09, p=0.0368
Heterogeneity:	Q=6.66 (df=1)	p=0.0099	I^2=85.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.71.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

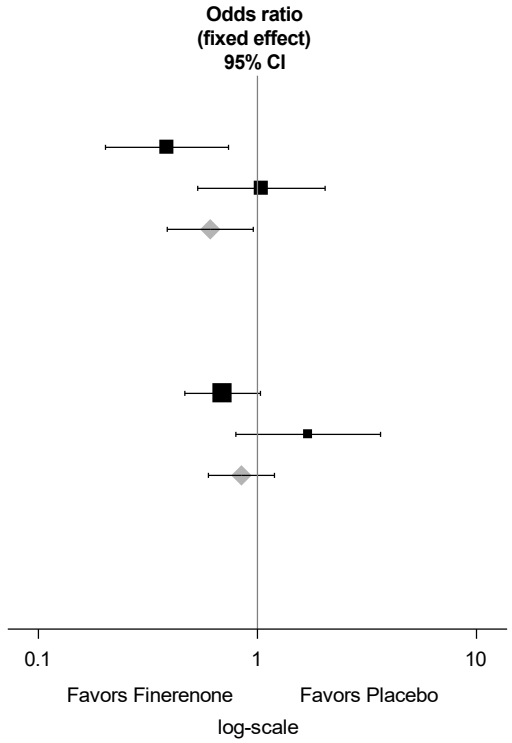
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	23 / 1062	64.0	0.64 [0.33,1.23]	
FIGARO-DKD	14 / 638	8 / 637	36.0	1.76 [0.73,4.23]	
Total	29 / 1713	31 / 1699		0.93 [0.56,1.54]	Z=-0.29, p=0.7697
Heterogeneity:	Q=3.31 (df=1)	p=0.0690	I^2=69.8%		
North America					
FIDELIO-DKD	9 / 424	13 / 436	65.0	0.71 [0.30,1.67]	
FIGARO-DKD	4 / 267	10 / 271	35.0	0.40 [0.12,1.28]	
Total	13 / 691	23 / 707		0.57 [0.29,1.13]	Z=-1.60, p=0.1097
Heterogeneity:	Q=0.60 (df=1)	p=0.4377	I^2=0.0%		
Asia					
FIDELIO-DKD	24 / 751	39 / 745	76.4	0.60 [0.36,1.00]	
FIGARO-DKD	13 / 289	7 / 290	23.6	1.90 [0.75,4.84]	
Total	37 / 1040	46 / 1035		0.79 [0.51,1.23]	Z=-1.03, p=0.3026
Heterogeneity:	Q=4.52 (df=1)	p=0.0334	I^2=77.9%		
Latin America					
FIDELIO-DKD	6 / 273	13 / 270	84.3	0.44 [0.17,1.19]	
FIGARO-DKD	1 / 102	3 / 101	15.7	0.32 [0.03,3.16]	
Total	7 / 375	16 / 371		0.42 [0.17,1.04]	Z=-1.88, p=0.0601
Heterogeneity:	Q=0.06 (df=1)	p=0.8021	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	6 / 97	100.0	0.33 [0.06,1.68]	
FIGARO-DKD	4 / 61	0 / 57	0.0	146E9 [146E9,146E9]	
Total	6 / 155	6 / 154		1.00 [0.31,3.17]	Z=-0.00, p=0.9977
Heterogeneity:	Q=1.78 (df=1)	p=0.1818	I^2=43.9%		
Subgroup Heterogeneity:	Q=3.14 (df=4)	p=0.5354	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.71.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

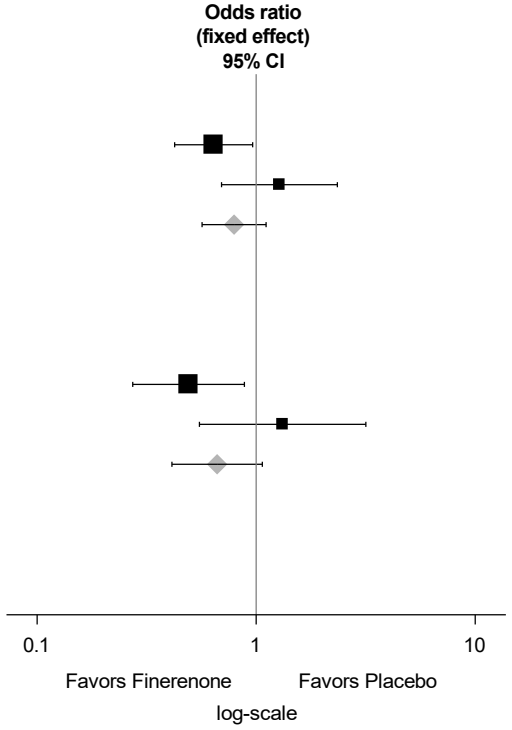
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1213	33 / 1210	51.7	0.39 [0.20,0.74]	
FIGARO-DKD	18 / 862	17 / 848	48.3	1.04 [0.53,2.04]	
Total	31 / 2075	50 / 2058		0.61 [0.39,0.96]	Z=-2.15, p=0.0316
Heterogeneity:	Q=4.38 (df=1)	p=0.0365	I^2=77.1%		
Absent					
FIDELIO-DKD	43 / 1404	61 / 1400	78.5	0.69 [0.47,1.03]	
FIGARO-DKD	18 / 495	11 / 508	21.5	1.70 [0.80,3.65]	
Total	61 / 1899	72 / 1908		0.85 [0.60,1.20]	Z=-0.95, p=0.3421
Heterogeneity:	Q=4.22 (df=1)	p=0.0399	I^2=76.3%		
Subgroup Heterogeneity:	Q=1.27 (df=1)	p=0.2599	I^2=21.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.71.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

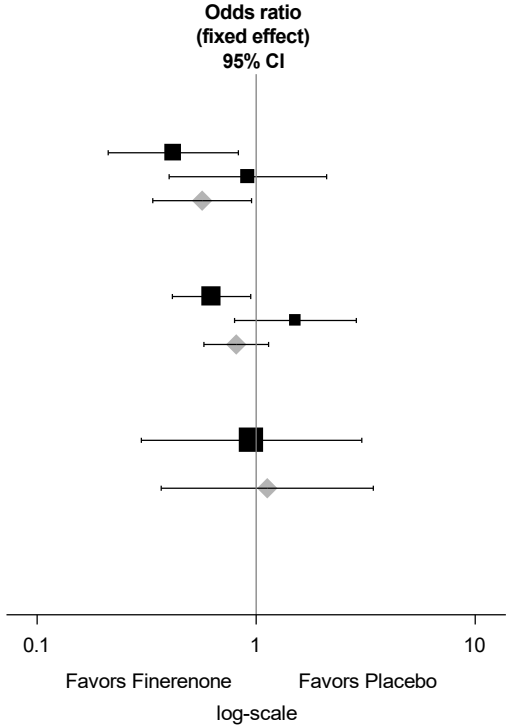
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	39 / 1735	59 / 1700	68.8	0.64 [0.42,0.96]	
FIGARO-DKD	24 / 924	19 / 929	31.2	1.28 [0.69,2.35]	
Total	63 / 2659	78 / 2629		0.79 [0.57,1.11]	Z=-1.35, p=0.1760
Heterogeneity:	Q=3.41 (df=1)	p=0.0648	I^2=70.7%		
> 4.5					
FIDELIO-DKD	17 / 882	35 / 910	69.0	0.49 [0.27,0.88]	
FIGARO-DKD	12 / 433	9 / 426	31.0	1.32 [0.55,3.17]	
Total	29 / 1315	44 / 1336		0.66 [0.41,1.07]	Z=-1.69, p=0.0904
Heterogeneity:	Q=3.38 (df=1)	p=0.0658	I^2=70.5%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5485	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.71.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

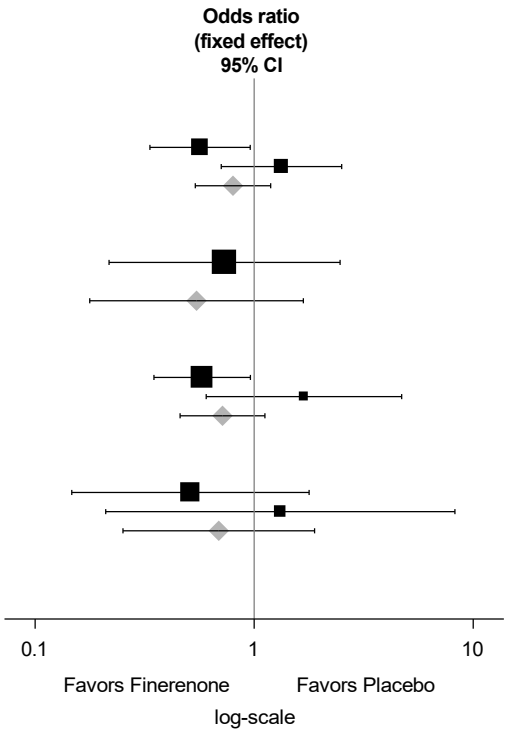
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	28 / 723	59.4	0.42 [0.21,0.83]	
FIGARO-DKD	11 / 494	12 / 495	40.6	0.92 [0.40,2.10]	
Total	23 / 1218	40 / 1218		0.57 [0.34,0.95]	Z=-2.14, p=0.0320
Heterogeneity:	Q=2.05 (df=1)	p=0.1520	I^2=51.3%		
130 - < 160					
FIDELIO-DKD	38 / 1759	60 / 1760	70.7	0.63 [0.41,0.94]	
FIGARO-DKD	24 / 829	16 / 827	29.3	1.51 [0.80,2.87]	
Total	62 / 2588	76 / 2587		0.81 [0.58,1.14]	Z=-1.21, p=0.2271
Heterogeneity:	Q=5.16 (df=1)	p=0.0231	I^2=80.6%		
>= 160					
FIDELIO-DKD	6 / 133	6 / 127	100.0	0.95 [0.30,3.04]	
FIGARO-DKD	1 / 34	0 / 34	0.0	172E9 [172E9,172E9]	
Total	7 / 167	6 / 161		1.12 [0.37,3.43]	Z=0.21, p=0.8375
Heterogeneity:	Q=0.08 (df=1)	p=0.7801	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=2)	p=0.4010	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.71.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

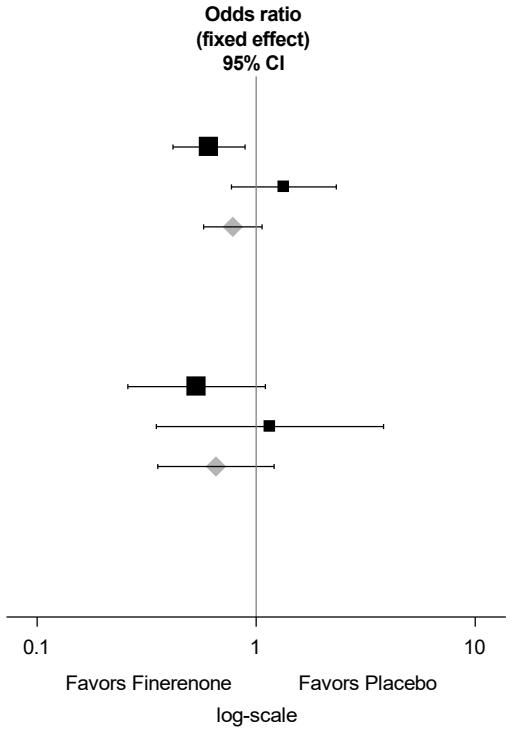
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	22 / 1634	39 / 1657	59.1	0.57 [0.33,0.96]	
FIGARO-DKD	23 / 1010	17 / 989	40.9	1.33 [0.71,2.51]	
Total	45 / 2644	56 / 2646		0.80 [0.54,1.19]	Z=-1.10, p=0.2703
Heterogeneity:	Q=4.15 (df=1)	p=0.0417	I^2=75.9%		
Black					
FIDELIO-DKD	5 / 129	6 / 115	100.0	0.73 [0.22,2.47]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,2E297]	
Total	5 / 172	9 / 186		0.55 [0.18,1.68]	Z=-1.06, p=0.2903
Heterogeneity:	Q=0.23 (df=1)	p=0.6345	I^2=0.0%		
Asian					
FIDELIO-DKD	25 / 678	42 / 677	80.4	0.58 [0.35,0.96]	
FIGARO-DKD	10 / 252	6 / 251	19.6	1.69 [0.60,4.71]	
Total	35 / 930	48 / 928		0.72 [0.46,1.12]	Z=-1.46, p=0.1431
Heterogeneity:	Q=3.35 (df=1)	p=0.0672	I^2=70.1%		
Others					
FIDELIO-DKD	4 / 176	7 / 161	68.4	0.51 [0.15,1.78]	
FIGARO-DKD	3 / 52	2 / 45	31.6	1.32 [0.21,8.25]	
Total	7 / 228	9 / 206		0.69 [0.25,1.89]	Z=-0.72, p=0.4690
Heterogeneity:	Q=0.70 (df=1)	p=0.4040	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.47 (df=3)	p=0.9251	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.71.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

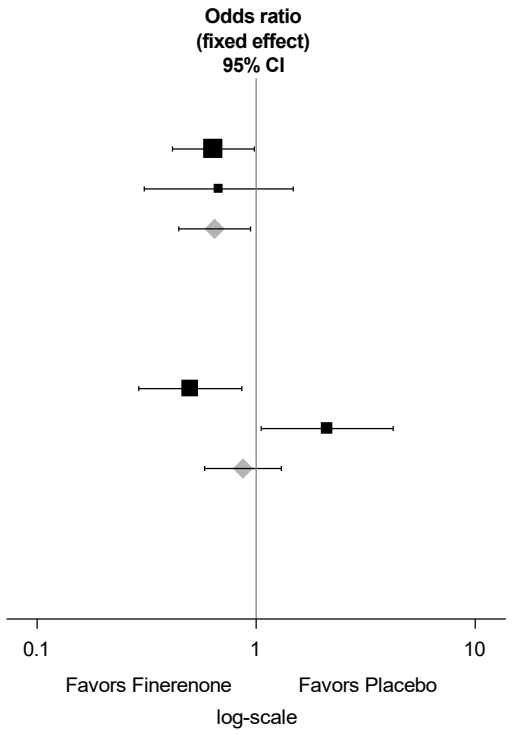
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	44 / 1797	74 / 1870	67.9	0.61 [0.42,0.89]	
FIGARO-DKD	30 / 917	23 / 933	32.1	1.34 [0.77,2.32]	
Total	74 / 2714	97 / 2803		0.78 [0.58,1.06]	Z=-1.57, p=0.1175
Heterogeneity:	Q=5.32 (df=1)	p=0.0211	I^2=81.2%		
Female					
FIDELIO-DKD	12 / 820	20 / 740	73.2	0.53 [0.26,1.10]	
FIGARO-DKD	6 / 440	5 / 423	26.8	1.16 [0.35,3.82]	
Total	18 / 1260	25 / 1163		0.66 [0.36,1.21]	Z=-1.36, p=0.1753
Heterogeneity:	Q=1.17 (df=1)	p=0.2791	I^2=14.6%		
Subgroup Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.71.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	36 / 1103	54 / 1075	76.8	0.64 [0.41,0.98]	
FIGARO-DKD	11 / 336	16 / 335	23.2	0.67 [0.31,1.48]	
Total	47 / 1439	70 / 1410		0.65 [0.44,0.94]	Z=-2.27, p=0.0233
Heterogeneity:	Q=0.02 (df=1)	p=0.9019	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1514	40 / 1535	62.1	0.50 [0.29,0.86]	
FIGARO-DKD	25 / 1021	12 / 1021	37.9	2.11 [1.05,4.22]	
Total	45 / 2535	52 / 2556		0.87 [0.58,1.30]	Z=-0.67, p=0.4998
Heterogeneity:	Q=10.28 (df=1)	p=0.0013	I^2=90.3%		
Subgroup Heterogeneity:	Q=1.12 (df=1)	p=0.2902	I^2=10.6%		

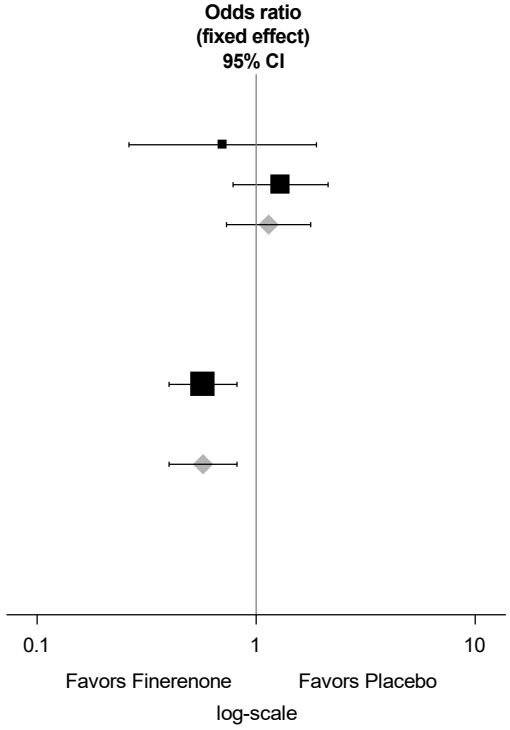


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.71.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

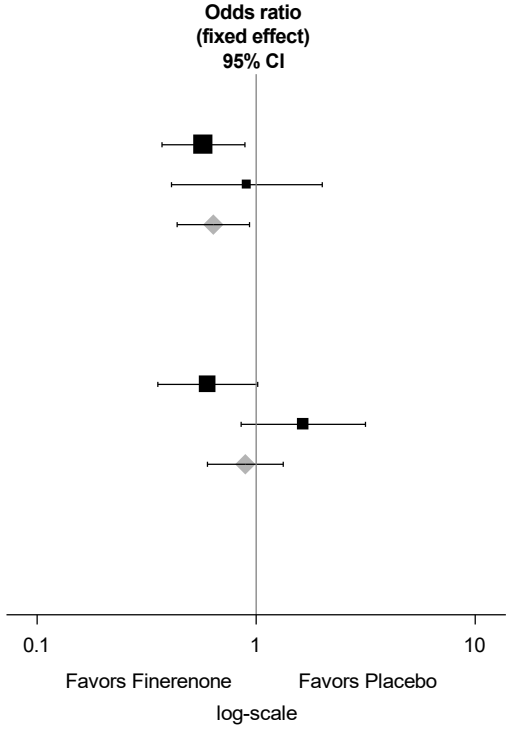
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	10 / 213	20.5	0.70 [0.26,1.88]	
FIGARO-DKD	36 / 1357	28 / 1356	79.5	1.29 [0.78,2.13]	
Total	43 / 1566	38 / 1569		1.14 [0.73,1.77]	Z=0.58, p=0.5630
Heterogeneity:	Q=1.16 (df=1)	p=0.2805	I^2=14.1%		
Very High					
FIDELIO-DKD	49 / 2408	84 / 2397	100.0	0.57 [0.40,0.82]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	49 / 2408	84 / 2397		0.57 [0.40,0.82]	Z=-3.07, p=0.0022
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.65 (df=1)	p=0.0175	I^2=82.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.71.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood creatine phosphokinase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

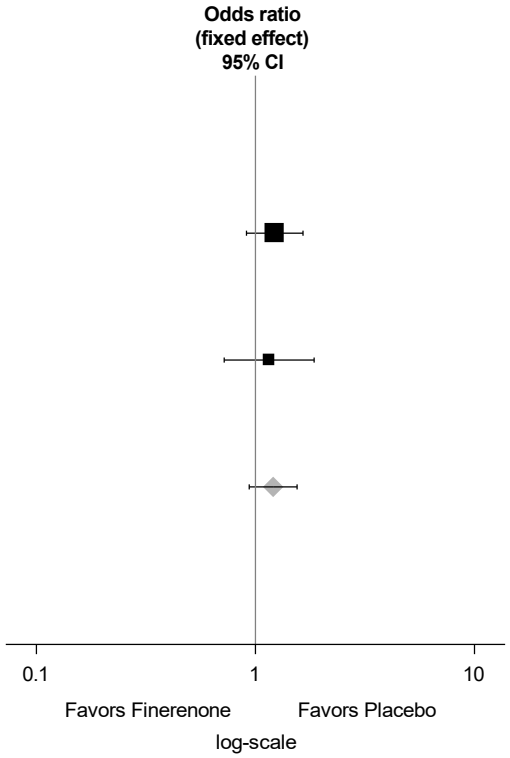
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	33 / 1556	56 / 1541	76.8	0.57 [0.37,0.89]	
FIGARO-DKD	12 / 637	13 / 627	23.2	0.91 [0.41,2.00]	
Total	45 / 2193	69 / 2168		0.64 [0.44,0.93]	Z=-2.32, p=0.0203
Heterogeneity:	Q=0.98 (df=1)	p=0.3227	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	23 / 1061	38 / 1069	60.8	0.60 [0.36,1.02]	
FIGARO-DKD	24 / 720	15 / 729	39.2	1.64 [0.85,3.16]	
Total	47 / 1781	53 / 1798		0.89 [0.60,1.33]	Z=-0.56, p=0.5751
Heterogeneity:	Q=5.52 (df=1)	p=0.0188	I^2=81.9%		
Subgroup Heterogeneity:	Q=1.43 (df=1)	p=0.2312	I^2=30.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.72: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood creatinine increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

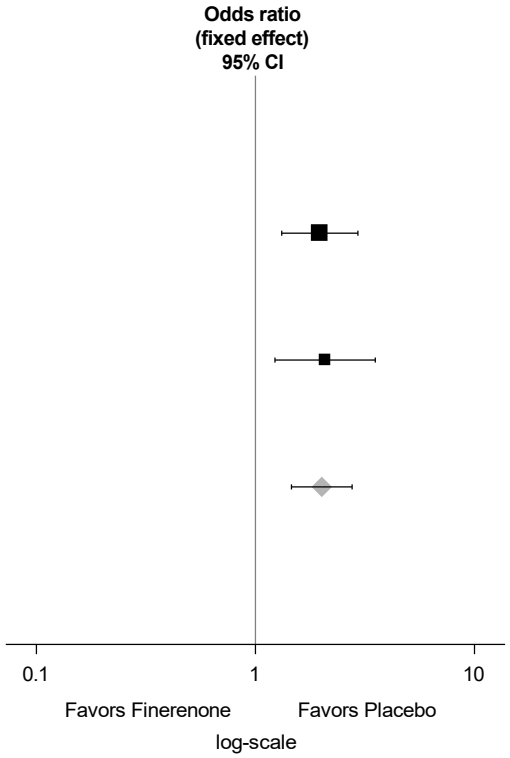
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	82 / 2610	71.7	1.22 [0.91,1.65]	
FIGARO-DKD	38 / 1357	33 / 1356	28.3	1.16 [0.72,1.85]	
Total	138 / 3974	115 / 3966		1.20 [0.94,1.55]	Z=1.45, p=0.1468
Heterogeneity:	Q=0.04 (df=1)	p=0.8367	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.73: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

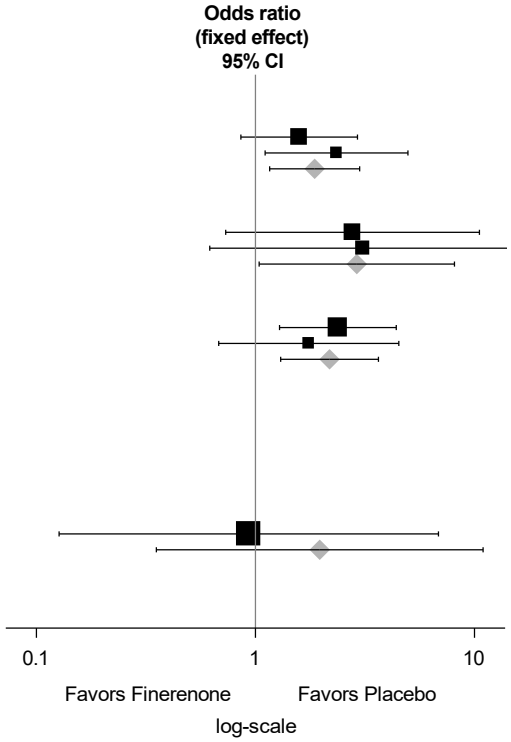
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	72 / 2617	37 / 2610	63.4	1.97 [1.32,2.94]	
FIGARO-DKD	43 / 1357	21 / 1356	36.6	2.08 [1.23,3.52]	
Total	115 / 3974	58 / 3966		2.01 [1.46,2.76]	Z=4.29, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8687	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.73.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

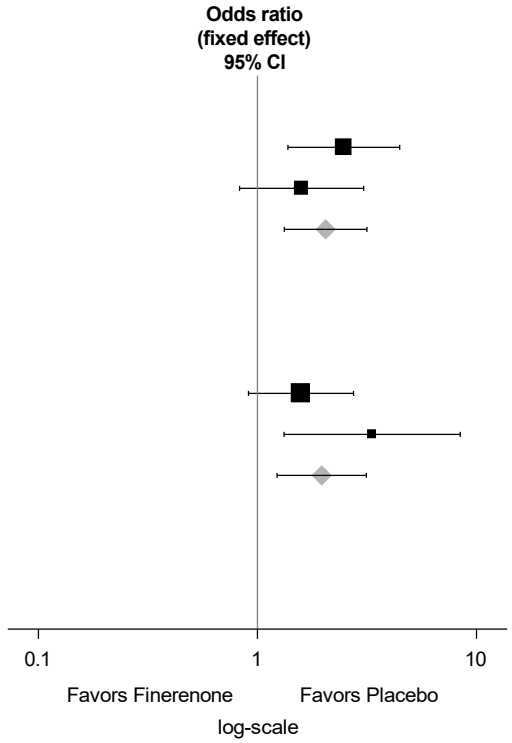
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 1075	17 / 1062	60.0	1.58 [0.86,2.92]	
FIGARO-DKD	23 / 638	10 / 637	40.0	2.34 [1.11,4.97]	
Total	50 / 1713	27 / 1699		1.86 [1.16,2.99]	Z=2.58, p=0.0099
Heterogeneity:	Q=0.63 (df=1)	p=0.4271	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	3 / 436	59.3	2.78 [0.73,10.53]	
FIGARO-DKD	6 / 267	2 / 271	40.7	3.09 [0.62,15.46]	
Total	14 / 691	5 / 707		2.90 [1.04,8.10]	Z=2.03, p=0.0419
Heterogeneity:	Q=0.01 (df=1)	p=0.9194	I^2=0.0%		
Asia					
FIDELIO-DKD	35 / 751	15 / 745	70.4	2.38 [1.29,4.39]	
FIGARO-DKD	12 / 289	7 / 290	29.6	1.75 [0.68,4.51]	
Total	47 / 1040	22 / 1035		2.18 [1.30,3.64]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.28 (df=1)	p=0.5946	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	2 / 270	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	0 / 375	2 / 371		0.00 [0.00,86E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	2 / 94	0 / 97	0.0	123E9 [123E9,123E9]	
FIGARO-DKD	2 / 61	2 / 57	100.0	0.93 [0.13,6.85]	
Total	4 / 155	2 / 154		1.97 [0.35,10.95]	Z=0.77, p=0.4408
Heterogeneity:	Q=0.54 (df=1)	p=0.4636	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.65 (df=4)	p=0.9576	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.73.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

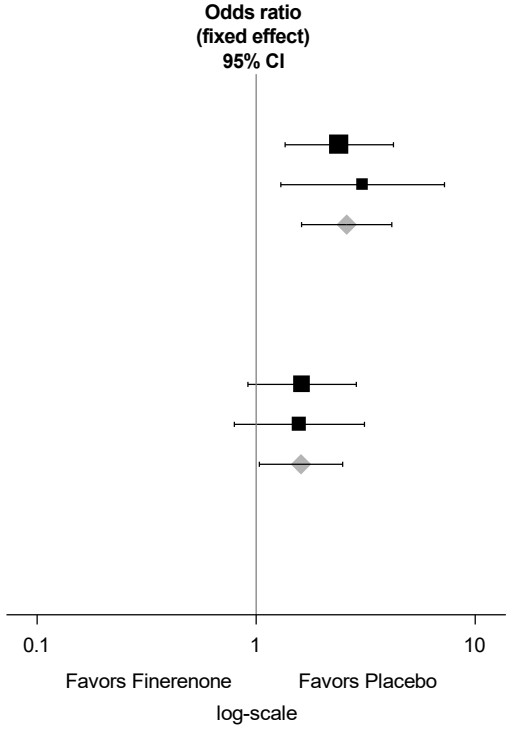
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	39 / 1213	16 / 1210	55.2	2.48 [1.38,4.46]	
FIGARO-DKD	24 / 862	15 / 848	44.8	1.59 [0.83,3.05]	
Total	63 / 2075	31 / 2058		2.05 [1.33,3.16]	Z=3.23, p=0.0012
Heterogeneity:	Q=0.98 (df=1)	p=0.3214	I^2=0.0%		
Absent					
FIDELIO-DKD	33 / 1404	21 / 1400	73.8	1.58 [0.91,2.75]	
FIGARO-DKD	19 / 495	6 / 508	26.2	3.34 [1.32,8.43]	
Total	52 / 1899	27 / 1908		1.96 [1.23,3.14]	Z=2.82, p=0.0048
Heterogeneity:	Q=1.86 (df=1)	p=0.1731	I^2=46.1%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8997	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.73.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

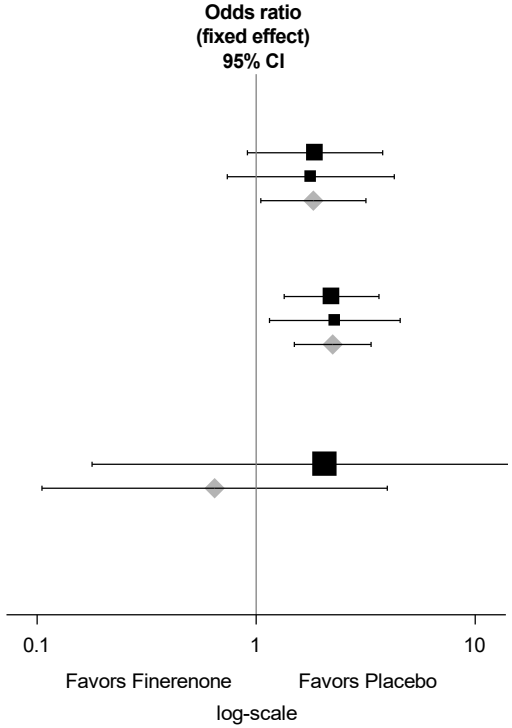
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	41 / 1735	17 / 1700	69.5	2.40 [1.36,4.23]	
FIGARO-DKD	21 / 924	7 / 929	30.5	3.06 [1.30,7.24]	
Total	62 / 2659	24 / 2629		2.59 [1.61,4.16]	Z=3.93, p=<.0001
Heterogeneity:	Q=0.22 (df=1)	p=0.6407	I^2=0.0%		
> 4.5					
FIDELIO-DKD	31 / 882	20 / 910	59.0	1.62 [0.92,2.87]	
FIGARO-DKD	22 / 433	14 / 426	41.0	1.58 [0.79,3.12]	
Total	53 / 1315	34 / 1336		1.60 [1.03,2.48]	Z=2.11, p=0.0349
Heterogeneity:	Q=0.00 (df=1)	p=0.9497	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.13 (df=1)	p=0.1448	I^2=53.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.73.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

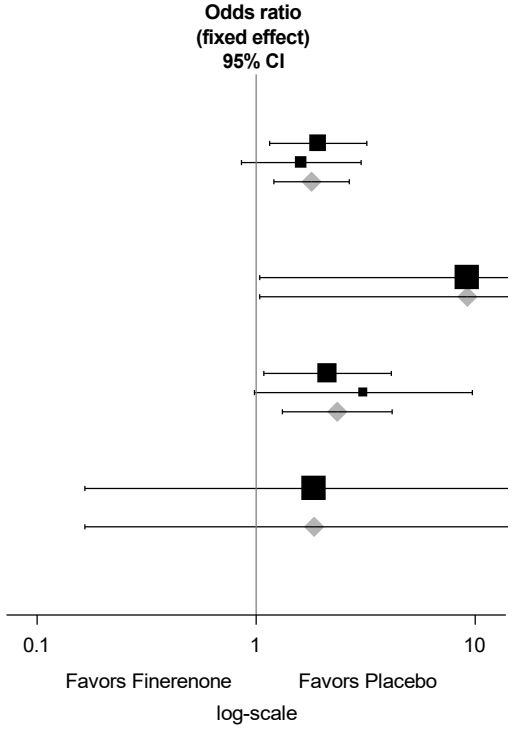
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	22 / 724	12 / 723	60.4	1.86 [0.91,3.78]	
FIGARO-DKD	14 / 494	8 / 495	39.6	1.78 [0.74,4.27]	
Total	36 / 1218	20 / 1218		1.82 [1.05,3.17]	Z=2.13, p=0.0329
Heterogeneity:	Q=0.01 (df=1)	p=0.9381	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	50 / 1759	23 / 1760	65.5	2.21 [1.34,3.64]	
FIGARO-DKD	27 / 829	12 / 827	34.5	2.29 [1.15,4.54]	
Total	77 / 2588	35 / 2587		2.24 [1.49,3.35]	Z=3.91, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9370	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	2 / 127	0.0	0.00 [0.00,73E295]	
FIGARO-DKD	2 / 34	1 / 34	100.0	2.06 [0.18,23.88]	
Total	2 / 167	3 / 161		0.65 [0.11,3.97]	Z=-0.47, p=0.6373
Heterogeneity:	Q=0.86 (df=1)	p=0.3530	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.89 (df=2)	p=0.3892	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.73.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

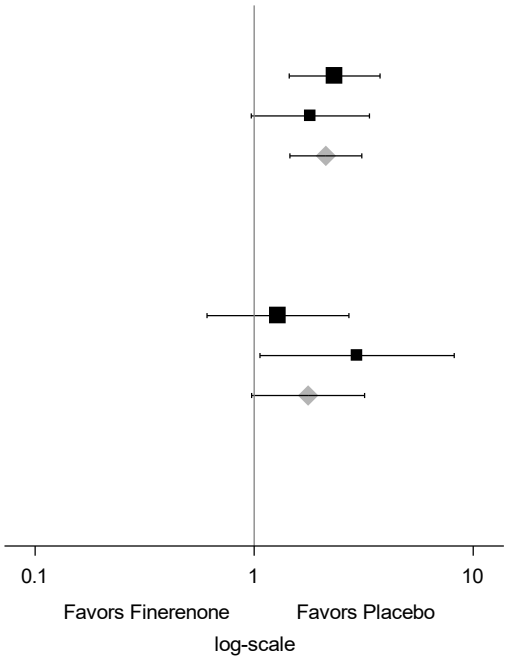
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	43 / 1634	23 / 1657	60.2	1.92 [1.15,3.20]	
FIGARO-DKD	26 / 1010	16 / 989	39.8	1.61 [0.86,3.01]	
Total	69 / 2644	39 / 2646		1.79 [1.20,2.66]	Z=2.88, p=0.0040
Heterogeneity:	Q=0.19 (df=1)	p=0.6666	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	0 / 115	0.0	-	
FIGARO-DKD	5 / 43	1 / 71	100.0	9.21 [1.04,81.73]	
Total	5 / 172	1 / 186		9.21 [1.04,81.73]	Z=1.99, p=0.0462
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asian					
FIDELIO-DKD	27 / 678	13 / 677	74.5	2.12 [1.08,4.14]	
FIGARO-DKD	12 / 252	4 / 251	25.5	3.09 [0.98,9.71]	
Total	39 / 930	17 / 928		2.35 [1.32,4.18]	Z=2.90, p=0.0038
Heterogeneity:	Q=0.31 (df=1)	p=0.5778	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.84 [0.17,20.48]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	2 / 228	1 / 206		1.84 [0.17,20.48]	Z=0.50, p=0.6203
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.47 (df=3)	p=0.4800	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.73.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

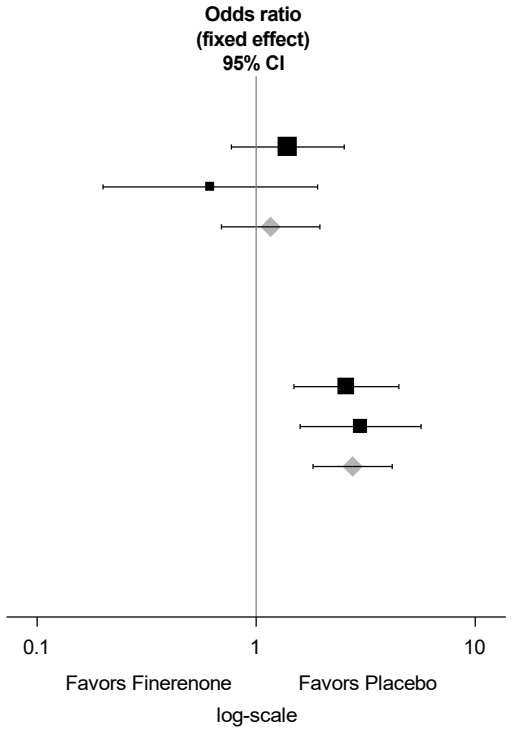
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	55 / 1797	25 / 1870	62.9	2.33 [1.45,3.76]	
FIGARO-DKD	28 / 917	16 / 933	37.1	1.81 [0.97,3.36]	
Total	83 / 2714	41 / 2803		2.12 [1.46,3.10]	Z=3.91, p=<.0001
Heterogeneity:	Q=0.41 (df=1)	p=0.5229	I^2=0.0%		
Female					
FIDELIO-DKD	17 / 820	12 / 740	65.2	1.28 [0.61,2.71]	
FIGARO-DKD	15 / 440	5 / 423	34.8	2.95 [1.06,8.19]	
Total	32 / 1260	17 / 1163		1.76 [0.97,3.19]	Z=1.87, p=0.0613
Heterogeneity:	Q=1.67 (df=1)	p=0.1962	I^2=40.1%		
Subgroup Heterogeneity:	Q=0.27 (df=1)	p=0.6038	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.73.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

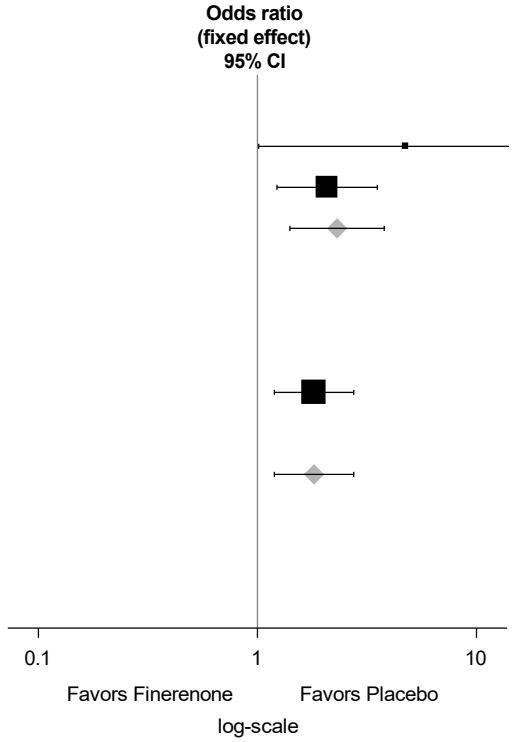
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	27 / 1103	19 / 1075	78.3	1.39 [0.77,2.52]	
FIGARO-DKD	5 / 336	8 / 335	21.7	0.62 [0.20,1.91]	
Total	32 / 1439	27 / 1410		1.16 [0.69,1.95]	Z=0.58, p=0.5640
Heterogeneity:	Q=1.57 (df=1)	p=0.2101	I^2=36.3%		
>= 65					
FIDELIO-DKD	45 / 1514	18 / 1535	57.1	2.58 [1.49,4.48]	
FIGARO-DKD	38 / 1021	13 / 1021	42.9	3.00 [1.59,5.66]	
Total	83 / 2535	31 / 2556		2.76 [1.82,4.18]	Z=4.77, p=<.0001
Heterogeneity:	Q=0.12 (df=1)	p=0.7280	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.46 (df=1)	p=0.0110	I^2=84.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.73.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Blood potassium increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	9 / 209	2 / 213	10.4	4.75 [1.01,22.24]	
FIGARO-DKD	43 / 1357	21 / 1356	89.6	2.08 [1.23,3.52]	
Total	52 / 1566	23 / 1569		2.31 [1.41,3.79]	Z=3.31, p=0.0009
Heterogeneity:	Q=0.99 (df=1)	p=0.3204	I^2=0.0%		
Very High					
FIDELIO-DKD	63 / 2408	35 / 2397	100.0	1.81 [1.19,2.75]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	63 / 2408	35 / 2397		1.81 [1.19,2.75]	Z=2.80, p=0.0052
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.54 (df=1)	p=0.4643	I^2=0.0%		

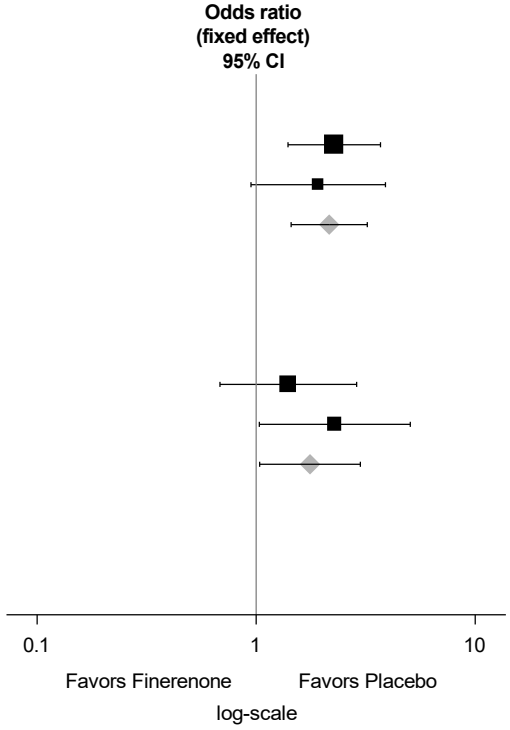


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.73.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Blood potassium increased (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

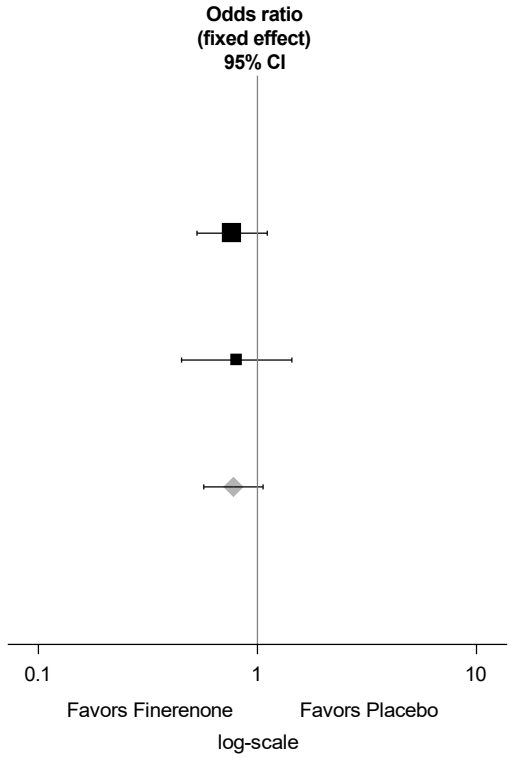
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	54 / 1556	24 / 1541	67.9	2.27 [1.40,3.69]	
FIGARO-DKD	23 / 637	12 / 627	32.1	1.92 [0.95,3.89]	
Total	77 / 2193	36 / 2168		2.15 [1.44,3.22]	Z=3.76, p=0.0002
Heterogeneity:	Q=0.15 (df=1)	p=0.7000	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	18 / 1061	13 / 1069	55.0	1.40 [0.68,2.88]	
FIGARO-DKD	20 / 720	9 / 729	45.0	2.29 [1.03,5.05]	
Total	38 / 1781	22 / 1798		1.76 [1.04,2.99]	Z=2.10, p=0.0361
Heterogeneity:	Q=0.80 (df=1)	p=0.3705	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.36 (df=1)	p=0.5512	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.74: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Blood pressure increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

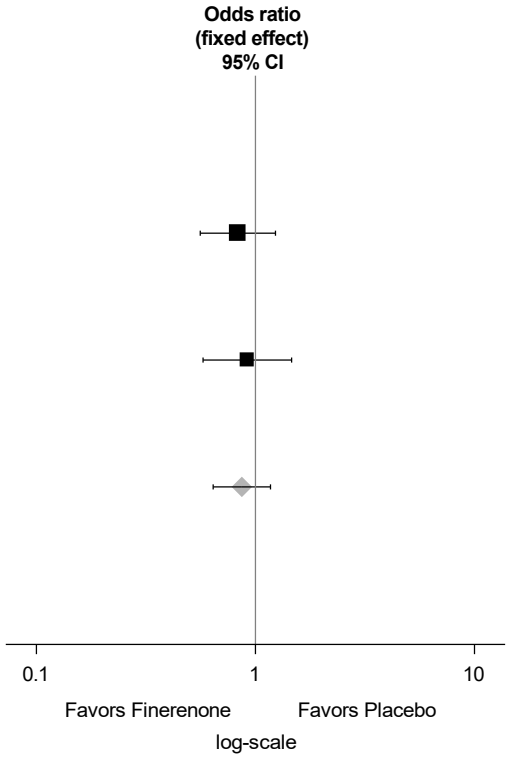
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	51 / 2617	66 / 2610	71.1	0.77 [0.53,1.11]	
FIGARO-DKD	21 / 1357	26 / 1356	28.9	0.80 [0.45,1.44]	
Total	72 / 3974	92 / 3966		0.78 [0.57,1.06]	Z=-1.59, p=0.1123
Heterogeneity:	Q=0.02 (df=1)	p=0.8904	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.75: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - C-reactive protein increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

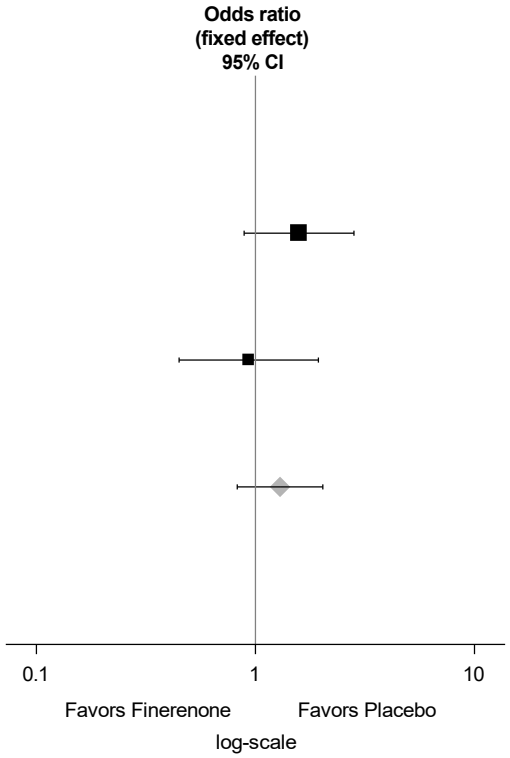
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	55 / 2610	58.1	0.83 [0.56,1.23]	
FIGARO-DKD	35 / 1357	38 / 1356	41.9	0.92 [0.58,1.46]	
Total	81 / 3974	93 / 3966		0.87 [0.64,1.17]	Z=-0.93, p=0.3514
Heterogeneity:	Q=0.10 (df=1)	p=0.7491	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.76: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gamma-glutamyltransferase increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

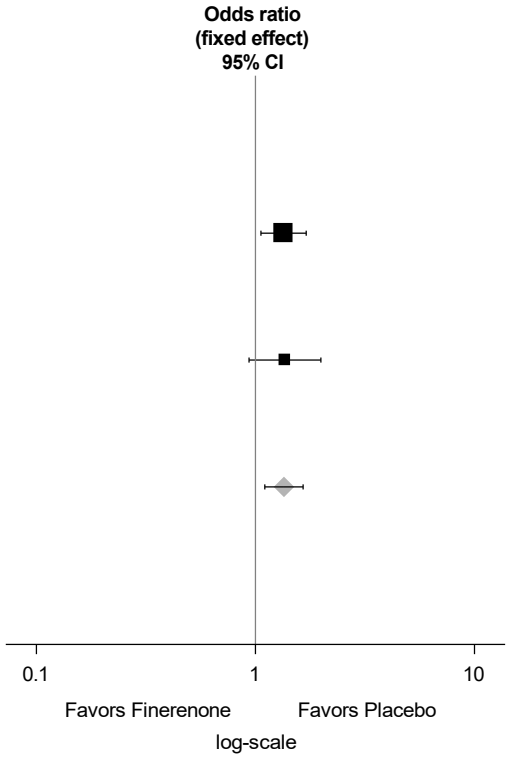
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	19 / 2610	61.7	1.58 [0.89,2.82]	
FIGARO-DKD	14 / 1357	15 / 1356	38.3	0.93 [0.45,1.94]	
Total	44 / 3974	34 / 3966		1.29 [0.83,2.03]	Z=1.13, p=0.2601
Heterogeneity:	Q=1.24 (df=1)	p=0.2663	I^2=19.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.77: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

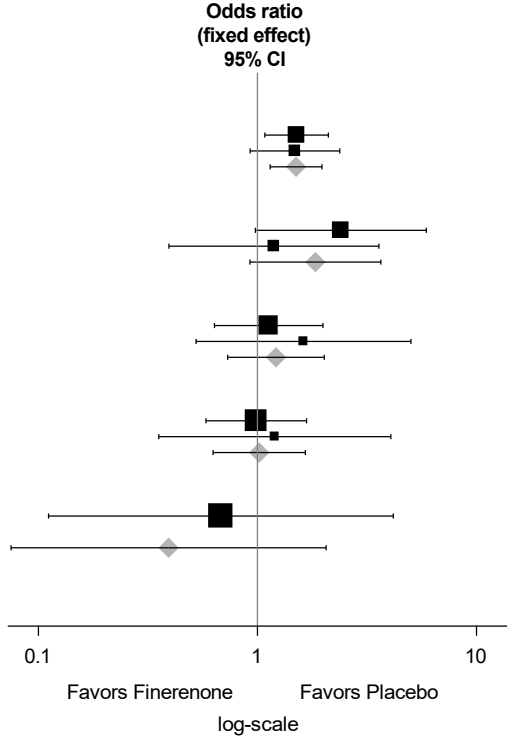
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	167 / 2617	126 / 2610	71.6	1.34 [1.06,1.70]	
FIGARO-DKD	66 / 1357	49 / 1356	28.4	1.36 [0.93,1.99]	
Total	233 / 3974	175 / 3966		1.35 [1.10,1.65]	Z=2.92, p=0.0035
Heterogeneity:	Q=0.00 (df=1)	p=0.9487	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.77.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

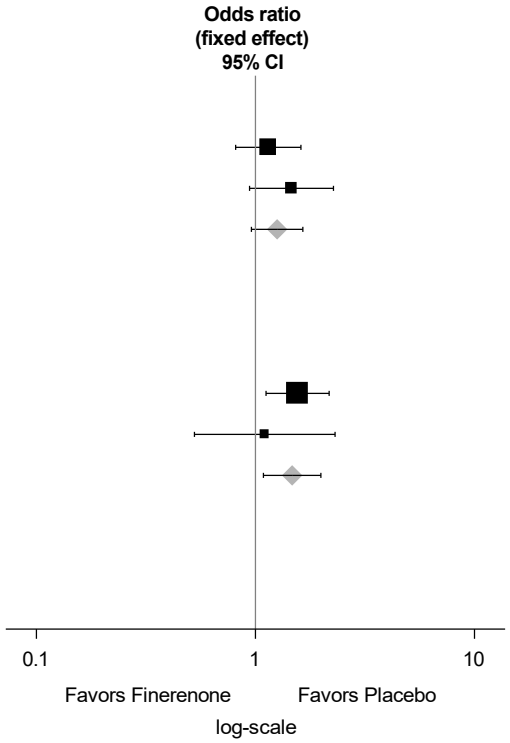
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	92 / 1075	62 / 1062	66.6	1.51 [1.08,2.11]	
FIGARO-DKD	45 / 638	31 / 637	33.4	1.48 [0.93,2.38]	
Total	137 / 1713	93 / 1699		1.50 [1.14,1.97]	Z=2.92, p=0.0035
Heterogeneity:	Q=0.00 (df=1)	p=0.9528	I^2=0.0%		
North America					
FIDELIO-DKD	16 / 424	7 / 436	60.1	2.40 [0.98,5.90]	
FIGARO-DKD	7 / 267	6 / 271	39.9	1.19 [0.39,3.59]	
Total	23 / 691	13 / 707		1.84 [0.92,3.66]	Z=1.73, p=0.0829
Heterogeneity:	Q=0.94 (df=1)	p=0.3322	I^2=0.0%		
Asia					
FIDELIO-DKD	26 / 751	23 / 745	79.7	1.13 [0.64,1.99]	
FIGARO-DKD	8 / 289	5 / 290	20.3	1.62 [0.52,5.02]	
Total	34 / 1040	28 / 1035		1.21 [0.73,2.02]	Z=0.75, p=0.4530
Heterogeneity:	Q=0.32 (df=1)	p=0.5711	I^2=0.0%		
Latin America					
FIDELIO-DKD	31 / 273	31 / 270	84.2	0.99 [0.58,1.68]	
FIGARO-DKD	6 / 102	5 / 101	15.8	1.20 [0.35,4.06]	
Total	37 / 375	36 / 371		1.02 [0.63,1.65]	Z=0.07, p=0.9405
Heterogeneity:	Q=0.08 (df=1)	p=0.7740	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	3 / 97	100.0	0.68 [0.11,4.17]	
FIGARO-DKD	0 / 61	2 / 57	0.0	0.00 [0.00,87E295]	
Total	2 / 155	5 / 154		0.39 [0.08,2.06]	Z=-1.11, p=0.2689
Heterogeneity:	Q=0.35 (df=1)	p=0.5518	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.95 (df=4)	p=0.2926	I^2=19.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.77.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

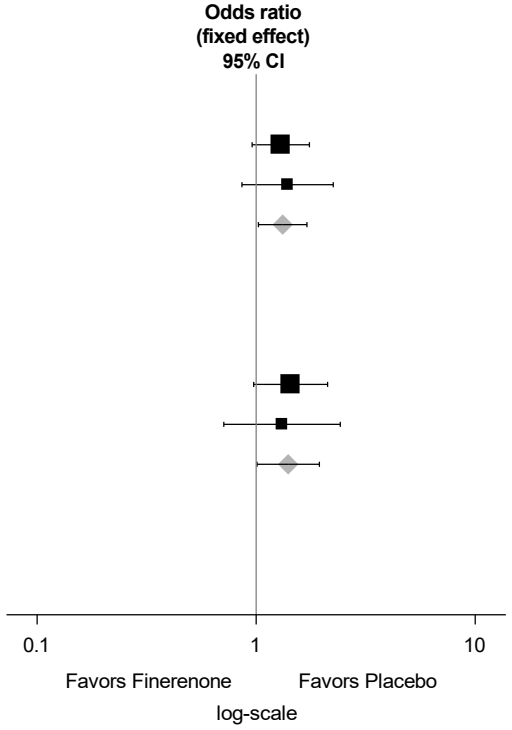
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	74 / 1213	65 / 1210	62.3	1.14 [0.81,1.61]	
FIGARO-DKD	51 / 862	35 / 848	37.7	1.46 [0.94,2.27]	
Total	125 / 2075	100 / 2058		1.26 [0.96,1.65]	Z=1.65, p=0.0987
Heterogeneity:	Q=0.73 (df=1)	p=0.3921	I^2=0.0%		
Absent					
FIDELIO-DKD	93 / 1404	61 / 1400	83.2	1.56 [1.12,2.17]	
FIGARO-DKD	15 / 495	14 / 508	16.8	1.10 [0.53,2.31]	
Total	108 / 1899	75 / 1908		1.47 [1.09,1.99]	Z=2.50, p=0.0123
Heterogeneity:	Q=0.70 (df=1)	p=0.4038	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.58 (df=1)	p=0.4450	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.77.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

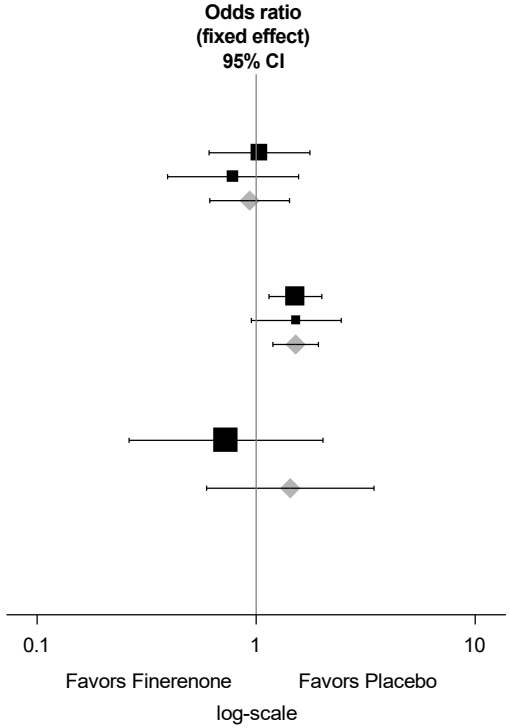
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	103 / 1735	79 / 1700	71.8	1.30 [0.96,1.75]	
FIGARO-DKD	41 / 924	30 / 929	28.2	1.39 [0.86,2.25]	
Total	144 / 2659	109 / 2629		1.32 [1.02,1.71]	Z=2.14, p=0.0321
Heterogeneity:	Q=0.06 (df=1)	p=0.8038	I^2=0.0%		
> 4.5					
FIDELIO-DKD	64 / 882	47 / 910	71.3	1.44 [0.97,2.12]	
FIGARO-DKD	25 / 433	19 / 426	28.7	1.31 [0.71,2.42]	
Total	89 / 1315	66 / 1336		1.40 [1.01,1.94]	Z=2.01, p=0.0444
Heterogeneity:	Q=0.06 (df=1)	p=0.8071	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.07 (df=1)	p=0.7858	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.77.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

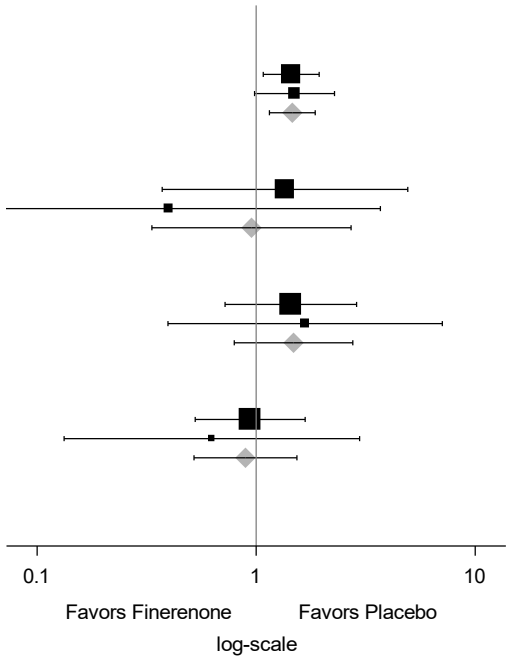
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	29 / 724	28 / 723	62.8	1.04 [0.61,1.76]	
FIGARO-DKD	15 / 494	19 / 495	37.2	0.78 [0.39,1.56]	
Total	44 / 1218	47 / 1218		0.93 [0.61,1.42]	Z=-0.32, p=0.7482
Heterogeneity:	Q=0.39 (df=1)	p=0.5310	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	131 / 1759	89 / 1760	74.3	1.51 [1.14,1.99]	
FIGARO-DKD	45 / 829	30 / 827	25.7	1.52 [0.95,2.45]	
Total	176 / 2588	119 / 2587		1.51 [1.19,1.92]	Z=3.40, p=0.0007
Heterogeneity:	Q=0.00 (df=1)	p=0.9735	I^2=0.0%		
>= 160					
FIDELIO-DKD	7 / 133	9 / 127	100.0	0.73 [0.26,2.02]	
FIGARO-DKD	6 / 34	0 / 34	0.0	446E9 [446E9,446E9]	
Total	13 / 167	9 / 161		1.43 [0.59,3.45]	Z=0.80, p=0.4244
Heterogeneity:	Q=1.69 (df=1)	p=0.1939	I^2=40.8%		
Subgroup Heterogeneity:	Q=3.88 (df=2)	p=0.1440	I^2=48.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.77.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

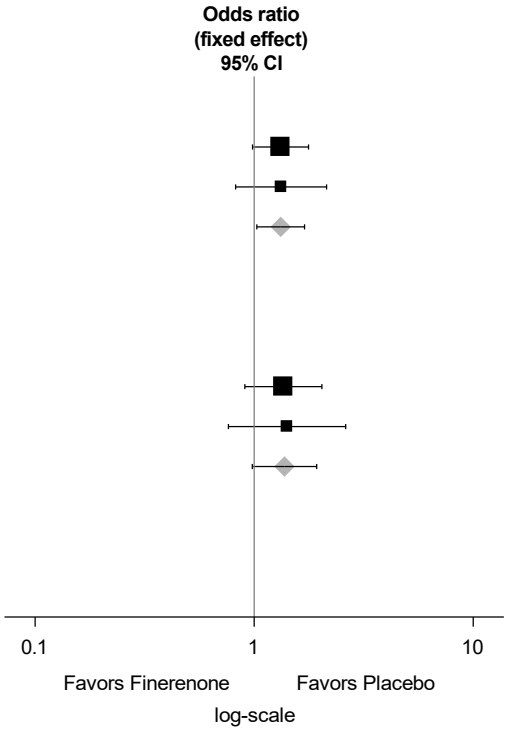
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	113 / 1634	81 / 1657	67.1	1.45 [1.08,1.94]	
FIGARO-DKD	57 / 1010	38 / 989	32.9	1.50 [0.98,2.28]	
Total	170 / 2644	119 / 2646		1.46 [1.15,1.86]	Z=3.09, p=0.0020
Heterogeneity:	Q=0.02 (df=1)	p=0.8939	I^2=0.0%		
Black					
FIDELIO-DKD	6 / 129	4 / 115	74.8	1.35 [0.37,4.92]	
FIGARO-DKD	1 / 43	4 / 71	25.2	0.40 [0.04,3.69]	
Total	7 / 172	8 / 186		0.95 [0.33,2.71]	Z=-0.09, p=0.9265
Heterogeneity:	Q=0.87 (df=1)	p=0.3501	I^2=0.0%		
Asian					
FIDELIO-DKD	20 / 678	14 / 677	81.3	1.44 [0.72,2.87]	
FIGARO-DKD	5 / 252	3 / 251	18.7	1.67 [0.40,7.08]	
Total	25 / 930	17 / 928		1.48 [0.79,2.76]	Z=1.24, p=0.2167
Heterogeneity:	Q=0.03 (df=1)	p=0.8536	I^2=0.0%		
Others					
FIDELIO-DKD	28 / 176	27 / 161	87.8	0.94 [0.53,1.67]	
FIGARO-DKD	3 / 52	4 / 45	12.2	0.63 [0.13,2.97]	
Total	31 / 228	31 / 206		0.89 [0.52,1.53]	Z=-0.41, p=0.6834
Heterogeneity:	Q=0.23 (df=1)	p=0.6337	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.17 (df=3)	p=0.3664	I^2=5.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.77.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

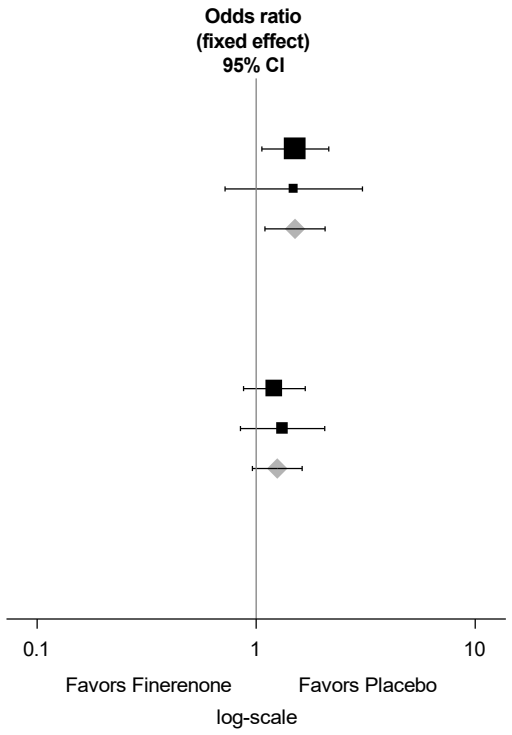
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	105 / 1797	84 / 1870	72.5	1.32 [0.98,1.77]	
FIGARO-DKD	40 / 917	31 / 933	27.5	1.33 [0.82,2.14]	
Total	145 / 2714	115 / 2803		1.32 [1.03,1.70]	Z=2.18, p=0.0293
Heterogeneity:	Q=0.00 (df=1)	p=0.9839	I^2=0.0%		
Female					
FIDELIO-DKD	62 / 820	42 / 740	69.8	1.36 [0.91,2.04]	
FIGARO-DKD	26 / 440	18 / 423	30.2	1.41 [0.76,2.62]	
Total	88 / 1260	60 / 1163		1.38 [0.98,1.93]	Z=1.85, p=0.0650
Heterogeneity:	Q=0.01 (df=1)	p=0.9180	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8527	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.77.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

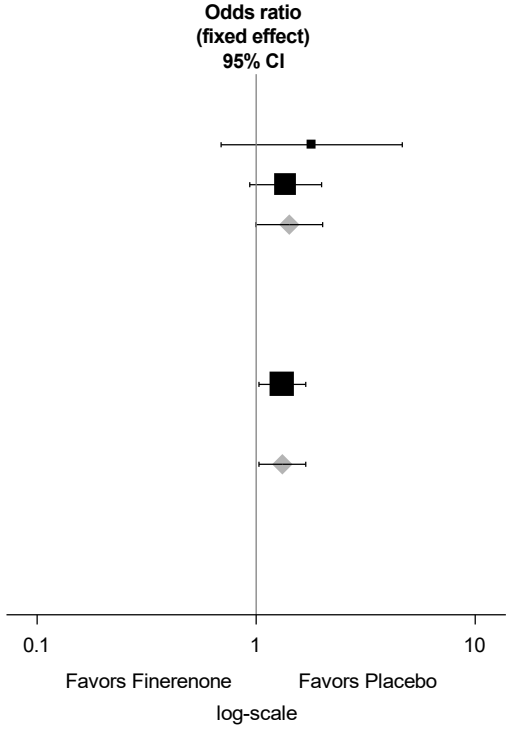
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	83 / 1103	55 / 1075	80.8	1.51 [1.06,2.15]	
FIGARO-DKD	19 / 336	13 / 335	19.2	1.48 [0.72,3.06]	
Total	102 / 1439	68 / 1410		1.50 [1.10,2.06]	Z=2.53, p=0.0114
Heterogeneity:	Q=0.00 (df=1)	p=0.9681	I^2=0.0%		
>= 65					
FIDELIO-DKD	84 / 1514	71 / 1535	65.1	1.21 [0.88,1.68]	
FIGARO-DKD	47 / 1021	36 / 1021	34.9	1.32 [0.85,2.06]	
Total	131 / 2535	107 / 2556		1.25 [0.96,1.62]	Z=1.66, p=0.0966
Heterogeneity:	Q=0.09 (df=1)	p=0.7582	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.79 (df=1)	p=0.3729	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.77.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

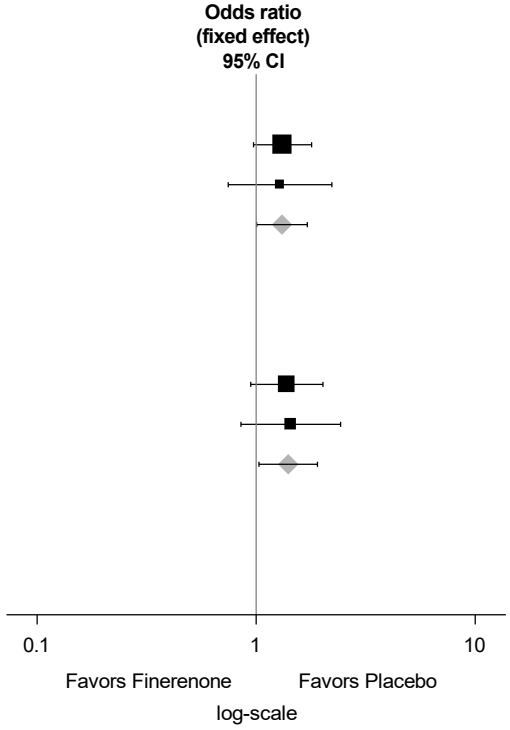
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	12 / 209	7 / 213	13.6	1.79 [0.69,4.65]	
FIGARO-DKD	66 / 1357	49 / 1356	86.4	1.36 [0.93,1.99]	
Total	78 / 1566	56 / 1569		1.42 [1.00,2.01]	Z=1.95, p=0.0517
Heterogeneity:	Q=0.27 (df=1)	p=0.6008	I^2=0.0%		
Very High					
FIDELIO-DKD	155 / 2408	119 / 2397	100.0	1.32 [1.03,1.68]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	155 / 2408	119 / 2397		1.32 [1.03,1.68]	Z=2.19, p=0.0282
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7389	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.77.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Glomerular filtration rate decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

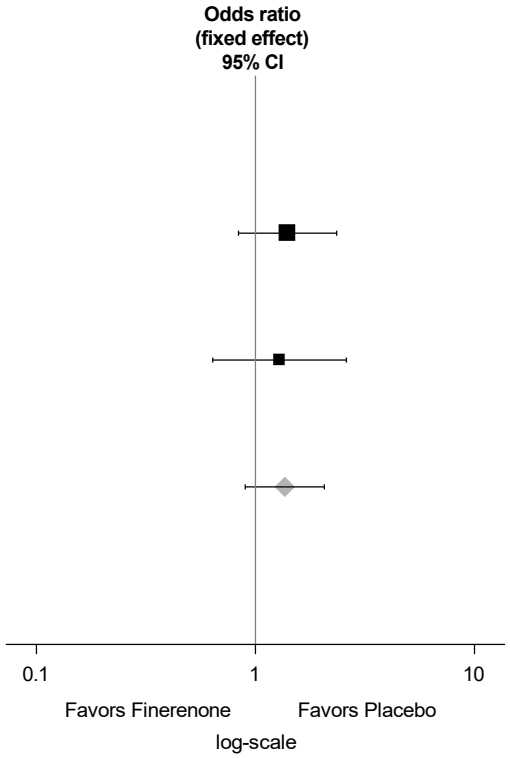
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	101 / 1556	77 / 1541	76.1	1.32 [0.97,1.79]	
FIGARO-DKD	31 / 637	24 / 627	23.9	1.29 [0.75,2.22]	
Total	132 / 2193	101 / 2168		1.31 [1.00,1.71]	Z=2.00, p=0.0460
Heterogeneity:	Q=0.01 (df=1)	p=0.9337	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	66 / 1061	49 / 1069	65.6	1.38 [0.94,2.02]	
FIGARO-DKD	35 / 720	25 / 729	34.4	1.44 [0.85,2.43]	
Total	101 / 1781	74 / 1798		1.40 [1.03,1.90]	Z=2.15, p=0.0318
Heterogeneity:	Q=0.02 (df=1)	p=0.9007	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7515	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.78: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Glycosylated haemoglobin increased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

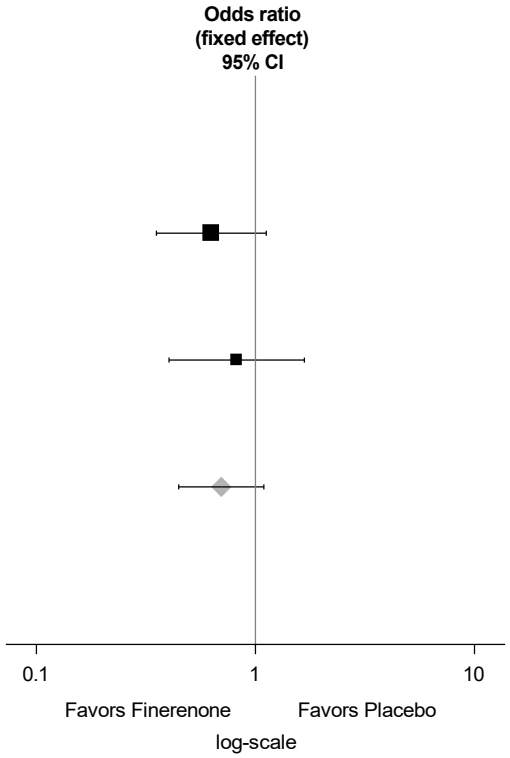
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	25 / 2610	64.9	1.40 [0.84,2.35]	
FIGARO-DKD	18 / 1357	14 / 1356	35.1	1.29 [0.64,2.60]	
Total	53 / 3974	39 / 3966		1.36 [0.90,2.06]	Z=1.45, p=0.1462
Heterogeneity:	Q=0.04 (df=1)	p=0.8501	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.79: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Weight decreased (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

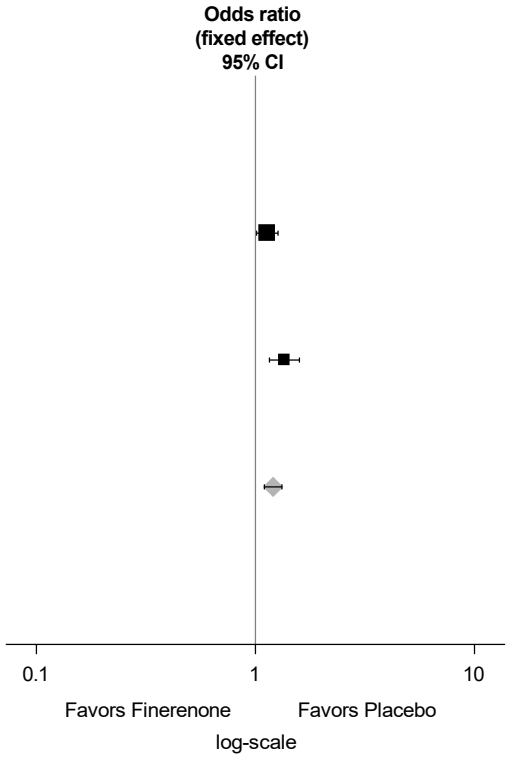
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	19 / 2617	30 / 2610	60.3	0.63 [0.35,1.12]	
FIGARO-DKD	14 / 1357	17 / 1356	39.7	0.82 [0.40,1.67]	
Total	33 / 3974	47 / 3966		0.70 [0.45,1.09]	Z=-1.57, p=0.1156
Heterogeneity:	Q=0.33 (df=1)	p=0.5685	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.80: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

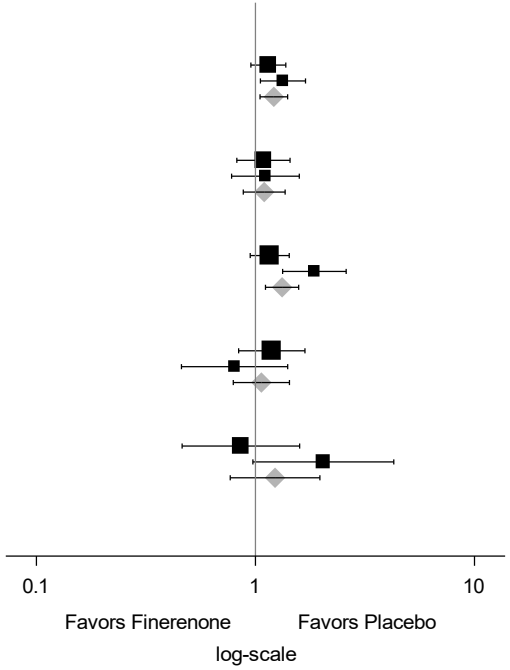
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	971 / 2617	894 / 2610	66.0	1.13 [1.01,1.27]	
FIGARO-DKD	532 / 1357	437 / 1356	34.0	1.36 [1.16,1.59]	
Total	1503 / 3974	1331 / 3966		1.20 [1.10,1.32]	Z=3.96, p=<.0001
Heterogeneity:	Q=3.32 (df=1)	p=0.0686	I^2=69.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.80.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

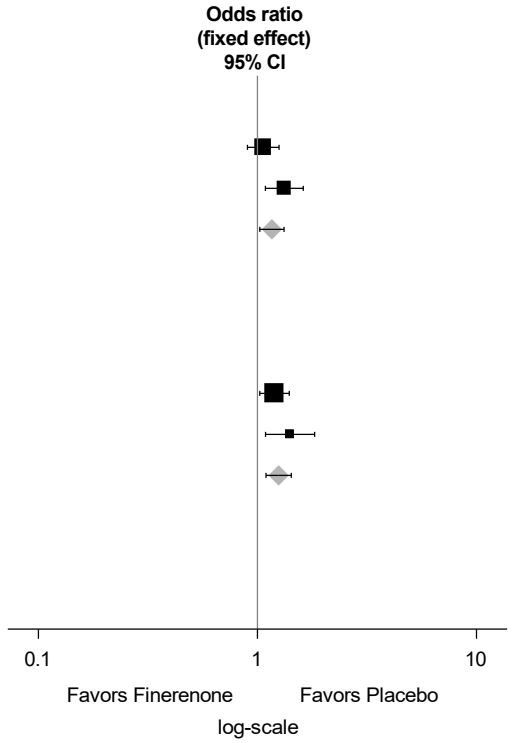
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	349 / 1075	314 / 1062	62.6	1.15 [0.95,1.38]	
FIGARO-DKD	221 / 638	181 / 637	37.4	1.34 [1.05,1.69]	
Total	570 / 1713	495 / 1699		1.21 [1.05,1.40]	Z=2.61, p=0.0091
Heterogeneity:	Q=1.01 (df=1)	p=0.3156	I^2=0.7%		
North America					
FIDELIO-DKD	154 / 424	150 / 436	61.8	1.09 [0.82,1.44]	
FIGARO-DKD	95 / 267	90 / 271	38.2	1.11 [0.78,1.59]	
Total	249 / 691	240 / 707		1.10 [0.88,1.37]	Z=0.82, p=0.4124
Heterogeneity:	Q=0.01 (df=1)	p=0.9269	I^2=0.0%		
Asia					
FIDELIO-DKD	334 / 751	304 / 745	72.6	1.16 [0.95,1.43]	
FIGARO-DKD	144 / 289	101 / 290	27.4	1.86 [1.33,2.60]	
Total	478 / 1040	405 / 1035		1.32 [1.11,1.58]	Z=3.14, p=0.0017
Heterogeneity:	Q=5.52 (df=1)	p=0.0188	I^2=81.9%		
Latin America					
FIDELIO-DKD	107 / 273	95 / 270	72.0	1.19 [0.84,1.68]	
FIGARO-DKD	40 / 102	45 / 101	28.0	0.80 [0.46,1.40]	
Total	147 / 375	140 / 371		1.06 [0.79,1.43]	Z=0.41, p=0.6806
Heterogeneity:	Q=1.36 (df=1)	p=0.2440	I^2=26.3%		
Others					
FIDELIO-DKD	27 / 94	31 / 97	59.0	0.86 [0.46,1.59]	
FIGARO-DKD	32 / 61	20 / 57	41.0	2.04 [0.97,4.28]	
Total	59 / 155	51 / 154		1.23 [0.77,1.97]	Z=0.86, p=0.3912
Heterogeneity:	Q=3.10 (df=1)	p=0.0781	I^2=67.8%		
Subgroup Heterogeneity:	Q=2.51 (df=4)	p=0.6433	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.80.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

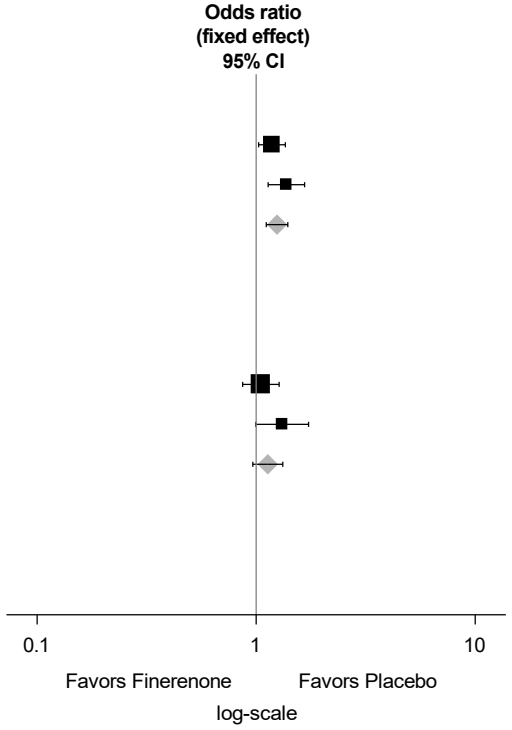
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	443 / 1213	425 / 1210	58.9	1.06 [0.90,1.25]	
FIGARO-DKD	332 / 862	272 / 848	41.1	1.33 [1.09,1.62]	
Total	775 / 2075	697 / 2058		1.16 [1.02,1.32]	Z=2.34, p=0.0194
Heterogeneity:	Q=2.81 (df=1)	p=0.0936	I^2=64.4%		
Absent					
FIDELIO-DKD	528 / 1404	469 / 1400	73.6	1.20 [1.02,1.40]	
FIGARO-DKD	200 / 495	165 / 508	26.4	1.41 [1.09,1.82]	
Total	728 / 1899	634 / 1908		1.25 [1.09,1.43]	Z=3.29, p=0.0010
Heterogeneity:	Q=1.14 (df=1)	p=0.2866	I^2=11.9%		
Subgroup Heterogeneity:	Q=0.57 (df=1)	p=0.4511	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.80.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

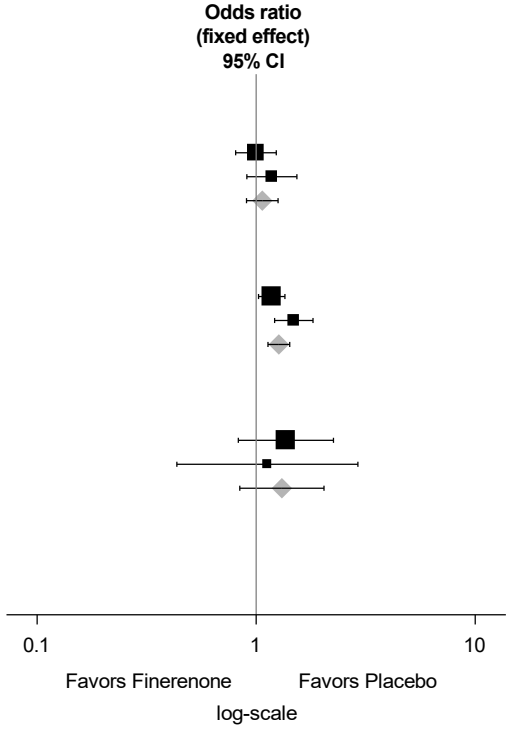
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	638 / 1735	561 / 1700	65.0	1.18 [1.03,1.36]	
FIGARO-DKD	357 / 924	292 / 929	35.0	1.37 [1.13,1.66]	
Total	995 / 2659	853 / 2629		1.25 [1.11,1.39]	Z=3.79, p=0.0001
Heterogeneity:	Q=1.56 (df=1)	p=0.2123	I^2=35.7%		
> 4.5					
FIDELIO-DKD	333 / 882	333 / 910	67.7	1.05 [0.87,1.27]	
FIGARO-DKD	175 / 433	145 / 426	32.3	1.31 [1.00,1.73]	
Total	508 / 1315	478 / 1336		1.13 [0.97,1.32]	Z=1.52, p=0.1288
Heterogeneity:	Q=1.69 (df=1)	p=0.1936	I^2=40.8%		
Subgroup Heterogeneity:	Q=0.96 (df=1)	p=0.3272	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.80.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

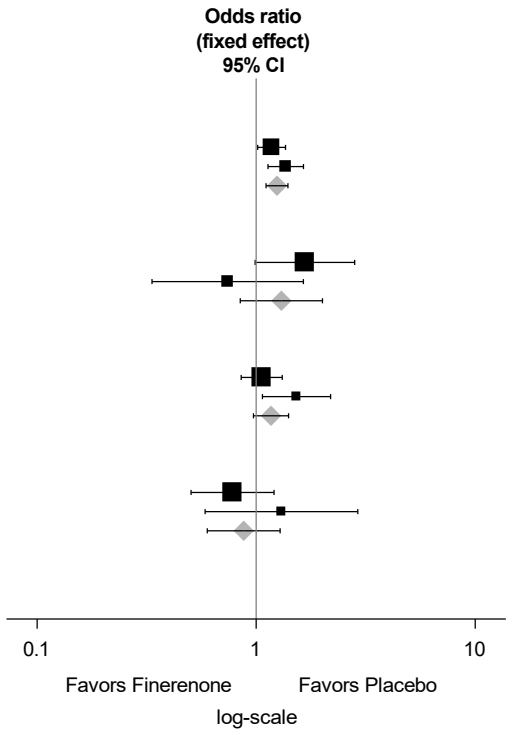
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	267 / 724	267 / 723	60.3	1.00 [0.81,1.24]	
FIGARO-DKD	178 / 494	160 / 495	39.7	1.18 [0.91,1.53]	
Total	445 / 1218	427 / 1218		1.07 [0.90,1.26]	Z=0.76, p=0.4474
Heterogeneity:	Q=0.94 (df=1)	p=0.3335	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	647 / 1759	582 / 1760	67.9	1.18 [1.03,1.35]	
FIGARO-DKD	337 / 829	261 / 827	32.1	1.49 [1.21,1.82]	
Total	984 / 2588	843 / 2587		1.27 [1.13,1.42]	Z=4.09, p=<.0001
Heterogeneity:	Q=3.45 (df=1)	p=0.0632	I^2=71.0%		
>= 160					
FIDELIO-DKD	57 / 133	45 / 127	78.4	1.37 [0.83,2.25]	
FIGARO-DKD	17 / 34	16 / 34	21.6	1.12 [0.43,2.91]	
Total	74 / 167	61 / 161		1.31 [0.84,2.04]	Z=1.20, p=0.2312
Heterogeneity:	Q=0.13 (df=1)	p=0.7227	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.02 (df=2)	p=0.2212	I^2=33.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.80.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

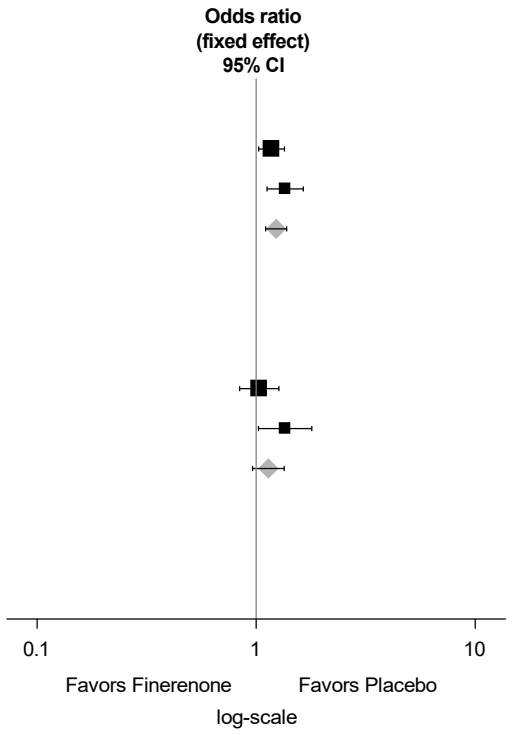
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	558 / 1634	507 / 1657	62.0	1.18 [1.02,1.36]	
FIGARO-DKD	373 / 1010	297 / 989	38.0	1.36 [1.13,1.64]	
Total	931 / 2644	804 / 2646		1.24 [1.11,1.40]	Z=3.73, p=0.0002
Heterogeneity:	Q=1.50 (df=1)	p=0.2201	I^2=33.5%		
Black					
FIDELIO-DKD	57 / 129	37 / 115	69.8	1.67 [0.99,2.82]	
FIGARO-DKD	14 / 43	28 / 71	30.2	0.74 [0.33,1.64]	
Total	71 / 172	65 / 186		1.30 [0.85,2.01]	Z=1.20, p=0.2296
Heterogeneity:	Q=2.79 (df=1)	p=0.0950	I^2=64.1%		
Asian					
FIDELIO-DKD	290 / 678	280 / 677	73.4	1.06 [0.85,1.31]	
FIGARO-DKD	115 / 252	89 / 251	26.6	1.53 [1.07,2.19]	
Total	405 / 930	369 / 928		1.17 [0.97,1.41]	Z=1.65, p=0.0979
Heterogeneity:	Q=2.94 (df=1)	p=0.0864	I^2=66.0%		
Others					
FIDELIO-DKD	66 / 176	70 / 161	77.2	0.78 [0.50,1.21]	
FIGARO-DKD	30 / 52	23 / 45	22.8	1.30 [0.58,2.91]	
Total	96 / 228	93 / 206		0.88 [0.60,1.29]	Z=-0.67, p=0.5019
Heterogeneity:	Q=1.22 (df=1)	p=0.2700	I^2=17.8%		
Subgroup Heterogeneity:	Q=3.18 (df=3)	p=0.3648	I^2=5.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.80.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

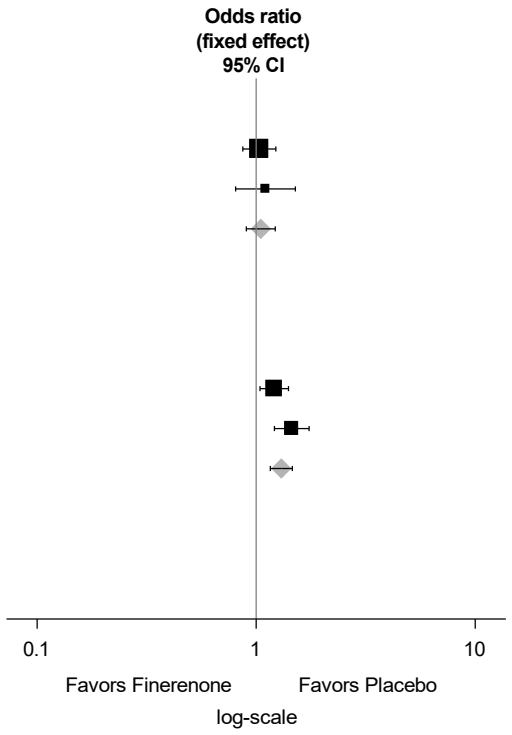
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	669 / 1797	627 / 1870	66.4	1.18 [1.03,1.35]	
FIGARO-DKD	361 / 917	302 / 933	33.6	1.36 [1.12,1.64]	
Total	1030 / 2714	929 / 2803		1.23 [1.10,1.38]	Z=3.73, p=0.0002
Heterogeneity:	Q=1.44 (df=1)	p=0.2306	I^2=30.4%		
Female					
FIDELIO-DKD	302 / 820	267 / 740	64.8	1.03 [0.84,1.27]	
FIGARO-DKD	171 / 440	135 / 423	35.2	1.36 [1.02,1.79]	
Total	473 / 1260	402 / 1163		1.14 [0.96,1.34]	Z=1.51, p=0.1298
Heterogeneity:	Q=2.35 (df=1)	p=0.1252	I^2=57.5%		
Subgroup Heterogeneity:	Q=0.64 (df=1)	p=0.4230	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.80.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

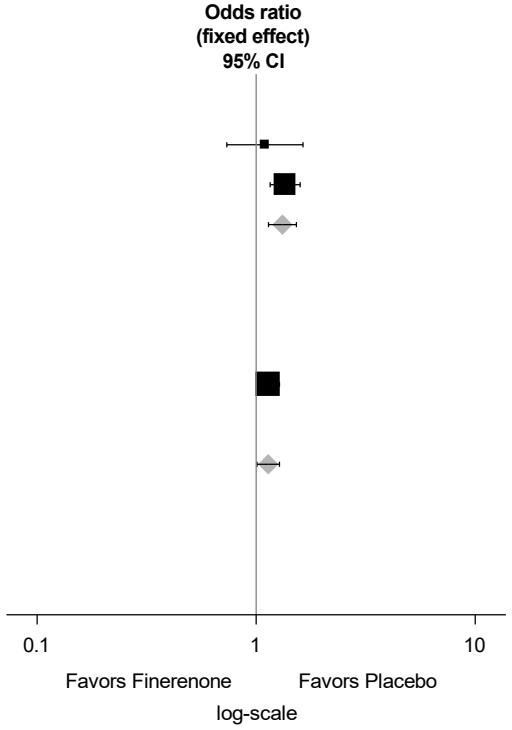
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	418 / 1103	399 / 1075	76.6	1.03 [0.87,1.23]	
FIGARO-DKD	127 / 336	119 / 335	23.4	1.10 [0.81,1.51]	
Total	545 / 1439	518 / 1410		1.05 [0.90,1.22]	Z=0.62, p=0.5320
Heterogeneity:	Q=0.12 (df=1)	p=0.7238	I^2=0.0%		
>= 65					
FIDELIO-DKD	553 / 1514	495 / 1535	59.8	1.21 [1.04,1.40]	
FIGARO-DKD	405 / 1021	318 / 1021	40.2	1.45 [1.21,1.74]	
Total	958 / 2535	813 / 2556		1.30 [1.16,1.46]	Z=4.48, p=<.0001
Heterogeneity:	Q=2.34 (df=1)	p=0.1261	I^2=57.3%		
Subgroup Heterogeneity:	Q=4.90 (df=1)	p=0.0268	I^2=79.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.80.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

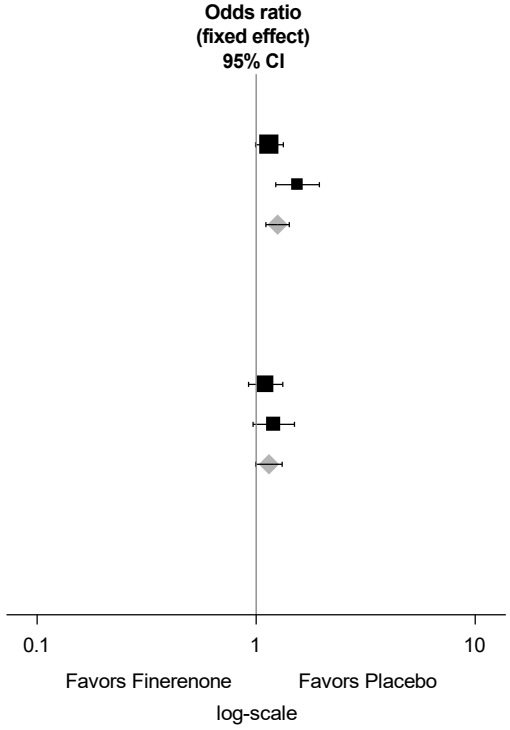
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	75 / 209	72 / 213	13.4	1.10 [0.73,1.64]	
FIGARO-DKD	532 / 1357	437 / 1356	86.6	1.36 [1.16,1.59]	
Total	607 / 1566	509 / 1569		1.32 [1.14,1.53]	Z=3.69, p=0.0002
Heterogeneity:	Q=0.94 (df=1)	p=0.3325	I^2=0.0%		
Very High					
FIDELIO-DKD	896 / 2408	822 / 2397	100.0	1.14 [1.01,1.28]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	896 / 2408	822 / 2397		1.14 [1.01,1.28]	Z=2.11, p=0.0350
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.41 (df=1)	p=0.1206	I^2=58.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.80.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

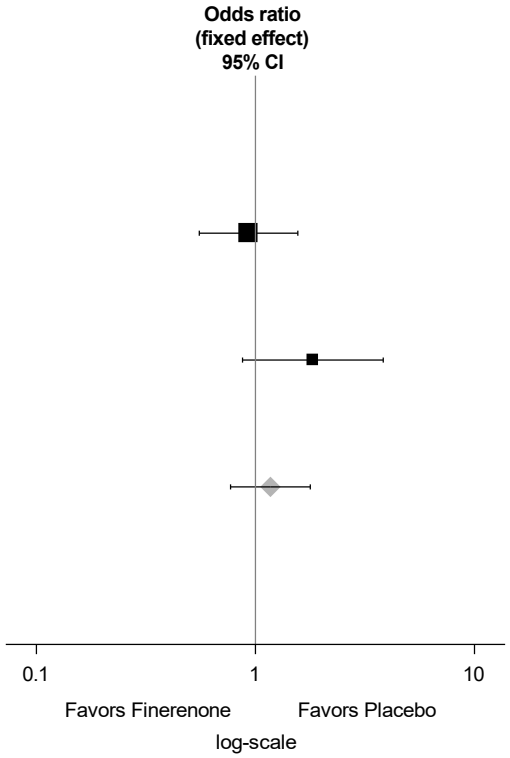
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	603 / 1556	547 / 1541	71.2	1.15 [0.99,1.33]	
FIGARO-DKD	272 / 637	204 / 627	28.8	1.55 [1.23,1.94]	
Total	875 / 2193	751 / 2168		1.25 [1.11,1.42]	Z=3.59, p=0.0003
Heterogeneity:	Q=4.54 (df=1)	p=0.0330	I^2=78.0%		
45 - < 60					
FIDELIO-DKD	368 / 1061	347 / 1069	59.4	1.10 [0.92,1.32]	
FIGARO-DKD	260 / 720	233 / 729	40.6	1.20 [0.97,1.50]	
Total	628 / 1781	580 / 1798		1.14 [1.00,1.31]	Z=1.90, p=0.0575
Heterogeneity:	Q=0.35 (df=1)	p=0.5541	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=1)	p=0.3368	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.81: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Decreased appetite (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

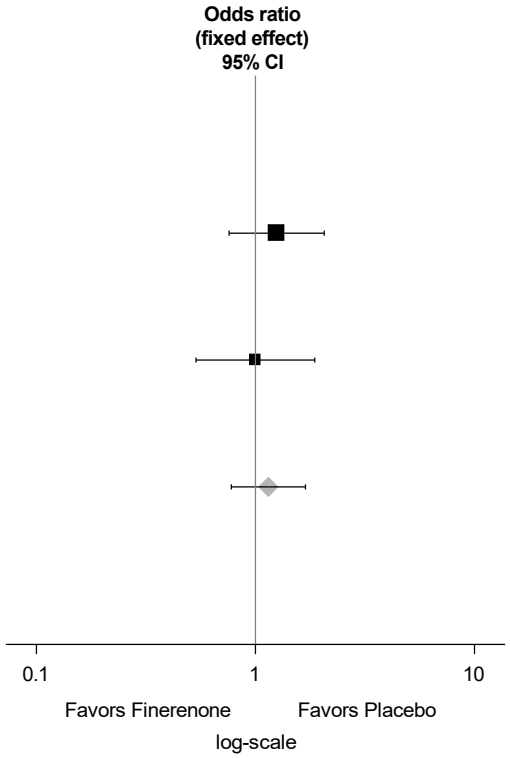
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	30 / 2610	67.1	0.93 [0.55,1.56]	
FIGARO-DKD	20 / 1357	11 / 1356	32.9	1.83 [0.87,3.83]	
Total	48 / 3974	41 / 3966		1.17 [0.77,1.78]	Z=0.74, p=0.4618
Heterogeneity:	Q=2.16 (df=1)	p=0.1420	I^2=53.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.82: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dehydration (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

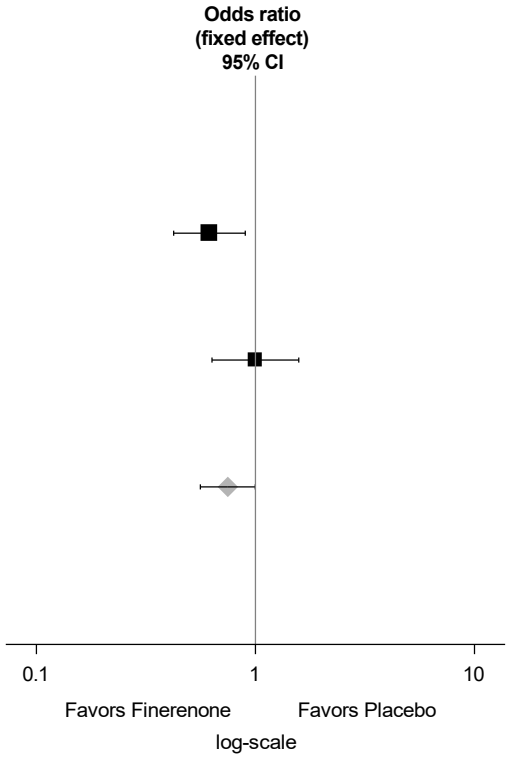
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	28 / 2610	60.9	1.25 [0.76,2.06]	
FIGARO-DKD	20 / 1357	20 / 1356	39.1	1.00 [0.54,1.87]	
Total	55 / 3974	48 / 3966		1.15 [0.78,1.69]	Z=0.68, p=0.4940
Heterogeneity:	Q=0.30 (df=1)	p=0.5833	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.83: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

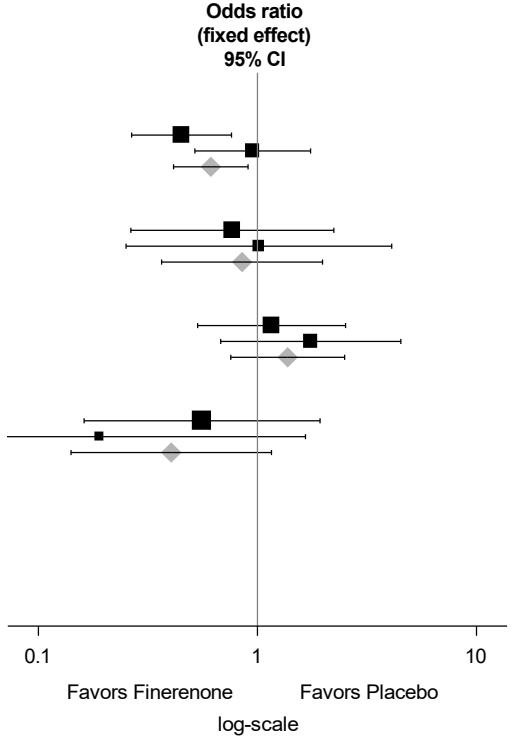
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	72 / 2610	59.5	0.62 [0.42,0.90]	
FIGARO-DKD	38 / 1357	38 / 1356	40.5	1.00 [0.63,1.58]	
Total	83 / 3974	110 / 3966		0.75 [0.56,1.00]	Z=-1.97, p=0.0483
Heterogeneity:	Q=2.56 (df=1)	p=0.1097	I^2=60.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.83.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

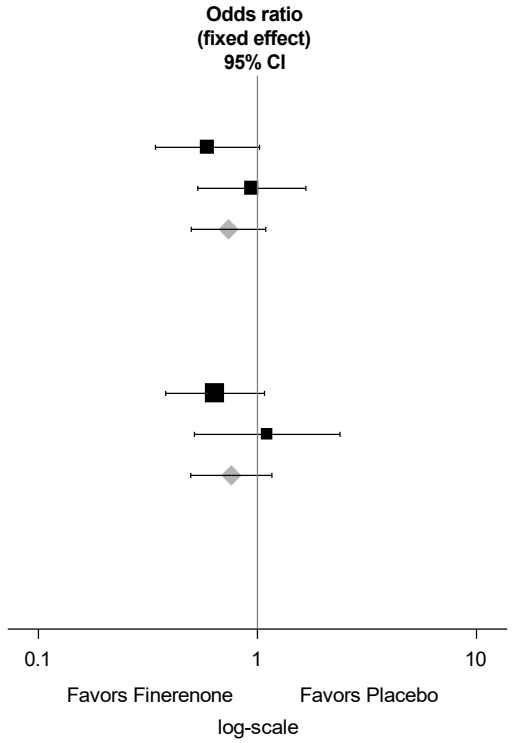
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	21 / 1075	45 / 1062	57.3	0.45 [0.27,0.76]	
FIGARO-DKD	21 / 638	22 / 637	42.7	0.95 [0.52,1.75]	
Total	42 / 1713	67 / 1699		0.61 [0.41,0.91]	Z=-2.45, p=0.0141
Heterogeneity:	Q=3.33 (df=1)	p=0.0679	I^2=70.0%		
North America					
FIDELIO-DKD	6 / 424	8 / 436	63.1	0.77 [0.26,2.23]	
FIGARO-DKD	4 / 267	4 / 271	36.9	1.02 [0.25,4.10]	
Total	10 / 691	12 / 707		0.85 [0.37,1.98]	Z=-0.37, p=0.7079
Heterogeneity:	Q=0.10 (df=1)	p=0.7556	I^2=0.0%		
Asia					
FIDELIO-DKD	14 / 751	12 / 745	59.7	1.16 [0.53,2.53]	
FIGARO-DKD	12 / 289	7 / 290	40.3	1.75 [0.68,4.51]	
Total	26 / 1040	19 / 1035		1.37 [0.76,2.50]	Z=1.04, p=0.2977
Heterogeneity:	Q=0.43 (df=1)	p=0.5101	I^2=0.0%		
Latin America					
FIDELIO-DKD	4 / 273	7 / 270	75.3	0.56 [0.16,1.93]	
FIGARO-DKD	1 / 102	5 / 101	24.7	0.19 [0.02,1.66]	
Total	5 / 375	12 / 371		0.40 [0.14,1.16]	Z=-1.69, p=0.0919
Heterogeneity:	Q=0.73 (df=1)	p=0.3935	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	0 / 97	0.0	-	
FIGARO-DKD	0 / 61	0 / 57	0.0	-	
Total	0 / 155	0 / 154		-	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=6.37 (df=4)	p=0.1731	I^2=37.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.83.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

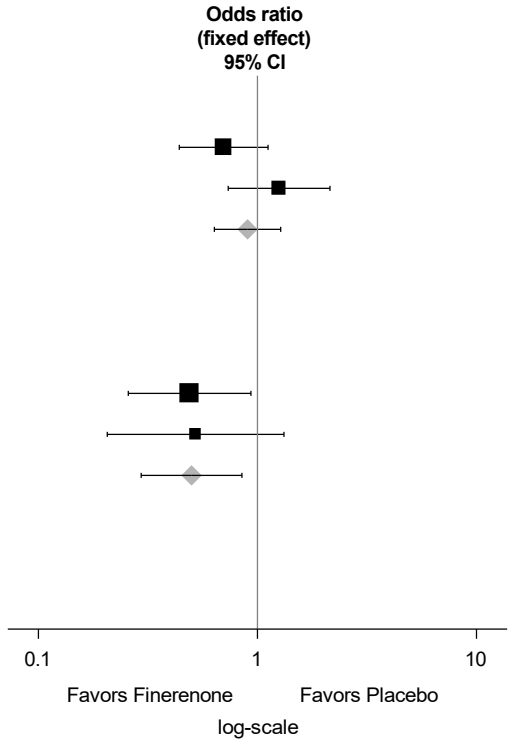
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	21 / 1213	35 / 1210	51.9	0.59 [0.34,1.02]	
FIGARO-DKD	24 / 862	25 / 848	48.1	0.94 [0.53,1.66]	
Total	45 / 2075	60 / 2058		0.74 [0.50,1.09]	Z=-1.52, p=0.1275
Heterogeneity:	Q=1.34 (df=1)	p=0.2465	I^2=25.5%		
Absent					
FIDELIO-DKD	24 / 1404	37 / 1400	68.5	0.64 [0.38,1.08]	
FIGARO-DKD	14 / 495	13 / 508	31.5	1.11 [0.52,2.38]	
Total	38 / 1899	50 / 1908		0.76 [0.50,1.16]	Z=-1.26, p=0.2068
Heterogeneity:	Q=1.35 (df=1)	p=0.2454	I^2=25.9%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9203	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.83.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	31 / 1735	43 / 1700	56.8	0.70 [0.44,1.12]	
FIGARO-DKD	31 / 924	25 / 929	43.2	1.26 [0.74,2.14]	
Total	62 / 2659	68 / 2629		0.90 [0.64,1.28]	Z=-0.59, p=0.5576
Heterogeneity:	Q=2.59 (df=1)	p=0.1078	I^2=61.3%		
> 4.5					
FIDELIO-DKD	14 / 882	29 / 910	67.5	0.49 [0.26,0.93]	
FIGARO-DKD	7 / 433	13 / 426	32.5	0.52 [0.21,1.32]	
Total	21 / 1315	42 / 1336		0.50 [0.29,0.85]	Z=-2.56, p=0.0103
Heterogeneity:	Q=0.01 (df=1)	p=0.9126	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.31 (df=1)	p=0.0688	I^2=69.8%		

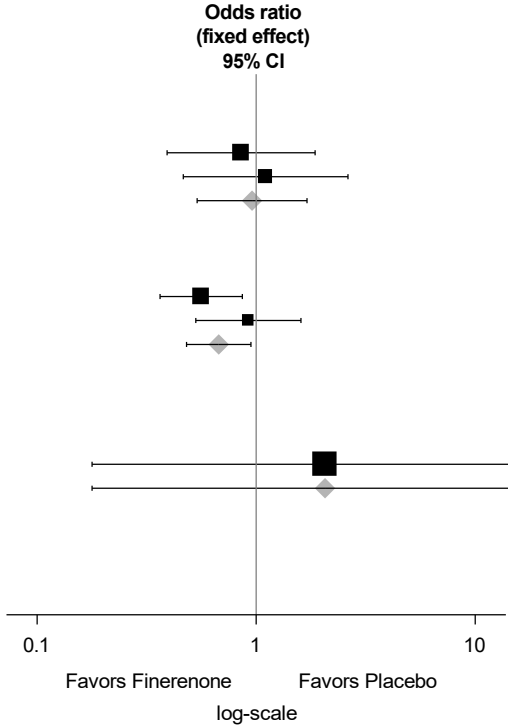


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.83.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Diabetes mellitus (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

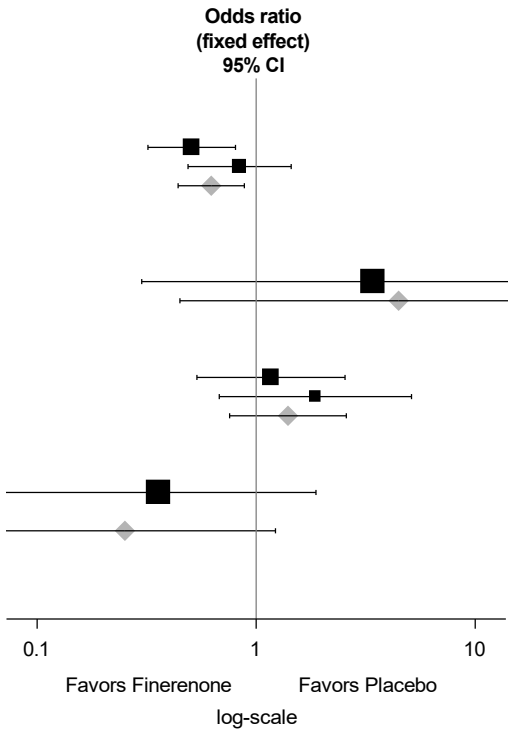
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	14 / 723	55.3	0.85 [0.39,1.86]	
FIGARO-DKD	11 / 494	10 / 495	44.7	1.10 [0.46,2.62]	
Total	23 / 1218	24 / 1218		0.96 [0.54,1.71]	Z=-0.15, p=0.8833
Heterogeneity:	Q=0.19 (df=1)	p=0.6642	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	33 / 1759	58 / 1760	62.0	0.56 [0.36,0.86]	
FIGARO-DKD	25 / 829	27 / 827	38.0	0.92 [0.53,1.60]	
Total	58 / 2588	85 / 2587		0.67 [0.48,0.95]	Z=-2.28, p=0.0226
Heterogeneity:	Q=1.92 (df=1)	p=0.1660	I^2=47.9%		
>= 160					
FIDELIO-DKD	0 / 133	0 / 127	0.0	-	
FIGARO-DKD	2 / 34	1 / 34	100.0	2.06 [0.18,23.88]	
Total	2 / 167	1 / 161		2.06 [0.18,23.88]	Z=0.58, p=0.5624
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.72 (df=2)	p=0.4233	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.83.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

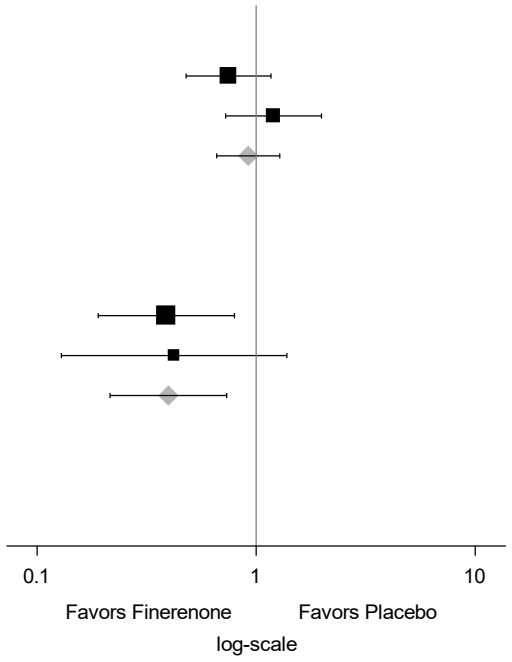
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	28 / 1634	55 / 1657	58.1	0.51 [0.32,0.80]	
FIGARO-DKD	25 / 1010	29 / 989	41.9	0.84 [0.49,1.45]	
Total	53 / 2644	84 / 2646		0.62 [0.44,0.88]	Z=-2.66, p=0.0078
Heterogeneity:	Q=1.93 (df=1)	p=0.1652	I^2=48.1%		
Black					
FIDELIO-DKD	1 / 129	0 / 115	0.0	12E10 [12E10,12E10]	
FIGARO-DKD	2 / 43	1 / 71	100.0	3.41 [0.30,38.83]	
Total	3 / 172	1 / 186		4.47 [0.45,44.54]	Z=1.28, p=0.2018
Heterogeneity:	Q=0.05 (df=1)	p=0.8281	I^2=0.0%		
Asian					
FIDELIO-DKD	14 / 678	12 / 677	62.8	1.17 [0.54,2.55]	
FIGARO-DKD	11 / 252	6 / 251	37.2	1.86 [0.68,5.12]	
Total	25 / 930	18 / 928		1.40 [0.76,2.58]	Z=1.07, p=0.2854
Heterogeneity:	Q=0.51 (df=1)	p=0.4730	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	5 / 161	100.0	0.36 [0.07,1.87]	
FIGARO-DKD	0 / 52	2 / 45	0.0	0.00 [0.00,68E295]	
Total	2 / 228	7 / 206		0.25 [0.05,1.23]	Z=-1.71, p=0.0875
Heterogeneity:	Q=0.18 (df=1)	p=0.6743	I^2=0.0%		
Subgroup Heterogeneity:	Q=9.18 (df=3)	p=0.0270	I^2=67.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.83.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

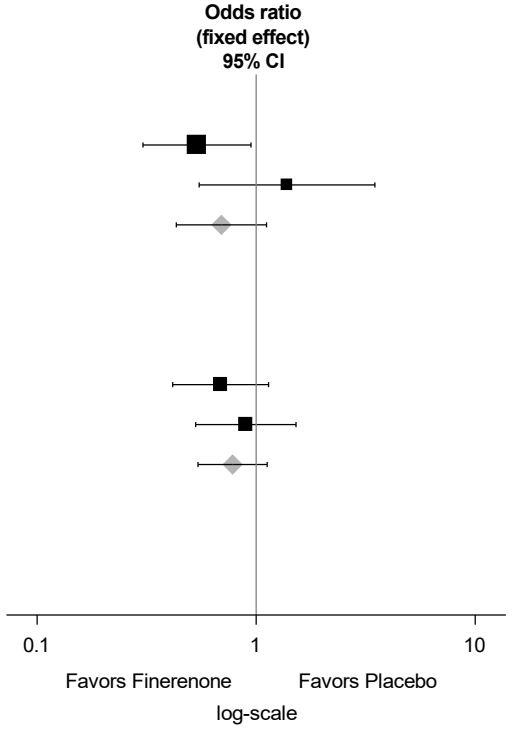
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	34 / 1797	47 / 1870	56.1	0.75 [0.48,1.17]	
FIGARO-DKD	34 / 917	29 / 933	43.9	1.20 [0.73,1.99]	
Total	68 / 2714	76 / 2803		0.92 [0.66,1.28]	Z=-0.49, p=0.6216
Heterogeneity:	Q=1.90 (df=1)	p=0.1685	I^2=47.3%		
Female					
FIDELIO-DKD	11 / 820	25 / 740	73.3	0.39 [0.19,0.80]	
FIGARO-DKD	4 / 440	9 / 423	26.7	0.42 [0.13,1.38]	
Total	15 / 1260	34 / 1163		0.40 [0.22,0.73]	Z=-2.95, p=0.0032
Heterogeneity:	Q=0.01 (df=1)	p=0.9079	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.57 (df=1)	p=0.0183	I^2=82.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.83.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

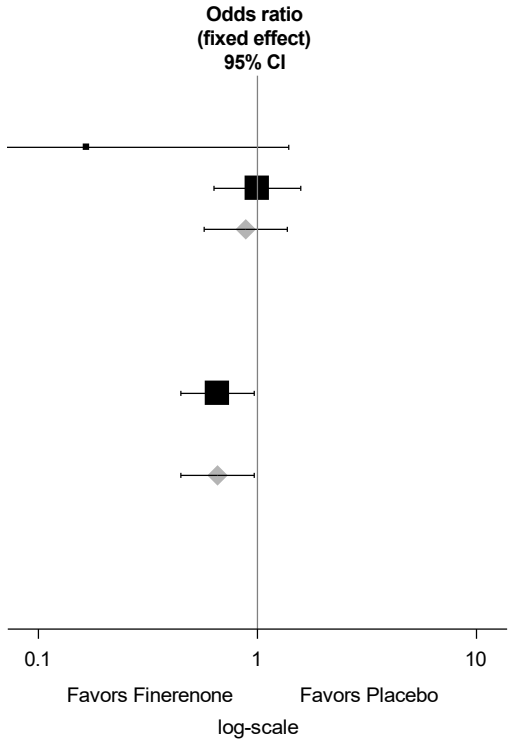
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	19 / 1103	34 / 1075	72.6	0.54 [0.30,0.95]	
FIGARO-DKD	11 / 336	8 / 335	27.4	1.38 [0.55,3.48]	
Total	30 / 1439	42 / 1410		0.69 [0.43,1.12]	Z=-1.51, p=0.1312
Heterogeneity:	Q=2.93 (df=1)	p=0.0869	I^2=65.9%		
>= 65					
FIDELIO-DKD	26 / 1514	38 / 1535	52.3	0.69 [0.42,1.14]	
FIGARO-DKD	27 / 1021	30 / 1021	47.7	0.90 [0.53,1.52]	
Total	53 / 2535	68 / 2556		0.78 [0.54,1.12]	Z=-1.34, p=0.1813
Heterogeneity:	Q=0.51 (df=1)	p=0.4763	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7001	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.83.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

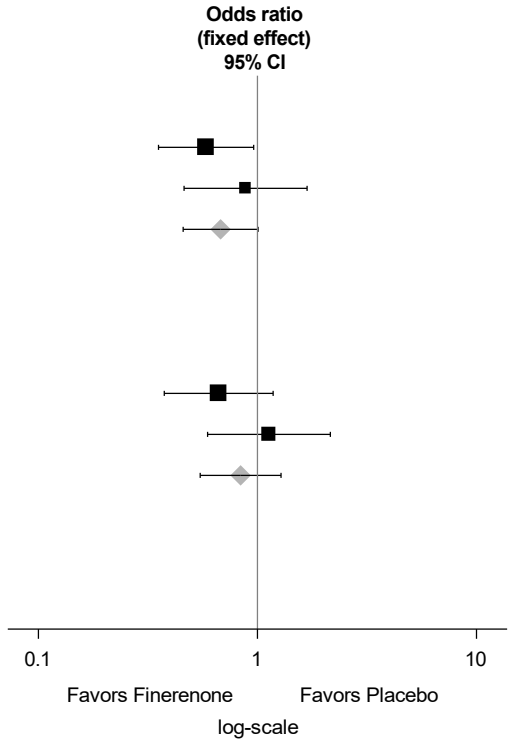
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	6 / 213	4.4	0.17 [0.02,1.39]	
FIGARO-DKD	38 / 1357	38 / 1356	95.6	1.00 [0.63,1.58]	
Total	39 / 1566	44 / 1569		0.88 [0.57,1.37]	Z=-0.55, p=0.5811
Heterogeneity:	Q=2.66 (df=1)	p=0.1031	I^2=62.4%		
Very High					
FIDELIO-DKD	44 / 2408	66 / 2397	100.0	0.66 [0.45,0.97]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	44 / 2408	66 / 2397		0.66 [0.45,0.97]	Z=-2.13, p=0.0330
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.99 (df=1)	p=0.3188	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.83.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

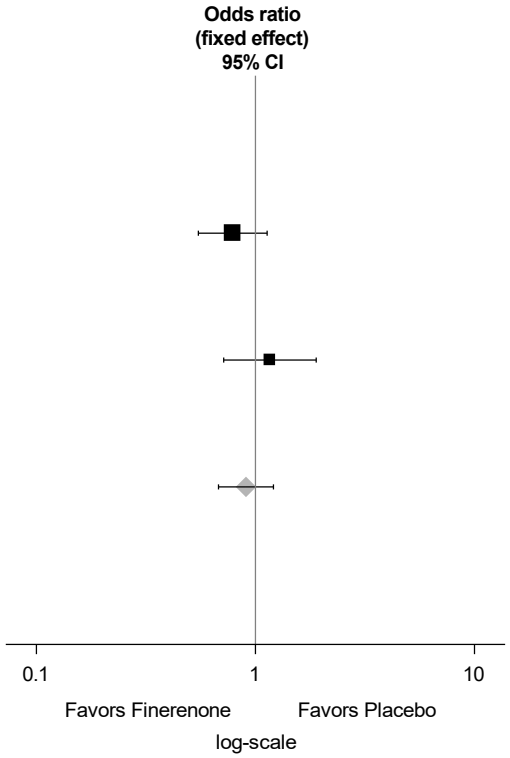
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	25 / 1556	42 / 1541	62.6	0.58 [0.35,0.96]	
FIGARO-DKD	18 / 637	20 / 627	37.4	0.88 [0.46,1.68]	
Total	43 / 2193	62 / 2168		0.68 [0.46,1.01]	Z=-1.93, p=0.0538
Heterogeneity:	Q=0.99 (df=1)	p=0.3197	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	20 / 1061	30 / 1069	56.0	0.67 [0.38,1.18]	
FIGARO-DKD	20 / 720	18 / 729	44.0	1.13 [0.59,2.15]	
Total	40 / 1781	48 / 1798		0.84 [0.55,1.28]	Z=-0.82, p=0.4140
Heterogeneity:	Q=1.44 (df=1)	p=0.2299	I^2=30.6%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4768	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.84: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetes mellitus inadequate control (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

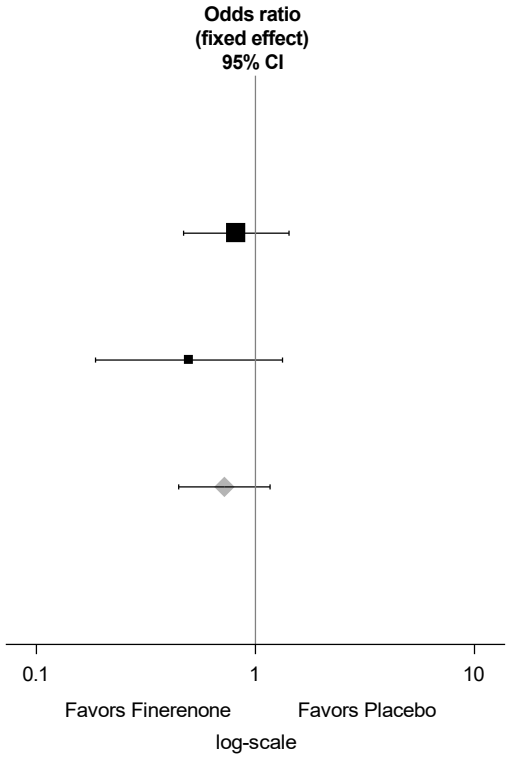
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	54 / 2617	68 / 2610	64.4	0.79 [0.55,1.13]	
FIGARO-DKD	36 / 1357	31 / 1356	35.6	1.16 [0.72,1.89]	
Total	90 / 3974	99 / 3966		0.91 [0.68,1.21]	Z=-0.68, p=0.4989
Heterogeneity:	Q=1.60 (df=1)	p=0.2056	I^2=37.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.85: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyslipidaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

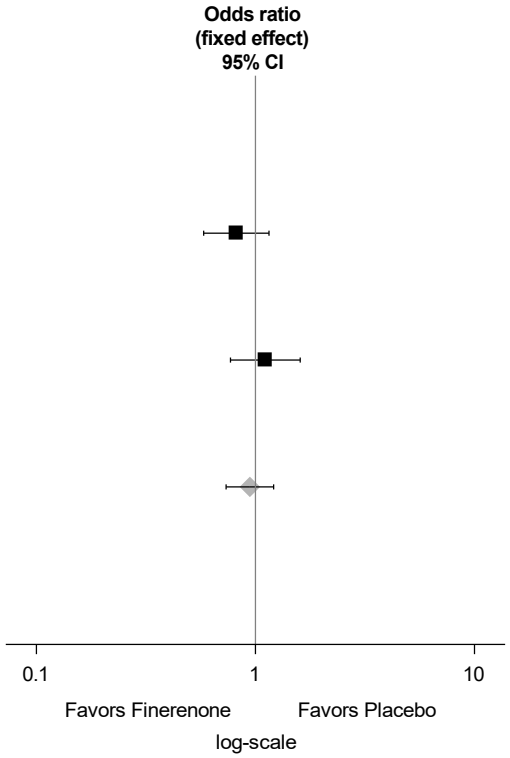
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	28 / 2610	75.9	0.82 [0.47,1.42]	
FIGARO-DKD	6 / 1357	12 / 1356	24.1	0.50 [0.19,1.33]	
Total	29 / 3974	40 / 3966		0.72 [0.45,1.17]	Z=-1.33, p=0.1824
Heterogeneity:	Q=0.75 (df=1)	p=0.3878	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.86: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Gout (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

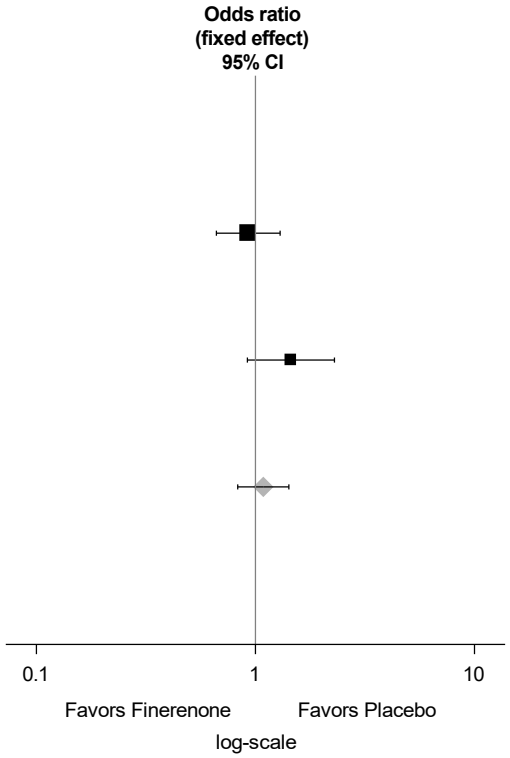
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	74 / 2610	53.2	0.82 [0.58,1.15]	
FIGARO-DKD	63 / 1357	57 / 1356	46.8	1.11 [0.77,1.60]	
Total	124 / 3974	131 / 3966		0.94 [0.73,1.21]	Z=-0.46, p=0.6452
Heterogeneity:	Q=1.42 (df=1)	p=0.2339	I^2=29.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.87: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

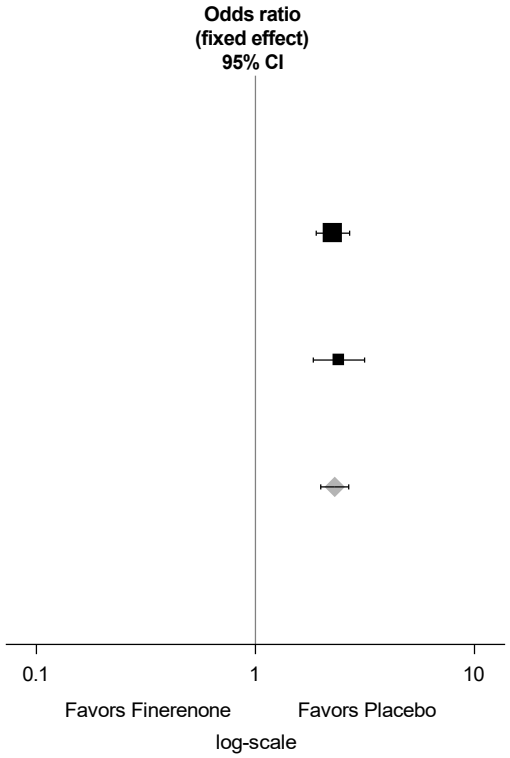
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	68 / 2617	73 / 2610	65.1	0.93 [0.66,1.30]	
FIGARO-DKD	46 / 1357	32 / 1356	34.9	1.45 [0.92,2.29]	
Total	114 / 3974	105 / 3966		1.09 [0.83,1.42]	Z=0.60, p=0.5474
Heterogeneity:	Q=2.40 (df=1)	p=0.1211	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.88: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

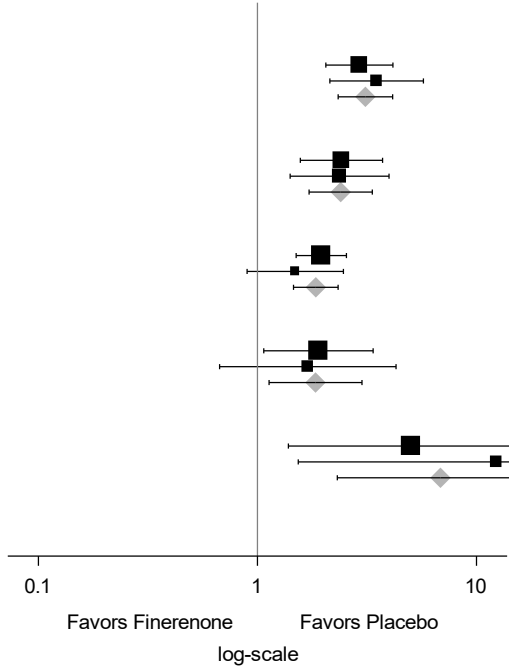
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	428 / 2617	208 / 2610	70.2	2.26 [1.89,2.69]	
FIGARO-DKD	186 / 1357	84 / 1356	29.8	2.41 [1.84,3.15]	
Total	614 / 3974	292 / 3966		2.30 [1.99,2.67]	Z=11.11, p=<.0001
Heterogeneity:	Q=0.15 (df=1)	p=0.7001	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.88.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

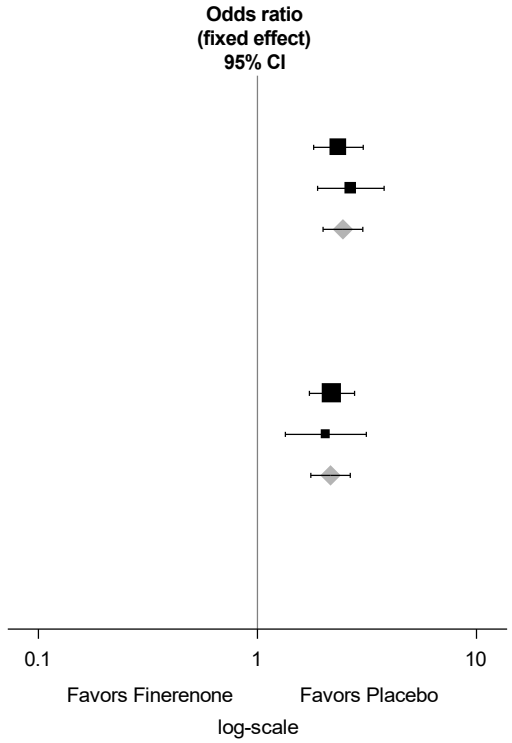
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	123 / 1075	45 / 1062	66.0	2.92 [2.05,4.15]	
FIGARO-DKD	71 / 638	22 / 637	34.0	3.50 [2.14,5.72]	
Total	194 / 1713	67 / 1699		3.11 [2.34,4.14]	Z=7.77, p=<.0001
Heterogeneity:	Q=0.35 (df=1)	p=0.5569	I^2=0.0%		
North America					
FIDELIO-DKD	72 / 424	34 / 436	59.1	2.42 [1.57,3.73]	
FIGARO-DKD	50 / 267	24 / 271	40.9	2.37 [1.41,3.99]	
Total	122 / 691	58 / 707		2.40 [1.72,3.34]	Z=5.16, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9545	I^2=0.0%		
Asia					
FIDELIO-DKD	184 / 751	106 / 745	78.6	1.96 [1.50,2.55]	
FIGARO-DKD	41 / 289	29 / 290	21.4	1.49 [0.90,2.47]	
Total	225 / 1040	135 / 1035		1.85 [1.46,2.33]	Z=5.13, p=<.0001
Heterogeneity:	Q=0.88 (df=1)	p=0.3477	I^2=0.0%		
Latin America					
FIDELIO-DKD	36 / 273	20 / 270	72.3	1.90 [1.07,3.37]	
FIGARO-DKD	13 / 102	8 / 101	27.7	1.70 [0.67,4.29]	
Total	49 / 375	28 / 371		1.84 [1.13,3.00]	Z=2.45, p=0.0143
Heterogeneity:	Q=0.04 (df=1)	p=0.8409	I^2=0.0%		
Others					
FIDELIO-DKD	13 / 94	3 / 97	72.3	5.03 [1.38,18.27]	
FIGARO-DKD	11 / 61	1 / 57	27.7	12.32 [1.54,98.85]	
Total	24 / 155	4 / 154		6.85 [2.32,20.25]	Z=3.48, p=0.0005
Heterogeneity:	Q=0.53 (df=1)	p=0.4685	I^2=0.0%		
Subgroup Heterogeneity:	Q=12.39 (df=4)	p=0.0147	I^2=67.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.88.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

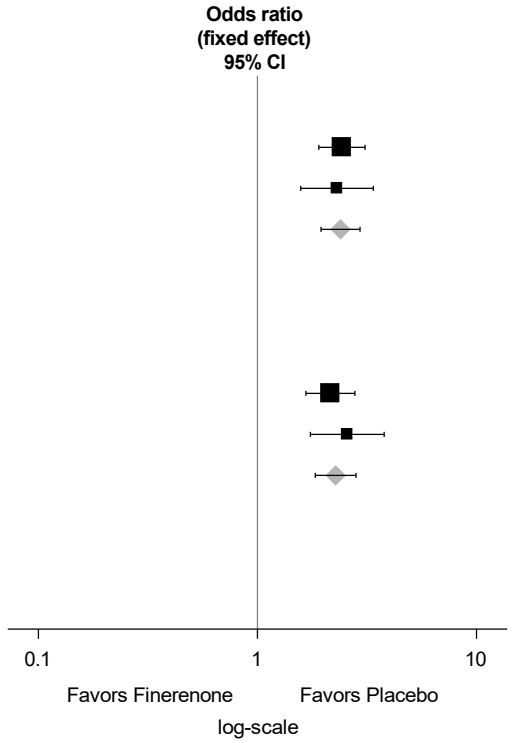
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	198 / 1213	93 / 1210	64.3	2.34 [1.81,3.04]	
FIGARO-DKD	119 / 862	48 / 848	35.7	2.67 [1.88,3.79]	
Total	317 / 2075	141 / 2058		2.46 [1.99,3.03]	Z=8.43, p=<.0001
Heterogeneity:	Q=0.34 (df=1)	p=0.5578	I^2=0.0%		
Absent					
FIDELIO-DKD	230 / 1404	115 / 1400	76.3	2.19 [1.73,2.78]	
FIGARO-DKD	67 / 495	36 / 508	23.7	2.05 [1.34,3.14]	
Total	297 / 1899	151 / 1908		2.16 [1.75,2.65]	Z=7.26, p=<.0001
Heterogeneity:	Q=0.07 (df=1)	p=0.7955	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.75 (df=1)	p=0.3853	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.88.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

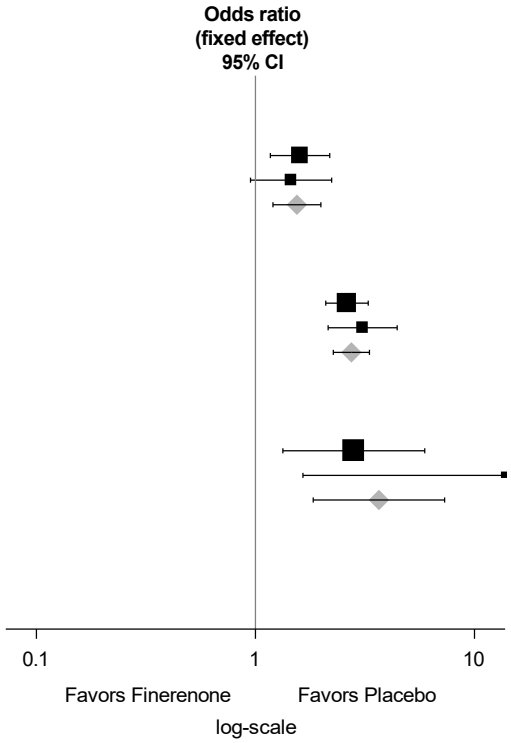
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	233 / 1735	102 / 1700	71.2	2.43 [1.91,3.10]	
FIGARO-DKD	89 / 924	41 / 929	28.8	2.31 [1.58,3.38]	
Total	322 / 2659	143 / 2629		2.39 [1.95,2.94]	Z=8.35, p=<.0001
Heterogeneity:	Q=0.05 (df=1)	p=0.8238	I^2=0.0%		
> 4.5					
FIDELIO-DKD	195 / 882	106 / 910	69.4	2.15 [1.66,2.79]	
FIGARO-DKD	97 / 433	43 / 426	30.6	2.57 [1.74,3.79]	
Total	292 / 1315	149 / 1336		2.28 [1.84,2.82]	Z=7.52, p=<.0001
Heterogeneity:	Q=0.56 (df=1)	p=0.4546	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.11 (df=1)	p=0.7349	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.88.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

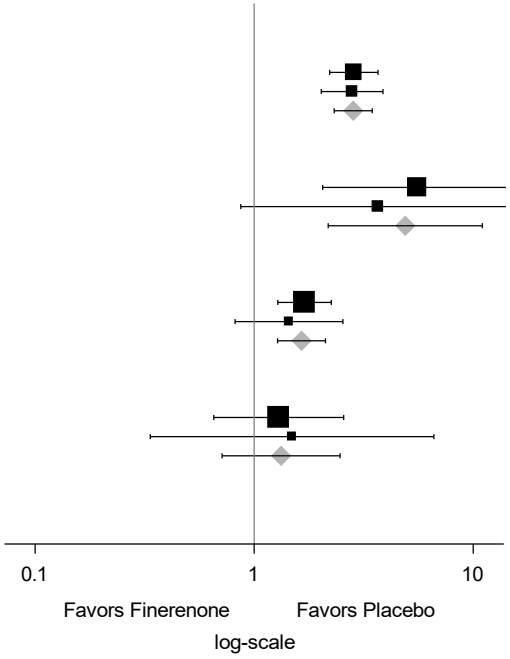
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	113 / 724	75 / 723	65.1	1.60 [1.17,2.18]	
FIGARO-DKD	56 / 494	40 / 495	34.9	1.45 [0.95,2.23]	
Total	169 / 1218	115 / 1218		1.55 [1.20,1.99]	Z=3.39, p=0.0007
Heterogeneity:	Q=0.12 (df=1)	p=0.7270	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	287 / 1759	122 / 1760	72.5	2.62 [2.09,3.27]	
FIGARO-DKD	120 / 829	43 / 827	27.5	3.09 [2.15,4.44]	
Total	407 / 2588	165 / 2587		2.74 [2.27,3.32]	Z=10.40, p=<.0001
Heterogeneity:	Q=0.57 (df=1)	p=0.4490	I^2=0.0%		
>= 160					
FIDELIO-DKD	28 / 133	11 / 127	89.0	2.81 [1.33,5.93]	
FIGARO-DKD	10 / 34	1 / 34	11.0	13.75 [1.65,114.76]	
Total	38 / 167	12 / 161		3.66 [1.84,7.31]	Z=3.68, p=0.0002
Heterogeneity:	Q=1.98 (df=1)	p=0.1599	I^2=49.4%		
Subgroup Heterogeneity:	Q=14.55 (df=2)	p=0.0007	I^2=86.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.88.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

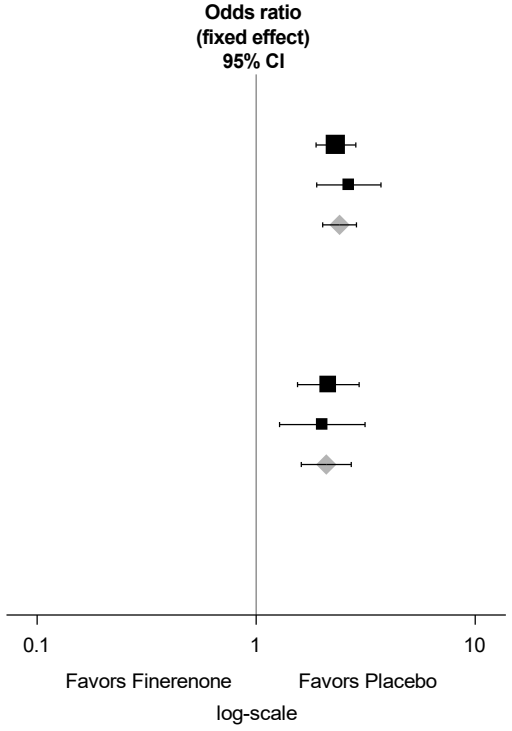
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	230 / 1634	90 / 1657	62.0	2.85 [2.21,3.68]	
FIGARO-DKD	143 / 1010	55 / 989	38.0	2.80 [2.02,3.87]	
Total	373 / 2644	145 / 2646		2.83 [2.32,3.46]	Z=10.20, p=<.0001
Heterogeneity:	Q=0.01 (df=1)	p=0.9312	I^2=0.0%		
Black					
FIDELIO-DKD	26 / 129	5 / 115	67.8	5.55 [2.06,15.01]	
FIGARO-DKD	6 / 43	3 / 71	32.2	3.68 [0.87,15.55]	
Total	32 / 172	8 / 186		4.90 [2.18,11.01]	Z=3.84, p=0.0001
Heterogeneity:	Q=0.21 (df=1)	p=0.6441	I^2=0.0%		
Asian					
FIDELIO-DKD	150 / 678	97 / 677	80.2	1.70 [1.28,2.25]	
FIGARO-DKD	32 / 252	23 / 251	19.8	1.44 [0.82,2.54]	
Total	182 / 930	120 / 928		1.65 [1.28,2.12]	Z=3.87, p=0.0001
Heterogeneity:	Q=0.26 (df=1)	p=0.6117	I^2=0.0%		
Others					
FIDELIO-DKD	22 / 176	16 / 161	82.7	1.29 [0.65,2.56]	
FIGARO-DKD	5 / 52	3 / 45	17.3	1.49 [0.34,6.61]	
Total	27 / 228	19 / 206		1.33 [0.71,2.47]	Z=0.89, p=0.3716
Heterogeneity:	Q=0.03 (df=1)	p=0.8670	I^2=0.0%		
Subgroup Heterogeneity:	Q=17.31 (df=3)	p=0.0006	I^2=82.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.88.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

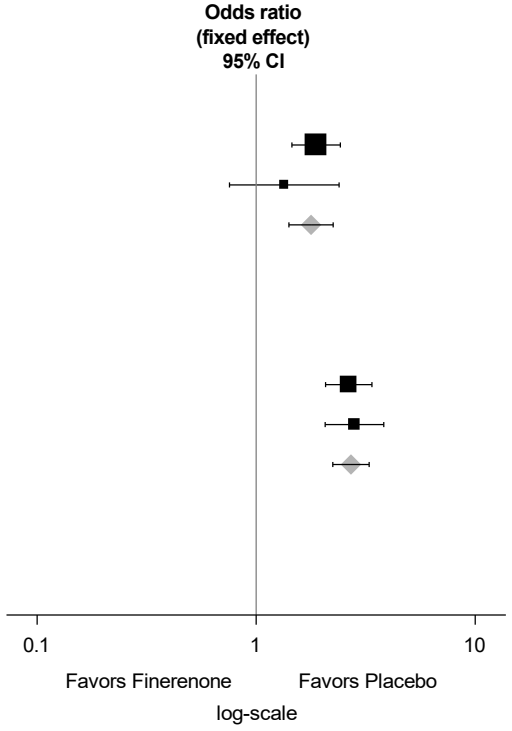
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	298 / 1797	148 / 1870	72.3	2.31 [1.88,2.85]	
FIGARO-DKD	124 / 917	52 / 933	27.7	2.65 [1.89,3.71]	
Total	422 / 2714	200 / 2803		2.40 [2.01,2.87]	Z=9.68, p=<.0001
Heterogeneity:	Q=0.45 (df=1)	p=0.5030	I^2=0.0%		
Female					
FIDELIO-DKD	130 / 820	60 / 740	65.8	2.14 [1.54,2.95]	
FIGARO-DKD	62 / 440	32 / 423	34.2	2.00 [1.28,3.14]	
Total	192 / 1260	92 / 1163		2.09 [1.61,2.72]	Z=5.50, p=<.0001
Heterogeneity:	Q=0.05 (df=1)	p=0.8225	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.75 (df=1)	p=0.3879	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.88.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

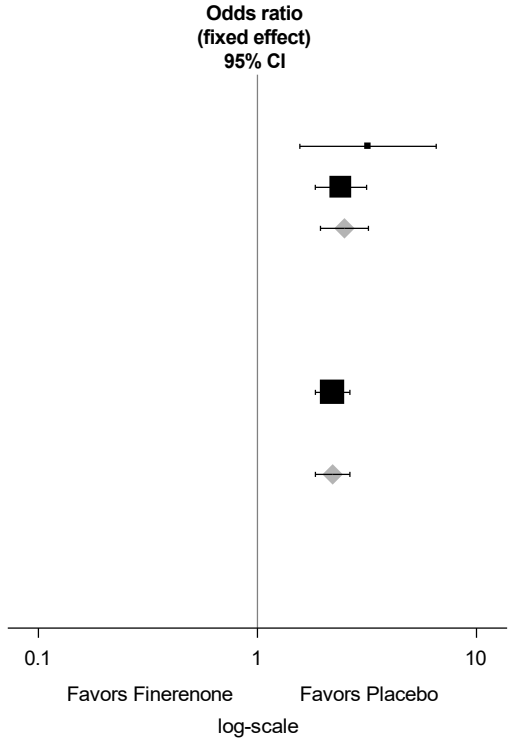
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	188 / 1103	106 / 1075	83.7	1.88 [1.46,2.42]	
FIGARO-DKD	29 / 336	22 / 335	16.3	1.34 [0.76,2.39]	
Total	217 / 1439	128 / 1410		1.78 [1.41,2.25]	Z=4.86, p=<.0001
Heterogeneity:	Q=1.09 (df=1)	p=0.2976	I^2=7.8%		
>= 65					
FIDELIO-DKD	240 / 1514	102 / 1535	61.5	2.65 [2.07,3.38]	
FIGARO-DKD	157 / 1021	62 / 1021	38.5	2.81 [2.07,3.82]	
Total	397 / 2535	164 / 2556		2.71 [2.24,3.28]	Z=10.22, p=<.0001
Heterogeneity:	Q=0.09 (df=1)	p=0.7640	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.46 (df=1)	p=0.0063	I^2=86.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.88.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

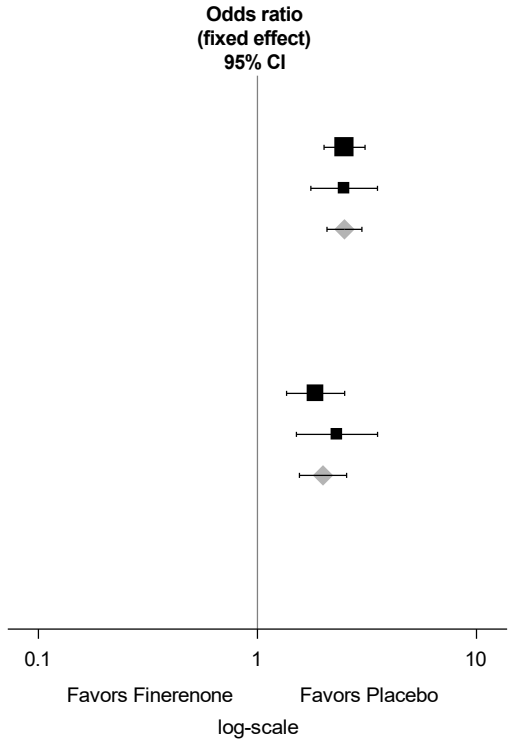
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	31 / 209	11 / 213	12.4	3.20 [1.56,6.55]	
FIGARO-DKD	186 / 1357	84 / 1356	87.6	2.41 [1.84,3.15]	
Total	217 / 1566	95 / 1569		2.50 [1.94,3.21]	Z=7.11, p=<.0001
Heterogeneity:	Q=0.53 (df=1)	p=0.4658	I^2=0.0%		
Very High					
FIDELIO-DKD	397 / 2408	197 / 2397	100.0	2.20 [1.84,2.64]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	397 / 2408	197 / 2397		2.20 [1.84,2.64]	Z=8.55, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4335	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.88.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

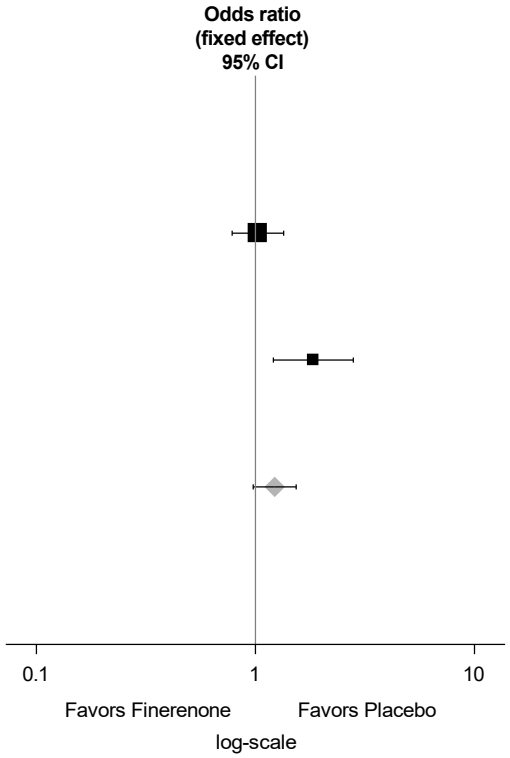
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	305 / 1556	137 / 1541	72.6	2.50 [2.01,3.10]	
FIGARO-DKD	115 / 637	51 / 627	27.4	2.49 [1.75,3.53]	
Total	420 / 2193	188 / 2168		2.50 [2.08,3.00]	Z=9.77, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9842	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	123 / 1061	71 / 1069	66.1	1.84 [1.36,2.50]	
FIGARO-DKD	71 / 720	33 / 729	33.9	2.31 [1.51,3.53]	
Total	194 / 1781	104 / 1798		1.99 [1.55,2.55]	Z=5.45, p=<.0001
Heterogeneity:	Q=0.70 (df=1)	p=0.4014	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.05 (df=1)	p=0.1522	I^2=51.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.89: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyperuricaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

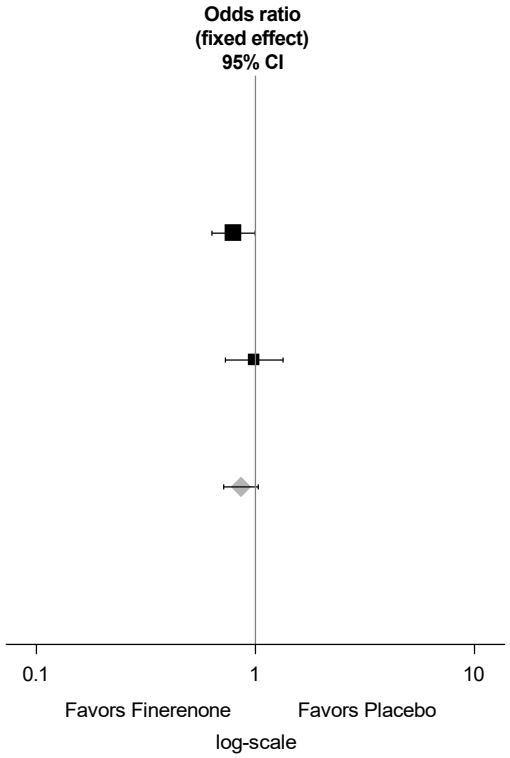
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	111 / 2617	108 / 2610	70.7	1.03 [0.78,1.35]	
FIGARO-DKD	63 / 1357	35 / 1356	29.3	1.84 [1.21,2.80]	
Total	174 / 3974	143 / 3966		1.22 [0.98,1.53]	Z=1.76, p=0.0792
Heterogeneity:	Q=5.22 (df=1)	p=0.0223	I^2=80.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.90: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

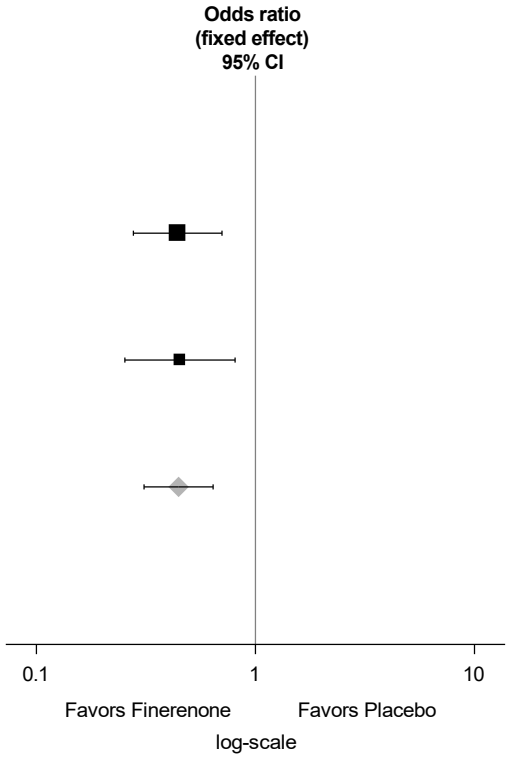
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	143 / 2617	177 / 2610	64.0	0.79 [0.63,1.00]	
FIGARO-DKD	89 / 1357	90 / 1356	36.0	0.99 [0.73,1.34]	
Total	232 / 3974	267 / 3966		0.86 [0.72,1.03]	Z=-1.64, p=0.1010
Heterogeneity:	Q=1.26 (df=1)	p=0.2611	I^2=20.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.91: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

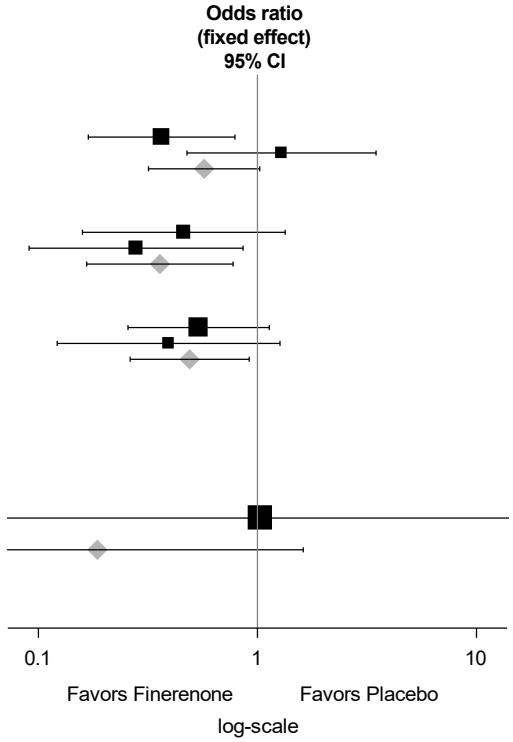
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	58 / 2610	60.7	0.44 [0.28,0.70]	
FIGARO-DKD	17 / 1357	37 / 1356	39.3	0.45 [0.25,0.81]	
Total	43 / 3974	95 / 3966		0.45 [0.31,0.64]	Z=-4.36, p=<.0001
Heterogeneity:	Q=0.00 (df=1)	p=0.9495	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.91.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

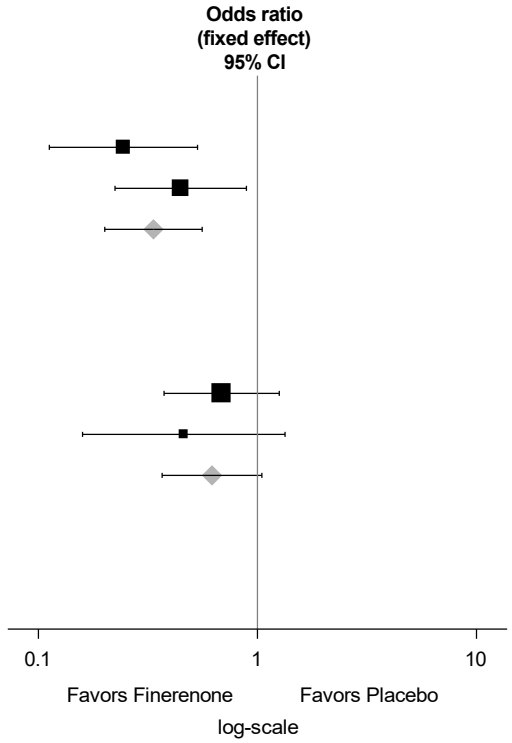
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	24 / 1062	62.4	0.37 [0.17,0.79]	
FIGARO-DKD	9 / 638	7 / 637	37.6	1.29 [0.48,3.48]	
Total	18 / 1713	31 / 1699		0.57 [0.32,1.02]	Z=-1.88, p=0.0604
Heterogeneity:	Q=3.86 (df=1)	p=0.0493	I^2=74.1%		
North America					
FIDELIO-DKD	5 / 424	11 / 436	52.7	0.46 [0.16,1.34]	
FIGARO-DKD	4 / 267	14 / 271	47.3	0.28 [0.09,0.86]	
Total	9 / 691	25 / 707		0.36 [0.17,0.77]	Z=-2.61, p=0.0090
Heterogeneity:	Q=0.40 (df=1)	p=0.5250	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 751	20 / 745	71.3	0.54 [0.26,1.13]	
FIGARO-DKD	4 / 289	10 / 290	28.7	0.39 [0.12,1.27]	
Total	15 / 1040	30 / 1035		0.49 [0.26,0.92]	Z=-2.23, p=0.0257
Heterogeneity:	Q=0.20 (df=1)	p=0.6554	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	2 / 270	0.0	0.00 [0.00,16E296]	
FIGARO-DKD	0 / 102	2 / 101	0.0	0.00 [0.00,16E296]	
Total	0 / 375	4 / 371		0.00 [0.00,11E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	1 / 97	100.0	1.03 [0.06,16.75]	
FIGARO-DKD	0 / 61	4 / 57	0.0	0.00 [0.00,11E296]	
Total	1 / 155	5 / 154		0.19 [0.02,1.62]	Z=-1.52, p=0.1276
Heterogeneity:	Q=1.45 (df=1)	p=0.2279	I^2=31.2%		
Subgroup Heterogeneity:	Q=1.62 (df=4)	p=0.8045	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.91.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

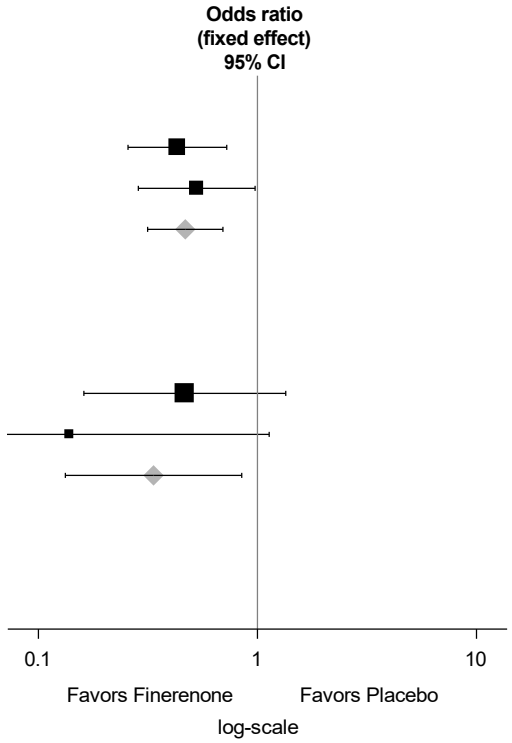
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	8 / 1213	32 / 1210	44.0	0.24 [0.11,0.53]	
FIGARO-DKD	12 / 862	26 / 848	56.0	0.45 [0.22,0.89]	
Total	20 / 2075	58 / 2058		0.34 [0.20,0.56]	Z=-4.18, p=<.0001
Heterogeneity:	Q=1.29 (df=1)	p=0.2556	I^2=22.6%		
Absent					
FIDELIO-DKD	18 / 1404	26 / 1400	75.5	0.69 [0.37,1.26]	
FIGARO-DKD	5 / 495	11 / 508	24.5	0.46 [0.16,1.34]	
Total	23 / 1899	37 / 1908		0.62 [0.37,1.05]	Z=-1.79, p=0.0740
Heterogeneity:	Q=0.41 (df=1)	p=0.5242	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.71 (df=1)	p=0.0999	I^2=63.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.91.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

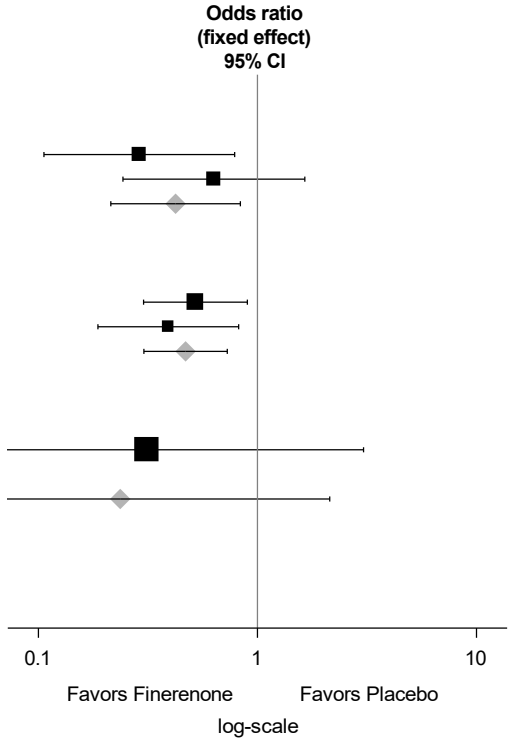
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	21 / 1735	47 / 1700	58.3	0.43 [0.26,0.72]	
FIGARO-DKD	16 / 924	30 / 929	41.7	0.53 [0.29,0.98]	
Total	37 / 2659	77 / 2629		0.47 [0.32,0.70]	Z=-3.76, p=0.0002
Heterogeneity:	Q=0.25 (df=1)	p=0.6200	I^2=0.0%		
> 4.5					
FIDELIO-DKD	5 / 882	11 / 910	79.7	0.47 [0.16,1.35]	
FIGARO-DKD	1 / 433	7 / 426	20.3	0.14 [0.02,1.13]	
Total	6 / 1315	18 / 1336		0.34 [0.13,0.85]	Z=-2.31, p=0.0209
Heterogeneity:	Q=1.05 (df=1)	p=0.3056	I^2=4.7%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5166	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.91.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

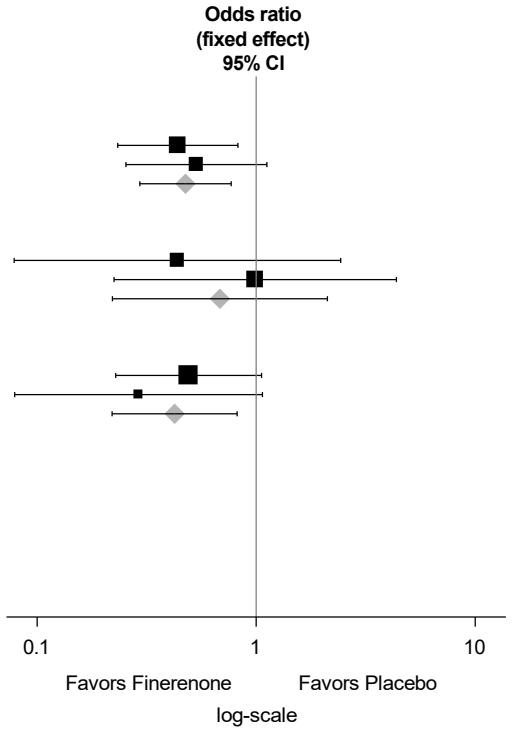
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	17 / 723	47.6	0.29 [0.11,0.79]	
FIGARO-DKD	7 / 494	11 / 495	52.4	0.63 [0.24,1.65]	
Total	12 / 1218	28 / 1218		0.42 [0.21,0.84]	Z=-2.48, p=0.0133
Heterogeneity:	Q=1.24 (df=1)	p=0.2661	I^2=19.2%		
130 - < 160					
FIDELIO-DKD	20 / 1759	38 / 1760	64.8	0.52 [0.30,0.90]	
FIGARO-DKD	10 / 829	25 / 827	35.2	0.39 [0.19,0.82]	
Total	30 / 2588	63 / 2587		0.47 [0.30,0.73]	Z=-3.38, p=0.0007
Heterogeneity:	Q=0.37 (df=1)	p=0.5424	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	3 / 127	100.0	0.31 [0.03,3.05]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,1E297]	
Total	1 / 167	4 / 161		0.24 [0.03,2.14]	Z=-1.28, p=0.1992
Heterogeneity:	Q=0.06 (df=1)	p=0.8086	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.40 (df=2)	p=0.8203	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.91.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

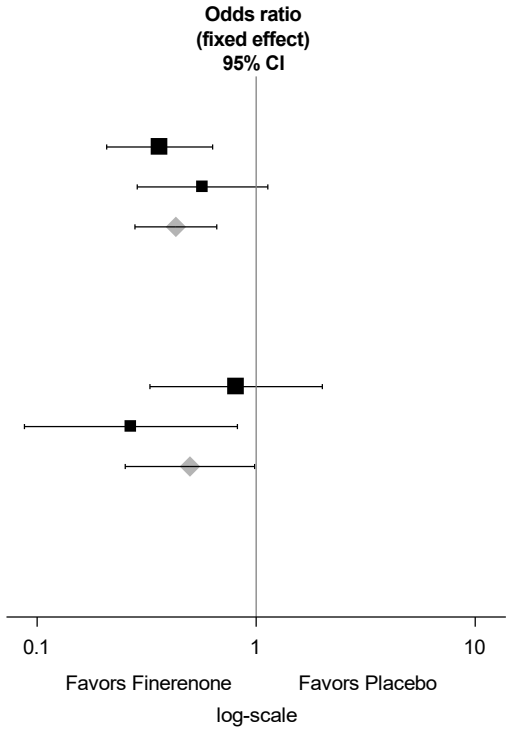
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	14 / 1634	32 / 1657	57.9	0.44 [0.23,0.83]	
FIGARO-DKD	11 / 1010	20 / 989	42.1	0.53 [0.25,1.12]	
Total	25 / 2644	52 / 2646		0.48 [0.29,0.77]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.15 (df=1)	p=0.6943	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	4 / 115	42.8	0.44 [0.08,2.43]	
FIGARO-DKD	3 / 43	5 / 71	57.2	0.99 [0.22,4.37]	
Total	5 / 172	9 / 186		0.68 [0.22,2.11]	Z=-0.66, p=0.5085
Heterogeneity:	Q=0.50 (df=1)	p=0.4794	I^2=0.0%		
Asian					
FIDELIO-DKD	10 / 678	20 / 677	74.3	0.49 [0.23,1.06]	
FIGARO-DKD	3 / 252	10 / 251	25.7	0.29 [0.08,1.07]	
Total	13 / 930	30 / 928		0.42 [0.22,0.82]	Z=-2.56, p=0.0106
Heterogeneity:	Q=0.47 (df=1)	p=0.4938	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 176	2 / 161	0.0	0.00 [0.00,93E295]	
FIGARO-DKD	0 / 52	2 / 45	0.0	0.00 [0.00,68E295]	
Total	0 / 228	4 / 206		0.00 [0.00,16E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.51 (df=3)	p=0.9167	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.91.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

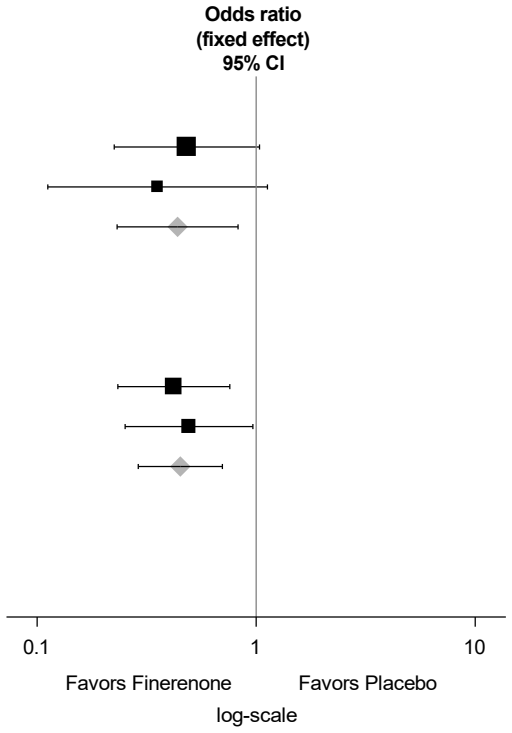
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	48 / 1870	60.3	0.36 [0.21,0.63]	
FIGARO-DKD	13 / 917	23 / 933	39.7	0.57 [0.29,1.13]	
Total	30 / 2714	71 / 2803		0.43 [0.28,0.66]	Z=-3.85, p=0.0001
Heterogeneity:	Q=1.00 (df=1)	p=0.3172	I^2=0.1%		
Female					
FIDELIO-DKD	9 / 820	10 / 740	60.4	0.81 [0.33,2.00]	
FIGARO-DKD	4 / 440	14 / 423	39.6	0.27 [0.09,0.82]	
Total	13 / 1260	24 / 1163		0.50 [0.25,0.98]	Z=-2.01, p=0.0448
Heterogeneity:	Q=2.28 (df=1)	p=0.1307	I^2=56.2%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7184	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.91.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

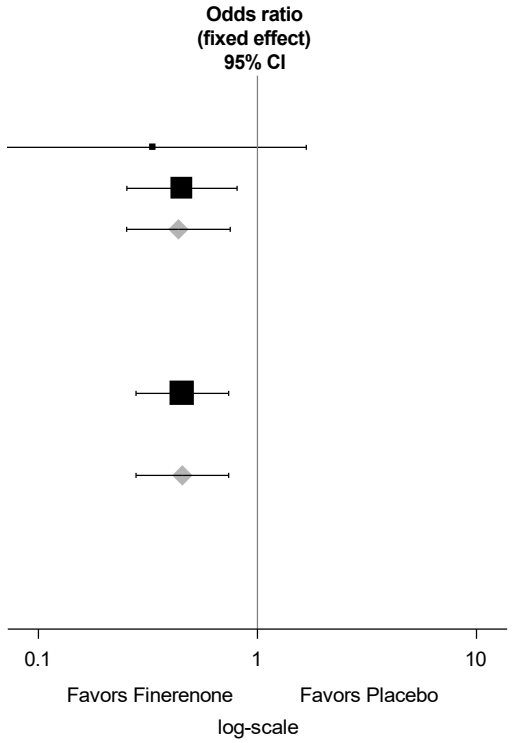
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	10 / 1103	20 / 1075	69.6	0.48 [0.22,1.04]	
FIGARO-DKD	4 / 336	11 / 335	30.4	0.35 [0.11,1.13]	
Total	14 / 1439	31 / 1410		0.44 [0.23,0.83]	Z=-2.55, p=0.0109
Heterogeneity:	Q=0.19 (df=1)	p=0.6632	I^2=0.0%		
>= 65					
FIDELIO-DKD	16 / 1514	38 / 1535	56.6	0.42 [0.23,0.76]	
FIGARO-DKD	13 / 1021	26 / 1021	43.4	0.49 [0.25,0.97]	
Total	29 / 2535	64 / 2556		0.45 [0.29,0.70]	Z=-3.53, p=0.0004
Heterogeneity:	Q=0.12 (df=1)	p=0.7262	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9421	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.91.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

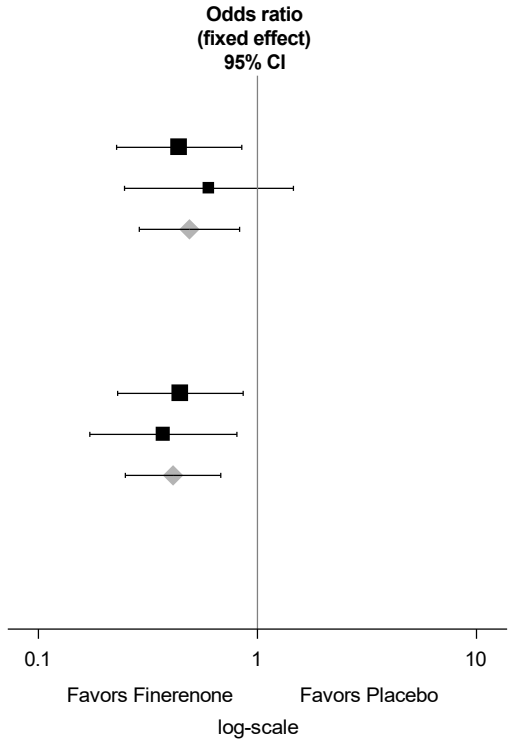
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	2 / 209	6 / 213	11.4	0.33 [0.07,1.67]	
FIGARO-DKD	17 / 1357	37 / 1356	88.6	0.45 [0.25,0.81]	
Total	19 / 1566	43 / 1569		0.44 [0.25,0.75]	Z=-2.99, p=0.0028
Heterogeneity:	Q=0.12 (df=1)	p=0.7269	I^2=0.0%		
Very High					
FIDELIO-DKD	24 / 2408	52 / 2397	100.0	0.45 [0.28,0.74]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	24 / 2408	52 / 2397		0.45 [0.28,0.74]	Z=-3.18, p=0.0015
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9127	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.91.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypokalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

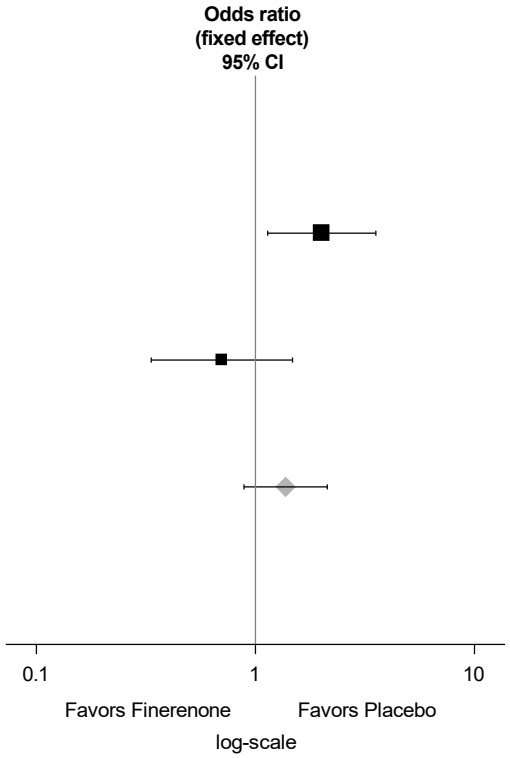
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	13 / 1556	29 / 1541	64.5	0.44 [0.23,0.85]	
FIGARO-DKD	8 / 637	13 / 627	35.5	0.60 [0.25,1.46]	
Total	21 / 2193	42 / 2168		0.49 [0.29,0.83]	Z=-2.66, p=0.0079
Heterogeneity:	Q=0.31 (df=1)	p=0.5787	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	13 / 1061	29 / 1069	57.9	0.44 [0.23,0.86]	
FIGARO-DKD	9 / 720	24 / 729	42.1	0.37 [0.17,0.81]	
Total	22 / 1781	53 / 1798		0.41 [0.25,0.68]	Z=-3.47, p=0.0005
Heterogeneity:	Q=0.12 (df=1)	p=0.7295	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6427	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.92: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hyponatraemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

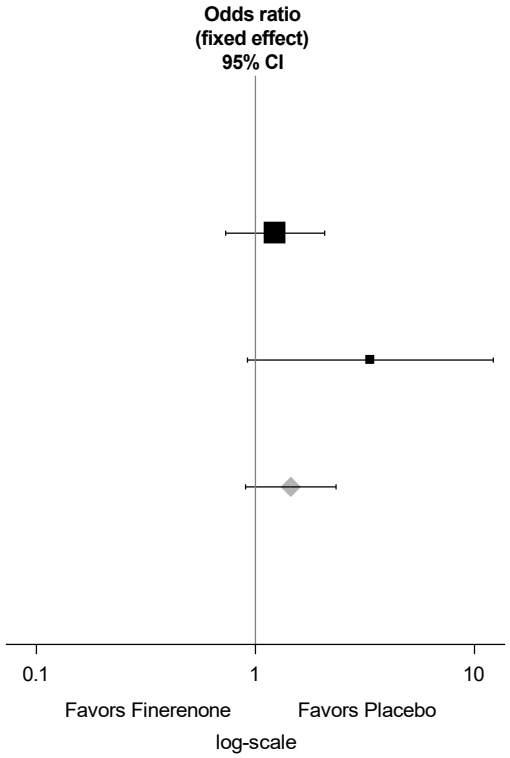
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	18 / 2610	63.1	2.01 [1.14,3.55]	
FIGARO-DKD	12 / 1357	17 / 1356	36.9	0.70 [0.33,1.48]	
Total	48 / 3974	35 / 3966		1.37 [0.89,2.13]	Z=1.42, p=0.1557
Heterogeneity:	Q=4.84 (df=1)	p=0.0278	I^2=79.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.93: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Metabolic acidosis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

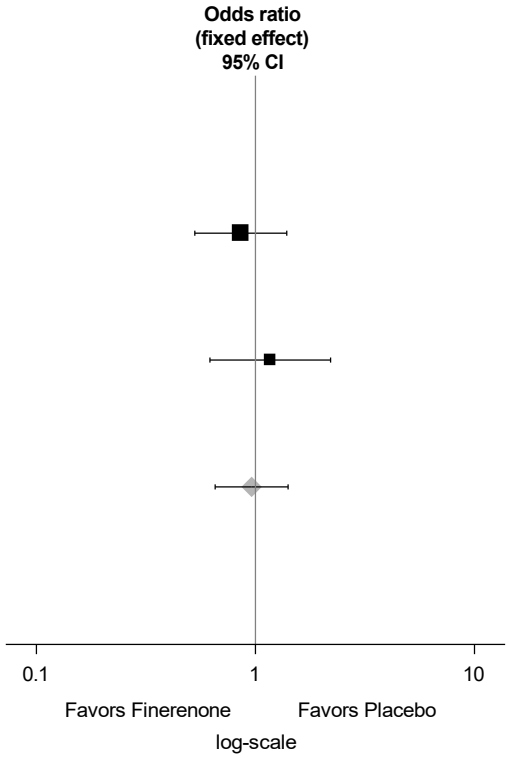
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	26 / 2610	86.1	1.23 [0.73,2.07]	
FIGARO-DKD	10 / 1357	3 / 1356	13.9	3.35 [0.92,12.19]	
Total	42 / 3974	29 / 3966		1.45 [0.90,2.33]	Z=1.53, p=0.1255
Heterogeneity:	Q=1.99 (df=1)	p=0.1579	I^2=49.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.94: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Type 2 diabetes mellitus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

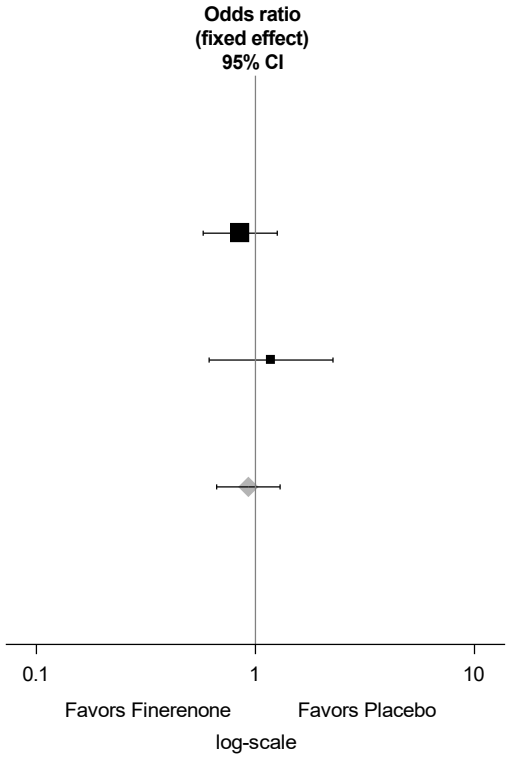
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	36 / 2610	63.3	0.86 [0.53,1.39]	
FIGARO-DKD	21 / 1357	18 / 1356	36.7	1.17 [0.62,2.20]	
Total	52 / 3974	54 / 3966		0.96 [0.65,1.41]	Z=-0.21, p=0.8370
Heterogeneity:	Q=0.58 (df=1)	p=0.4463	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.95: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vitamin D deficiency (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

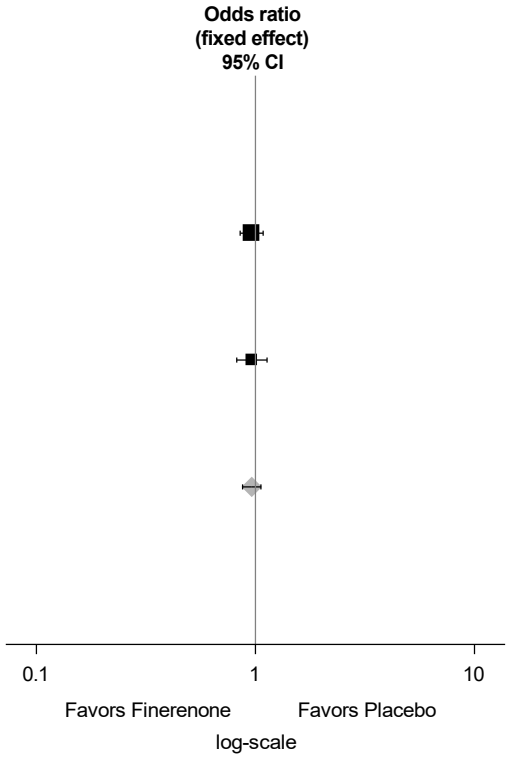
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	48 / 2617	56 / 2610	73.6	0.85 [0.58,1.26]	
FIGARO-DKD	20 / 1357	17 / 1356	26.4	1.18 [0.61,2.26]	
Total	68 / 3974	73 / 3966		0.93 [0.67,1.30]	Z=-0.44, p=0.6615
Heterogeneity:	Q=0.70 (df=1)	p=0.4025	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.96: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

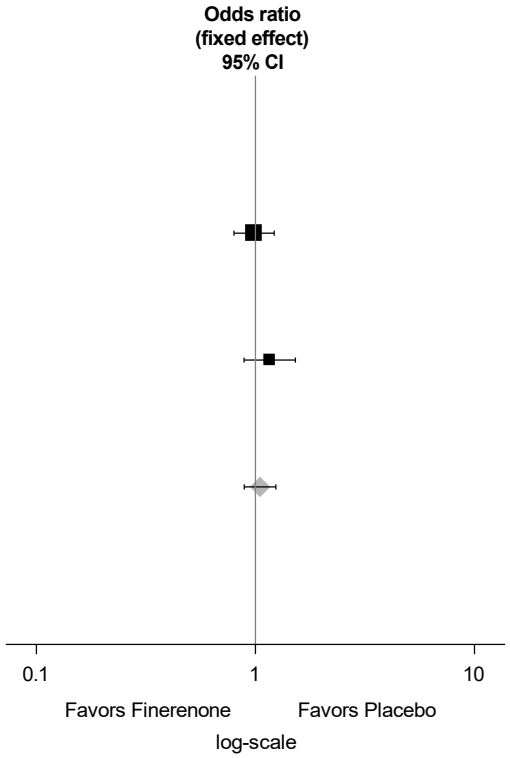
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	720 / 2617	739 / 2610	63.5	0.96 [0.85,1.08]	
FIGARO-DKD	450 / 1357	461 / 1356	36.5	0.96 [0.82,1.13]	
Total	1170 / 3974	1200 / 3966		0.96 [0.87,1.06]	Z=-0.79, p=0.4276
Heterogeneity:	Q=0.00 (df=1)	p=0.9814	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.97: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Arthralgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

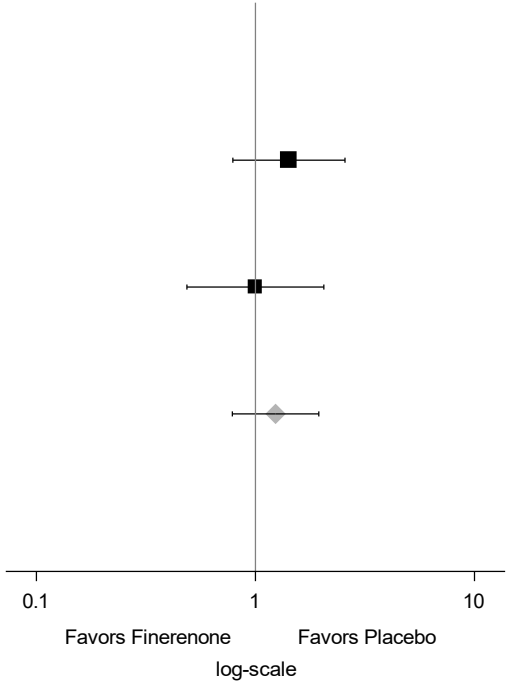
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	184 / 2617	186 / 2610	61.9	0.99 [0.80,1.22]	
FIGARO-DKD	124 / 1357	108 / 1356	38.1	1.16 [0.89,1.52]	
Total	308 / 3974	294 / 3966		1.05 [0.89,1.24]	Z=0.57, p=0.5693
Heterogeneity:	Q=0.89 (df=1)	p=0.3460	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.98: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Arthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

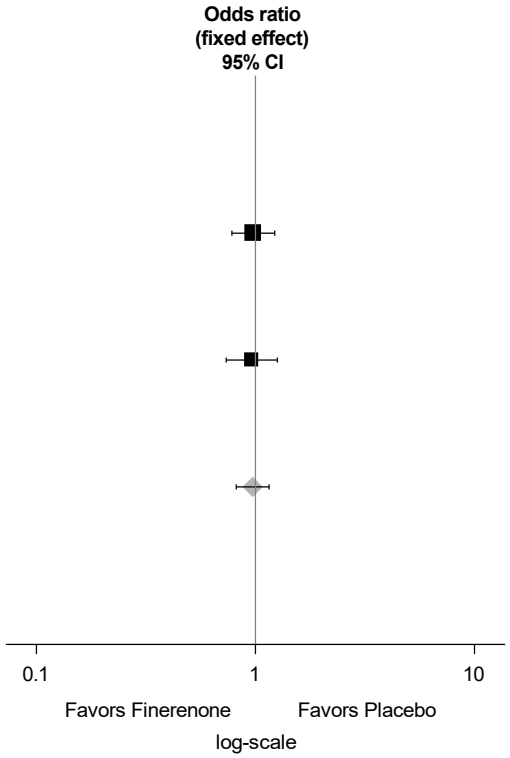
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	19 / 2610	59.9	1.42 [0.79,2.56]	
FIGARO-DKD	15 / 1357	15 / 1356	40.1	1.00 [0.49,2.05]	
Total	42 / 3974	34 / 3966		1.24 [0.78,1.95]	Z=0.91, p=0.3617
Heterogeneity:	Q=0.55 (df=1)	p=0.4576	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.99: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Back pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

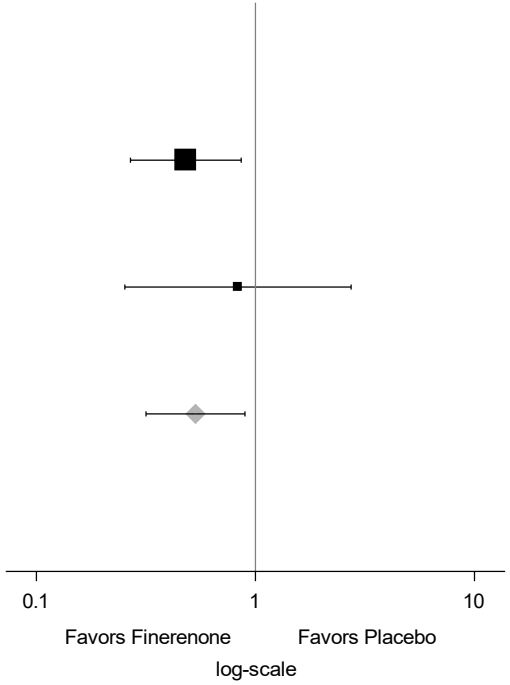
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	160 / 2617	163 / 2610	58.8	0.98 [0.78,1.22]	
FIGARO-DKD	114 / 1357	118 / 1356	41.2	0.96 [0.74,1.26]	
Total	274 / 3974	281 / 3966		0.97 [0.82,1.15]	Z=-0.33, p=0.7405
Heterogeneity:	Q=0.01 (df=1)	p=0.9294	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.100: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

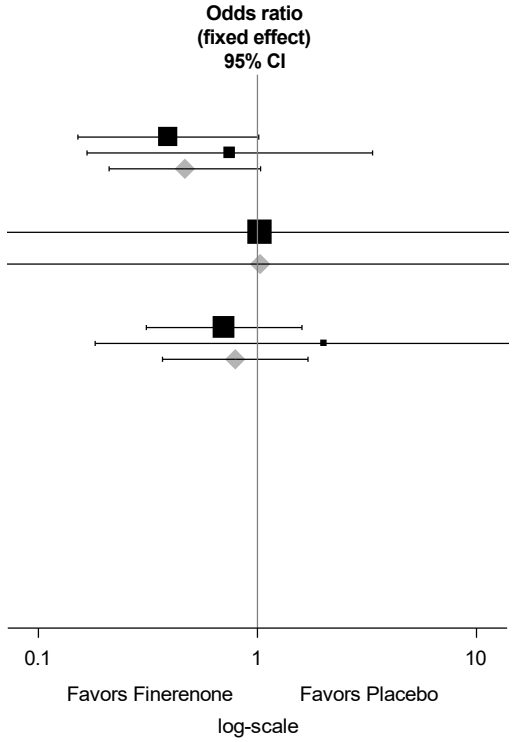
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	17 / 2617	35 / 2610	80.7	0.48 [0.27,0.86]	
FIGARO-DKD	5 / 1357	6 / 1356	19.3	0.83 [0.25,2.73]	
Total	22 / 3974	41 / 3966		0.53 [0.32,0.90]	Z=-2.38, p=0.0175
Heterogeneity:	Q=0.66 (df=1)	p=0.4171	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.100.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

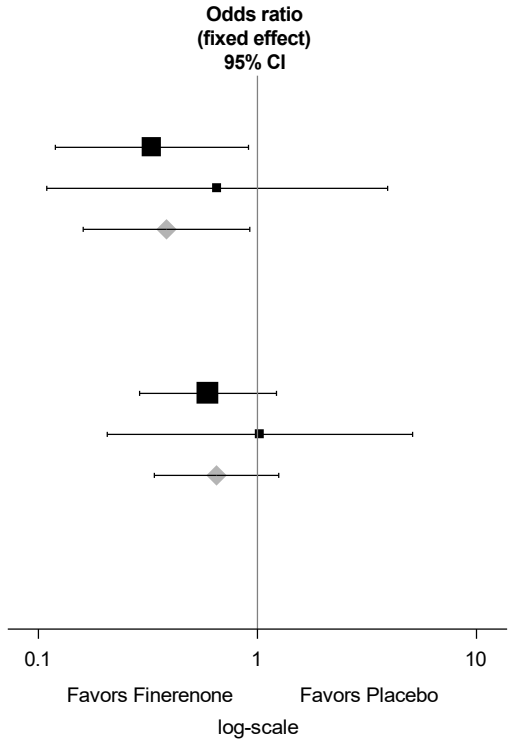
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	6 / 1075	15 / 1062	71.4	0.39 [0.15,1.01]	
FIGARO-DKD	3 / 638	4 / 637	28.6	0.75 [0.17,3.35]	
Total	9 / 1713	19 / 1699		0.47 [0.21,1.03]	Z=-1.88, p=0.0603
Heterogeneity:	Q=0.51 (df=1)	p=0.4756	I^2=0.0%		
North America					
FIDELIO-DKD	1 / 424	1 / 436	100.0	1.03 [0.06,16.49]	
FIGARO-DKD	0 / 267	0 / 271	0.0	-	
Total	1 / 691	1 / 707		1.03 [0.06,16.49]	Z=0.02, p=0.9842
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Asia					
FIDELIO-DKD	10 / 751	14 / 745	89.6	0.70 [0.31,1.60]	
FIGARO-DKD	2 / 289	1 / 290	10.4	2.01 [0.18,22.33]	
Total	12 / 1040	15 / 1035		0.79 [0.37,1.70]	Z=-0.60, p=0.5498
Heterogeneity:	Q=0.66 (df=1)	p=0.4178	I^2=0.0%		
Latin America					
FIDELIO-DKD	0 / 273	3 / 270	0.0	0.00 [0.00,1E297]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	0 / 375	3 / 371		0.00 [0.00,57E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	0 / 61	1 / 57	0.0	0.00 [0.00,18E296]	
Total	0 / 155	3 / 154		0.00 [0.00,16E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.01 (df=4)	p=0.9079	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.100.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

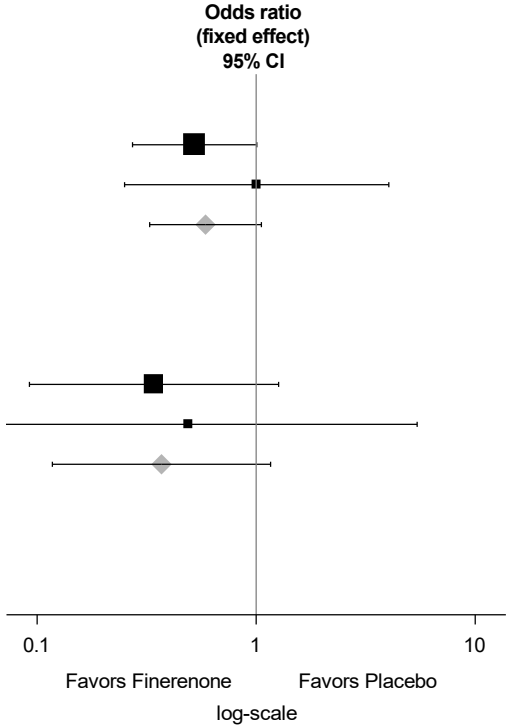
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	5 / 1213	15 / 1210	75.7	0.33 [0.12,0.91]	
FIGARO-DKD	2 / 862	3 / 848	24.3	0.66 [0.11,3.93]	
Total	7 / 2075	18 / 2058		0.38 [0.16,0.92]	Z=-2.14, p=0.0323
Heterogeneity:	Q=0.43 (df=1)	p=0.5132	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 1404	20 / 1400	83.3	0.59 [0.29,1.22]	
FIGARO-DKD	3 / 495	3 / 508	16.7	1.03 [0.21,5.11]	
Total	15 / 1899	23 / 1908		0.65 [0.34,1.25]	Z=-1.29, p=0.1971
Heterogeneity:	Q=0.37 (df=1)	p=0.5432	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.89 (df=1)	p=0.3456	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.100.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

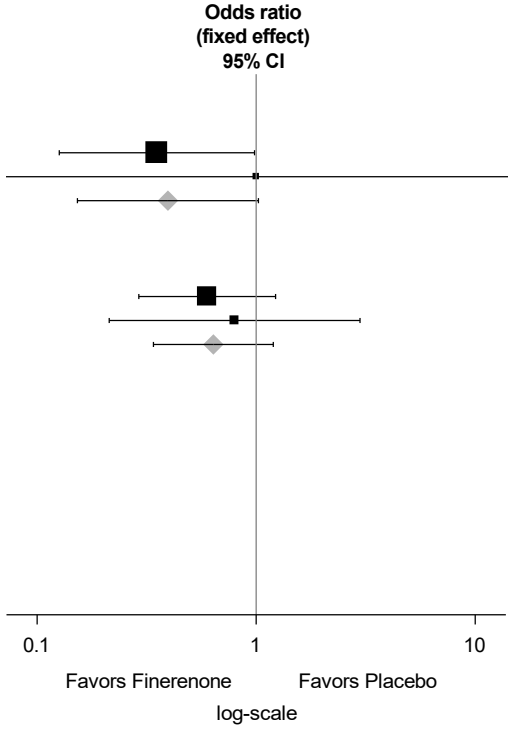
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	14 / 1735	26 / 1700	81.9	0.52 [0.27,1.01]	
FIGARO-DKD	4 / 924	4 / 929	18.1	1.01 [0.25,4.03]	
Total	18 / 2659	30 / 2629		0.59 [0.33,1.06]	Z=-1.78, p=0.0756
Heterogeneity:	Q=0.69 (df=1)	p=0.4049	I^2=0.0%		
> 4.5					
FIDELIO-DKD	3 / 882	9 / 910	77.1	0.34 [0.09,1.27]	
FIGARO-DKD	1 / 433	2 / 426	22.9	0.49 [0.04,5.43]	
Total	4 / 1315	11 / 1336		0.37 [0.12,1.16]	Z=-1.70, p=0.0890
Heterogeneity:	Q=0.07 (df=1)	p=0.7954	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4812	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.100.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

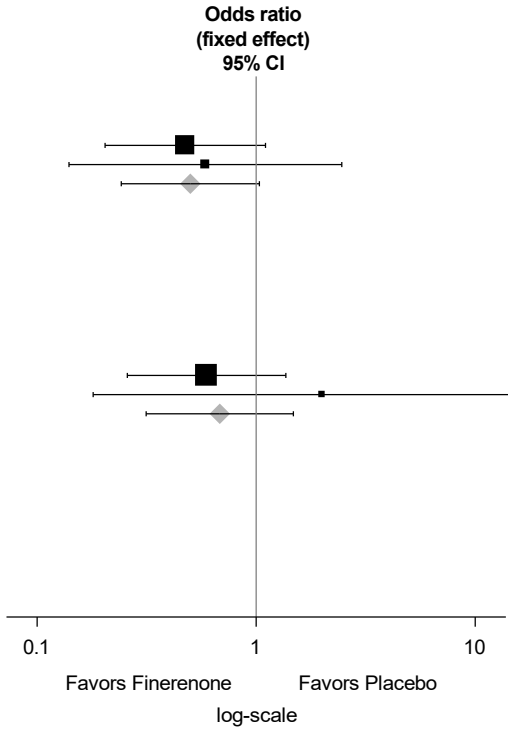
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	14 / 723	88.0	0.35 [0.13,0.98]	
FIGARO-DKD	1 / 494	1 / 495	12.0	1.00 [0.06,16.06]	
Total	6 / 1218	15 / 1218		0.40 [0.15,1.02]	Z=-1.91, p=0.0560
Heterogeneity:	Q=0.48 (df=1)	p=0.4883	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	12 / 1759	20 / 1760	77.1	0.60 [0.29,1.23]	
FIGARO-DKD	4 / 829	5 / 827	22.9	0.80 [0.21,2.98]	
Total	16 / 2588	25 / 2587		0.64 [0.34,1.20]	Z=-1.40, p=0.1615
Heterogeneity:	Q=0.14 (df=1)	p=0.7069	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	1 / 127	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	1 / 161		0.00 [0.00,73E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.67 (df=2)	p=0.7141	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.100.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

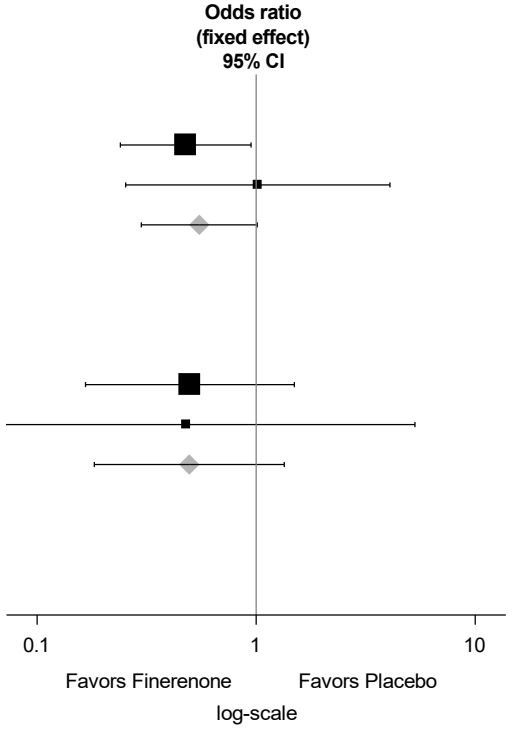
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	8 / 1634	17 / 1657	74.3	0.47 [0.20,1.10]	
FIGARO-DKD	3 / 1010	5 / 989	25.7	0.59 [0.14,2.46]	
Total	11 / 2644	22 / 2646		0.50 [0.24,1.03]	Z=-1.87, p=0.0617
Heterogeneity:	Q=0.06 (df=1)	p=0.8034	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	1 / 115	0.0	0.00 [0.00,13E296]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	0 / 172	1 / 186		0.00 [0.00,71E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	9 / 678	15 / 677	89.3	0.59 [0.26,1.37]	
FIGARO-DKD	2 / 252	1 / 251	10.7	2.00 [0.18,22.20]	
Total	11 / 930	16 / 928		0.68 [0.31,1.48]	Z=-0.97, p=0.3324
Heterogeneity:	Q=0.87 (df=1)	p=0.3499	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 176	2 / 161	0.0	0.00 [0.00,93E295]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	0 / 228	2 / 206		0.00 [0.00,12E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=0.33 (df=3)	p=0.9549	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.100.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

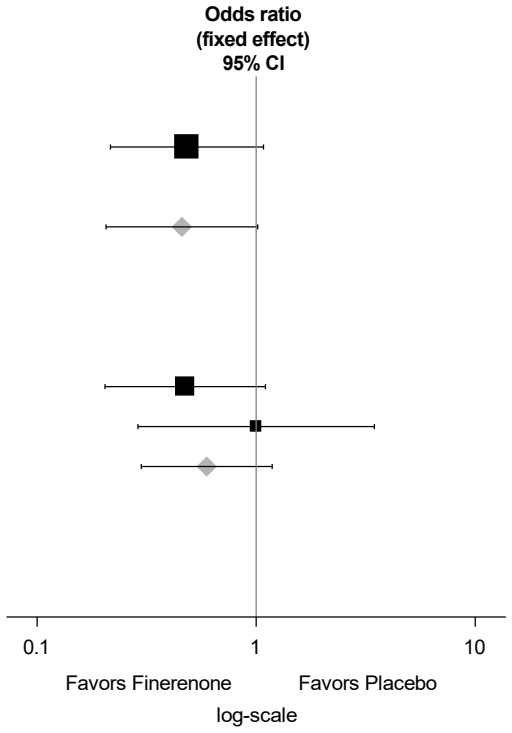
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	12 / 1797	26 / 1870	80.3	0.48 [0.24,0.95]	
FIGARO-DKD	4 / 917	4 / 933	19.7	1.02 [0.25,4.08]	
Total	16 / 2714	30 / 2803		0.55 [0.30,1.01]	Z=-1.92, p=0.0544
Heterogeneity:	Q=0.92 (df=1)	p=0.3375	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 820	9 / 740	82.7	0.50 [0.17,1.49]	
FIGARO-DKD	1 / 440	2 / 423	17.3	0.48 [0.04,5.31]	
Total	6 / 1260	11 / 1163		0.49 [0.18,1.34]	Z=-1.38, p=0.1675
Heterogeneity:	Q=0.00 (df=1)	p=0.9773	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8602	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.100.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

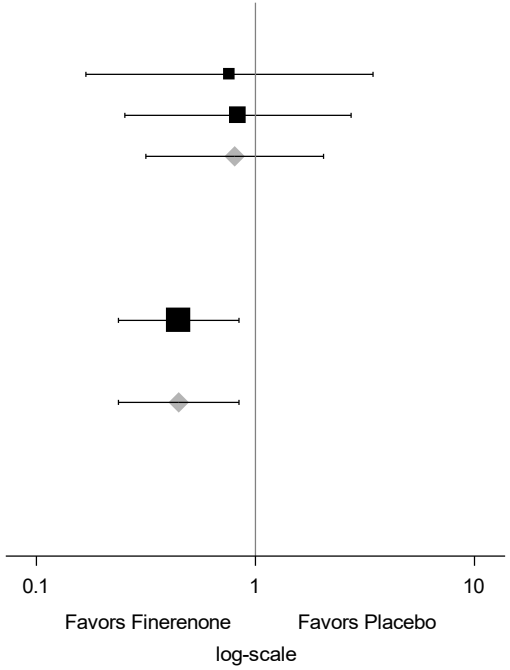
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	9 / 1103	18 / 1075	100.0	0.48 [0.22,1.08]	
FIGARO-DKD	0 / 336	1 / 335	0.0	0.00 [0.00,14E296]	
Total	9 / 1439	19 / 1410		0.46 [0.21,1.02]	Z=-1.92, p=0.0548
Heterogeneity:	Q=0.02 (df=1)	p=0.8962	I^2=0.0%		
>= 65					
FIDELIO-DKD	8 / 1514	17 / 1535	68.5	0.47 [0.20,1.10]	
FIGARO-DKD	5 / 1021	5 / 1021	31.5	1.00 [0.29,3.46]	
Total	13 / 2535	22 / 2556		0.59 [0.30,1.18]	Z=-1.48, p=0.1385
Heterogeneity:	Q=0.95 (df=1)	p=0.3302	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6269	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.100.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

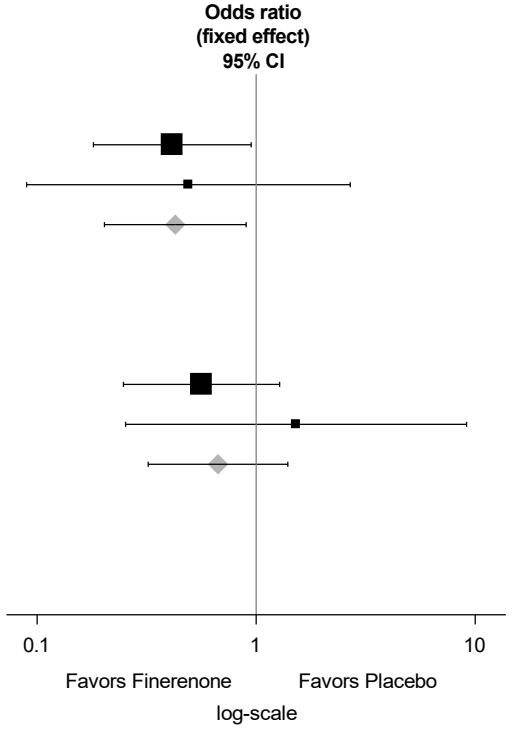
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	4 / 213	38.3	0.76 [0.17,3.44]	
FIGARO-DKD	5 / 1357	6 / 1356	61.7	0.83 [0.25,2.73]	
Total	8 / 1566	10 / 1569		0.80 [0.32,2.05]	Z=-0.46, p=0.6470
Heterogeneity:	Q=0.01 (df=1)	p=0.9273	I^2=0.0%		
Very High					
FIDELIO-DKD	14 / 2408	31 / 2397	100.0	0.45 [0.24,0.84]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	14 / 2408	31 / 2397		0.45 [0.24,0.84]	Z=-2.50, p=0.0126
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.04 (df=1)	p=0.3067	I^2=4.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.100.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Intervertebral disc protrusion (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

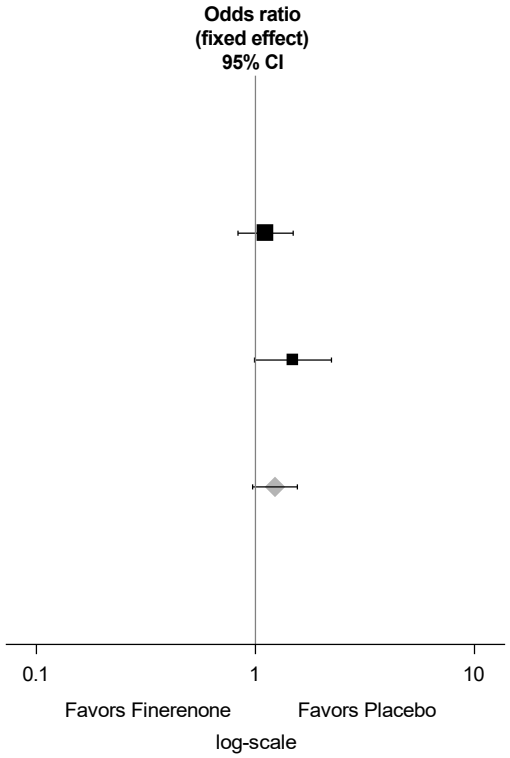
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	8 / 1556	19 / 1541	80.8	0.41 [0.18,0.95]	
FIGARO-DKD	2 / 637	4 / 627	19.2	0.49 [0.09,2.69]	
Total	10 / 2193	23 / 2168		0.43 [0.20,0.90]	Z=-2.24, p=0.0253
Heterogeneity:	Q=0.03 (df=1)	p=0.8605	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	9 / 1061	16 / 1069	82.7	0.56 [0.25,1.28]	
FIGARO-DKD	3 / 720	2 / 729	17.3	1.52 [0.25,9.13]	
Total	12 / 1781	18 / 1798		0.67 [0.32,1.39]	Z=-1.07, p=0.2841
Heterogeneity:	Q=0.98 (df=1)	p=0.3231	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.71 (df=1)	p=0.4002	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.101: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Muscle spasms (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

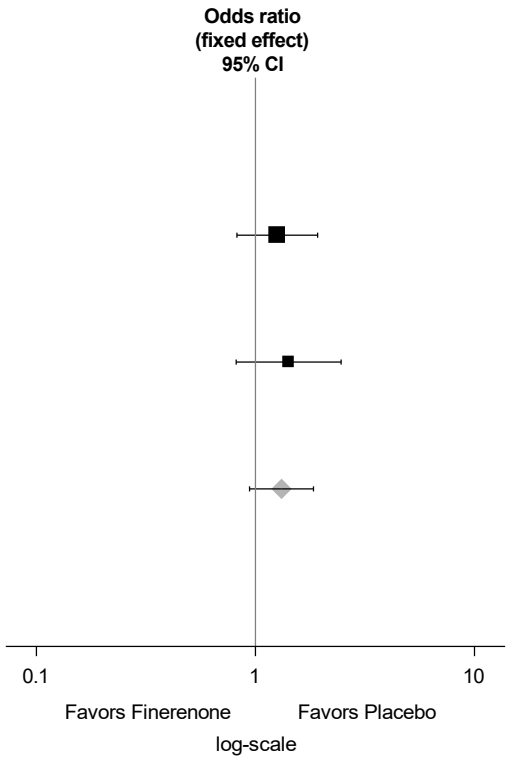
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	90 / 2610	66.0	1.11 [0.83,1.49]	
FIGARO-DKD	60 / 1357	41 / 1356	34.0	1.48 [0.99,2.22]	
Total	160 / 3974	131 / 3966		1.23 [0.97,1.55]	Z=1.71, p=0.0869
Heterogeneity:	Q=1.29 (df=1)	p=0.2567	I^2=22.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.102: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Myalgia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

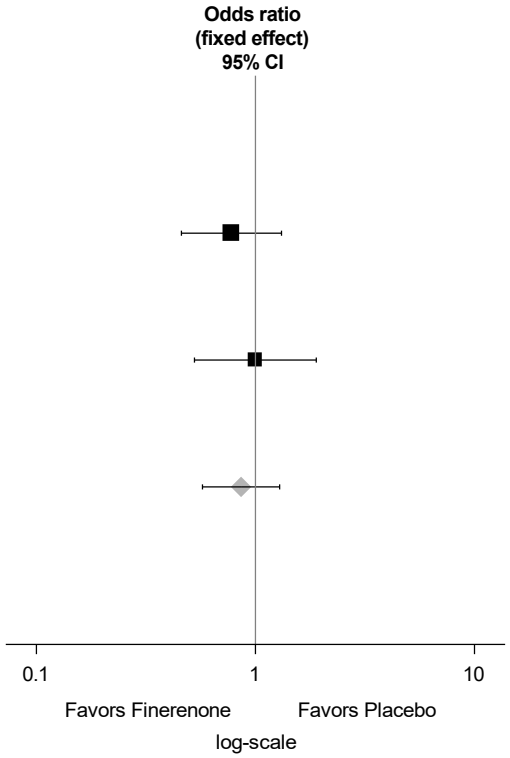
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	49 / 2617	39 / 2610	62.8	1.26 [0.82,1.92]	
FIGARO-DKD	31 / 1357	22 / 1356	37.2	1.42 [0.82,2.46]	
Total	80 / 3974	61 / 3966		1.32 [0.94,1.84]	Z=1.60, p=0.1100
Heterogeneity:	Q=0.11 (df=1)	p=0.7363	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.103: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neck pain (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

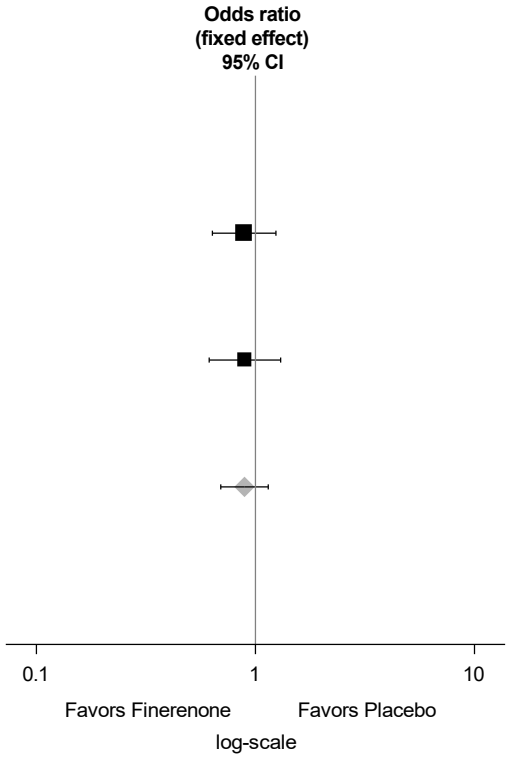
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	32 / 2610	59.7	0.78 [0.46,1.31]	
FIGARO-DKD	19 / 1357	19 / 1356	40.3	1.00 [0.53,1.90]	
Total	44 / 3974	51 / 3966		0.86 [0.57,1.29]	Z=-0.73, p=0.4646
Heterogeneity:	Q=0.35 (df=1)	p=0.5519	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.104: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

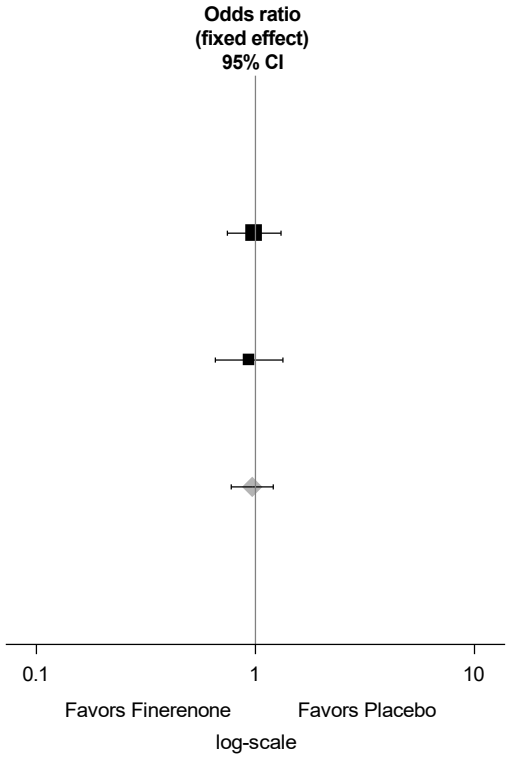
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	67 / 2617	75 / 2610	55.8	0.89 [0.64,1.24]	
FIGARO-DKD	54 / 1357	60 / 1356	44.2	0.90 [0.61,1.30]	
Total	121 / 3974	135 / 3966		0.89 [0.69,1.14]	Z=-0.90, p=0.3657
Heterogeneity:	Q=0.00 (df=1)	p=0.9753	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.105: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pain in extremity (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

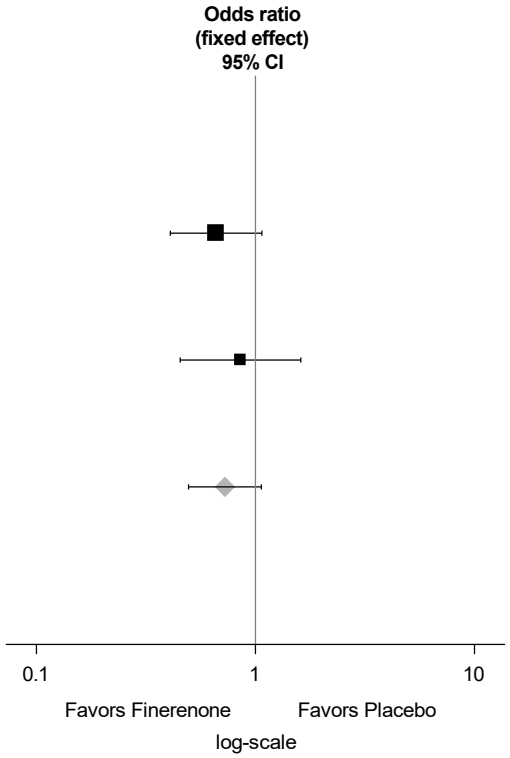
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	100 / 2617	101 / 2610	61.3	0.99 [0.74,1.31]	
FIGARO-DKD	62 / 1357	66 / 1356	38.7	0.94 [0.66,1.33]	
Total	162 / 3974	167 / 3966		0.97 [0.78,1.21]	Z=-0.30, p=0.7646
Heterogeneity:	Q=0.05 (df=1)	p=0.8179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.106: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Spinal osteoarthritis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

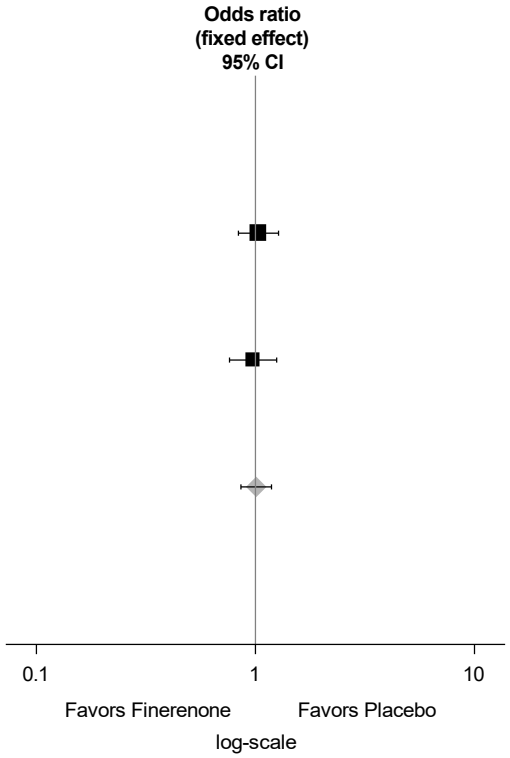
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	42 / 2610	63.4	0.66 [0.41,1.07]	
FIGARO-DKD	18 / 1357	21 / 1356	36.6	0.85 [0.45,1.61]	
Total	46 / 3974	63 / 3966		0.73 [0.49,1.06]	Z=-1.64, p=0.1003
Heterogeneity:	Q=0.40 (df=1)	p=0.5277	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.107: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

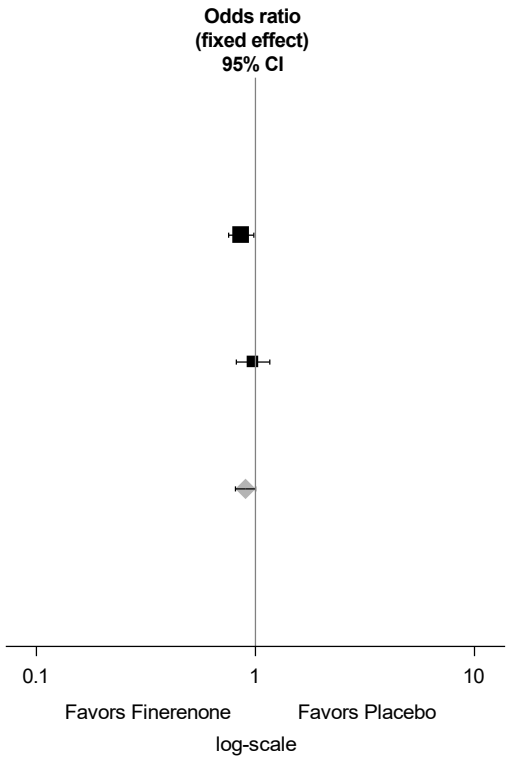
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	189 / 2617	183 / 2610	58.0	1.03 [0.84,1.27]	
FIGARO-DKD	138 / 1357	141 / 1356	42.0	0.98 [0.76,1.25]	
Total	327 / 3974	324 / 3966		1.01 [0.86,1.18]	Z=0.10, p=0.9217
Heterogeneity:	Q=0.12 (df=1)	p=0.7330	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.108: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

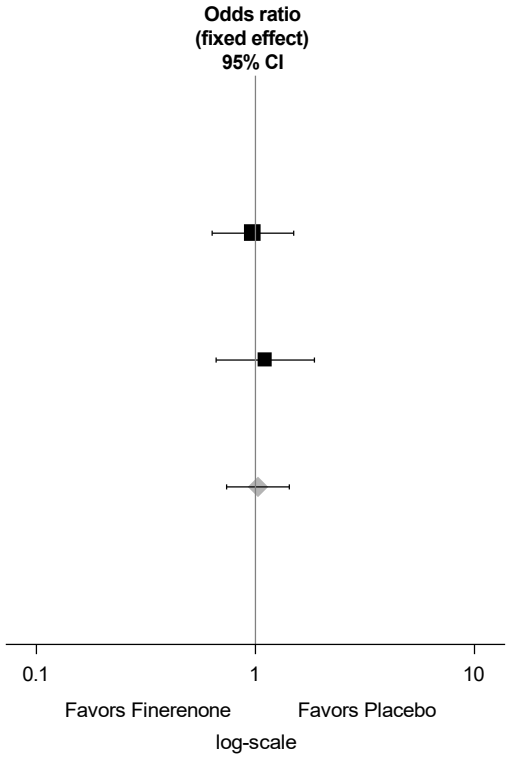
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	526 / 2617	590 / 2610	63.8	0.86 [0.75,0.98]	
FIGARO-DKD	325 / 1357	331 / 1356	36.2	0.98 [0.82,1.16]	
Total	851 / 3974	921 / 3966		0.90 [0.81,1.00]	Z=-1.93, p=0.0531
Heterogeneity:	Q=1.22 (df=1)	p=0.2685	I^2=18.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.109: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic neuropathy (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

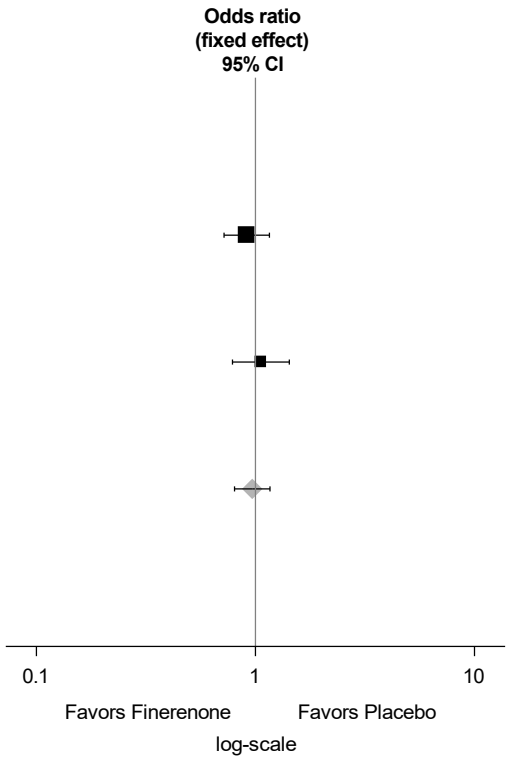
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	42 / 2617	43 / 2610	59.2	0.97 [0.63,1.49]	
FIGARO-DKD	31 / 1357	28 / 1356	40.8	1.11 [0.66,1.86]	
Total	73 / 3974	71 / 3966		1.03 [0.74,1.43]	Z=0.16, p=0.8754
Heterogeneity:	Q=0.14 (df=1)	p=0.7044	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.110: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dizziness (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

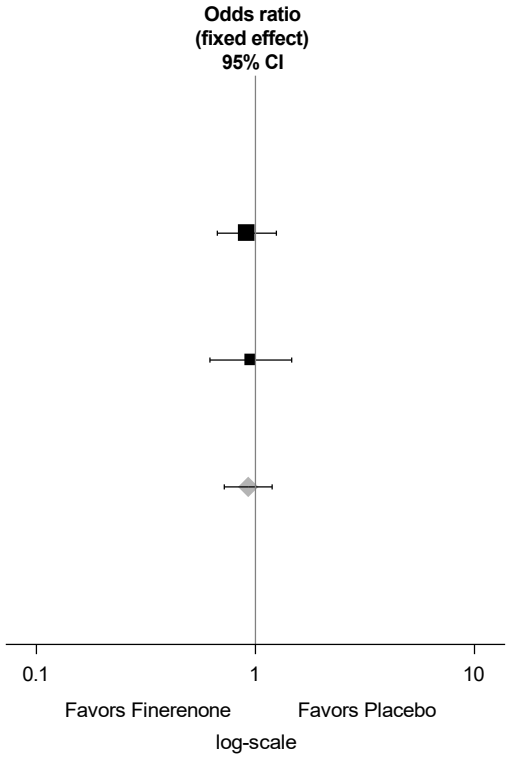
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	137 / 2617	149 / 2610	61.0	0.91 [0.72,1.16]	
FIGARO-DKD	95 / 1357	90 / 1356	39.0	1.06 [0.79,1.43]	
Total	232 / 3974	239 / 3966		0.97 [0.80,1.16]	Z=-0.35, p=0.7233
Heterogeneity:	Q=0.58 (df=1)	p=0.4452	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.111: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Headache (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

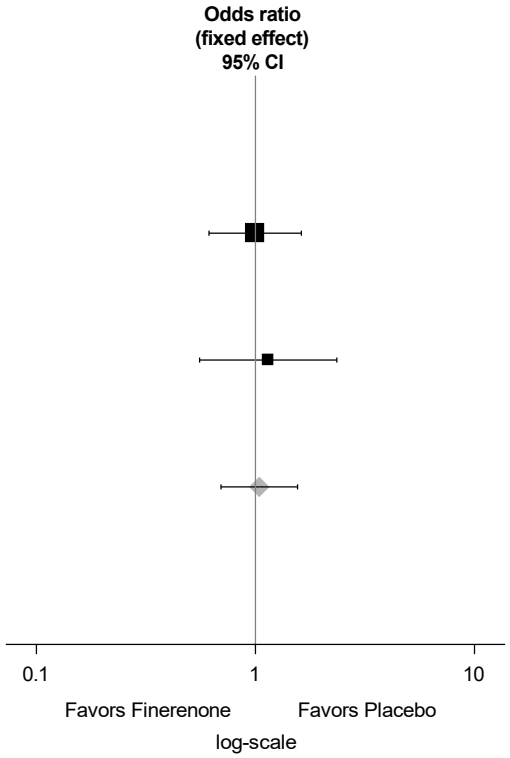
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	79 / 2617	86 / 2610	65.7	0.91 [0.67,1.25]	
FIGARO-DKD	42 / 1357	44 / 1356	34.3	0.95 [0.62,1.46]	
Total	121 / 3974	130 / 3966		0.93 [0.72,1.19]	Z=-0.59, p=0.5529
Heterogeneity:	Q=0.02 (df=1)	p=0.8777	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.112: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypoaesthesia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

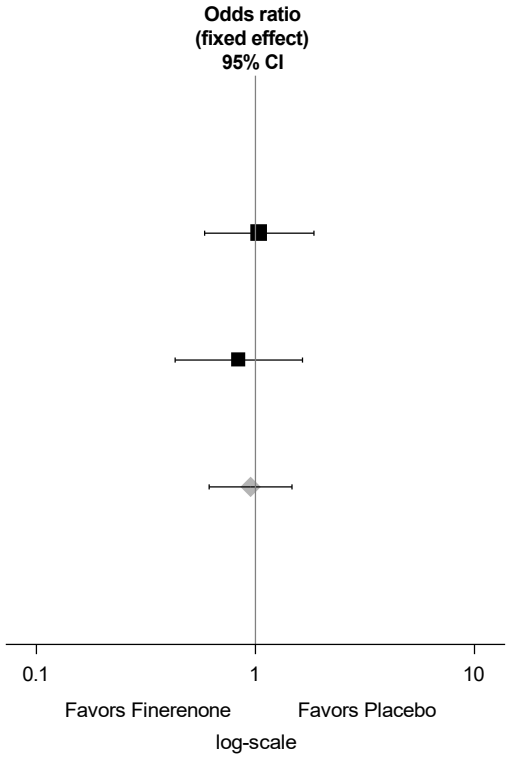
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2617	33 / 2610	68.8	1.00 [0.61,1.62]	
FIGARO-DKD	16 / 1357	14 / 1356	31.2	1.14 [0.56,2.35]	
Total	49 / 3974	47 / 3966		1.04 [0.70,1.56]	Z=0.20, p=0.8453
Heterogeneity:	Q=0.10 (df=1)	p=0.7575	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.113: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sciatica (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

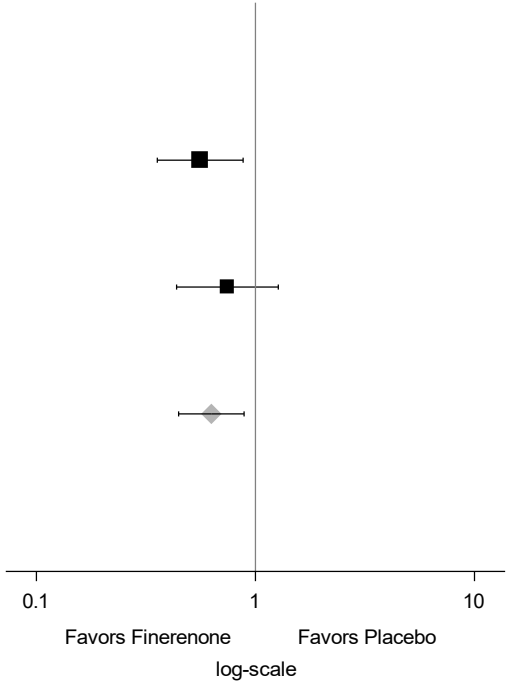
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	24 / 2617	23 / 2610	57.6	1.04 [0.59,1.85]	
FIGARO-DKD	16 / 1357	19 / 1356	42.4	0.84 [0.43,1.64]	
Total	40 / 3974	42 / 3966		0.95 [0.61,1.47]	Z=-0.23, p=0.8177
Heterogeneity:	Q=0.23 (df=1)	p=0.6327	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.114: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

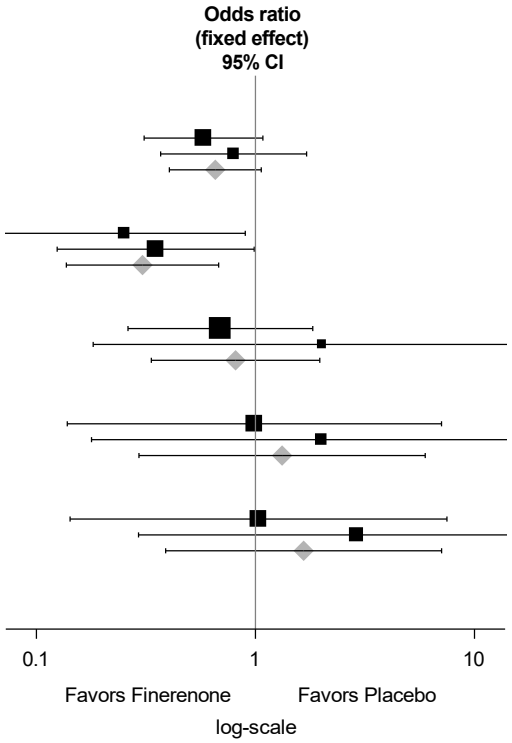
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	53 / 2610	58.4	0.56 [0.36,0.88]	
FIGARO-DKD	24 / 1357	32 / 1356	41.6	0.74 [0.44,1.27]	
Total	54 / 3974	85 / 3966		0.63 [0.45,0.89]	Z=-2.64, p=0.0082
Heterogeneity:	Q=0.64 (df=1)	p=0.4224	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.114.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

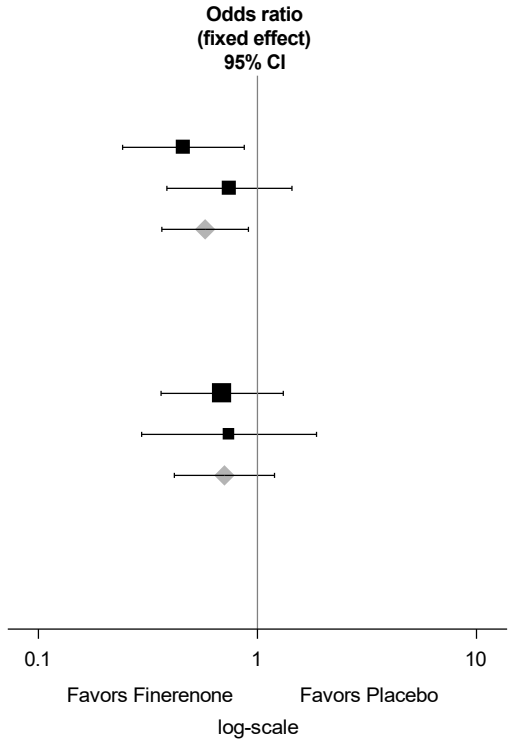
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	27 / 1062	60.2	0.58 [0.31,1.08]	
FIGARO-DKD	12 / 638	15 / 637	39.8	0.79 [0.37,1.71]	
Total	28 / 1713	42 / 1699		0.66 [0.40,1.06]	Z=-1.71, p=0.0867
Heterogeneity:	Q=0.39 (df=1)	p=0.5303	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	12 / 436	39.8	0.25 [0.07,0.90]	
FIGARO-DKD	5 / 267	14 / 271	60.2	0.35 [0.12,0.99]	
Total	8 / 691	26 / 707		0.31 [0.14,0.68]	Z=-2.91, p=0.0036
Heterogeneity:	Q=0.16 (df=1)	p=0.6928	I^2=0.0%		
Asia					
FIDELIO-DKD	7 / 751	10 / 745	86.0	0.69 [0.26,1.83]	
FIGARO-DKD	2 / 289	1 / 290	14.0	2.01 [0.18,22.33]	
Total	9 / 1040	11 / 1035		0.81 [0.33,1.97]	Z=-0.46, p=0.6434
Heterogeneity:	Q=0.65 (df=1)	p=0.4192	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	2 / 270	60.1	0.99 [0.14,7.07]	
FIGARO-DKD	2 / 102	1 / 101	39.9	2.00 [0.18,22.41]	
Total	4 / 375	3 / 371		1.32 [0.29,5.96]	Z=0.36, p=0.7153
Heterogeneity:	Q=0.20 (df=1)	p=0.6576	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	2 / 97	57.3	1.03 [0.14,7.49]	
FIGARO-DKD	3 / 61	1 / 57	42.7	2.90 [0.29,28.68]	
Total	5 / 155	3 / 154		1.66 [0.39,7.08]	Z=0.68, p=0.4937
Heterogeneity:	Q=0.45 (df=1)	p=0.5037	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.13 (df=4)	p=0.1896	I^2=34.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.114.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

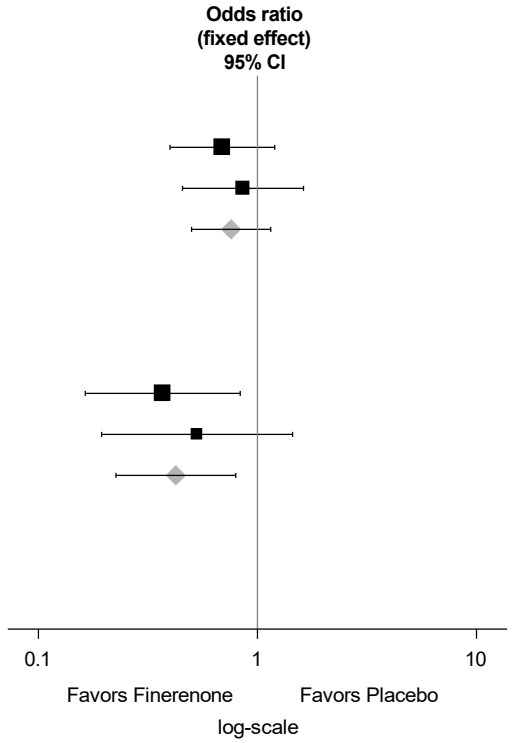
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	14 / 1213	30 / 1210	51.4	0.46 [0.24,0.87]	
FIGARO-DKD	16 / 862	21 / 848	48.6	0.74 [0.39,1.44]	
Total	30 / 2075	51 / 2058		0.58 [0.37,0.91]	Z=-2.37, p=0.0179
Heterogeneity:	Q=1.07 (df=1)	p=0.3013	I^2=6.4%		
Absent					
FIDELIO-DKD	16 / 1404	23 / 1400	67.2	0.69 [0.36,1.31]	
FIGARO-DKD	8 / 495	11 / 508	32.8	0.74 [0.30,1.86]	
Total	24 / 1899	34 / 1908		0.71 [0.42,1.20]	Z=-1.29, p=0.1964
Heterogeneity:	Q=0.02 (df=1)	p=0.8988	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.33 (df=1)	p=0.5676	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.114.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

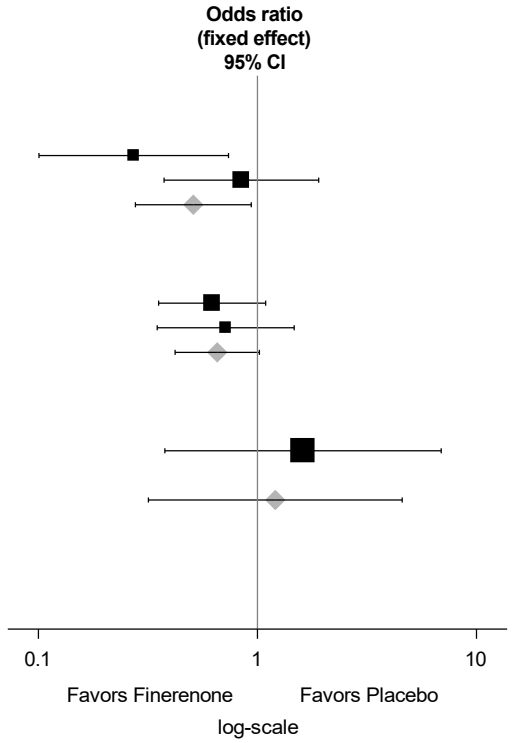
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 1735	31 / 1700	57.2	0.69 [0.40,1.20]	
FIGARO-DKD	18 / 924	21 / 929	42.8	0.86 [0.45,1.62]	
Total	40 / 2659	52 / 2629		0.76 [0.50,1.15]	Z=-1.30, p=0.1922
Heterogeneity:	Q=0.26 (df=1)	p=0.6132	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	22 / 910	60.3	0.37 [0.16,0.83]	
FIGARO-DKD	6 / 433	11 / 426	39.7	0.53 [0.19,1.45]	
Total	14 / 1315	33 / 1336		0.42 [0.23,0.80]	Z=-2.67, p=0.0076
Heterogeneity:	Q=0.30 (df=1)	p=0.5839	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.28 (df=1)	p=0.1312	I^2=56.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.114.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

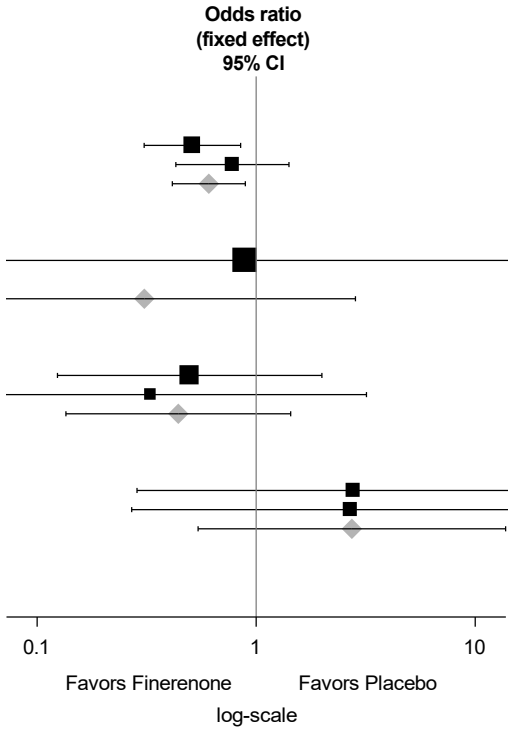
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	18 / 723	40.0	0.27 [0.10,0.74]	
FIGARO-DKD	11 / 494	13 / 495	60.0	0.84 [0.37,1.90]	
Total	16 / 1218	31 / 1218		0.51 [0.28,0.94]	Z=-2.17, p=0.0300
Heterogeneity:	Q=3.00 (df=1)	p=0.0832	I^2=66.7%		
130 - < 160					
FIDELIO-DKD	20 / 1759	32 / 1760	62.1	0.62 [0.35,1.09]	
FIGARO-DKD	13 / 829	18 / 827	37.9	0.72 [0.35,1.47]	
Total	33 / 2588	50 / 2587		0.66 [0.42,1.02]	Z=-1.87, p=0.0614
Heterogeneity:	Q=0.09 (df=1)	p=0.7602	I^2=0.0%		
>= 160					
FIDELIO-DKD	5 / 133	3 / 127	100.0	1.61 [0.38,6.90]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,1E297]	
Total	5 / 167	4 / 161		1.21 [0.32,4.58]	Z=0.28, p=0.7829
Heterogeneity:	Q=0.15 (df=1)	p=0.6940	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.41 (df=2)	p=0.4948	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.114.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

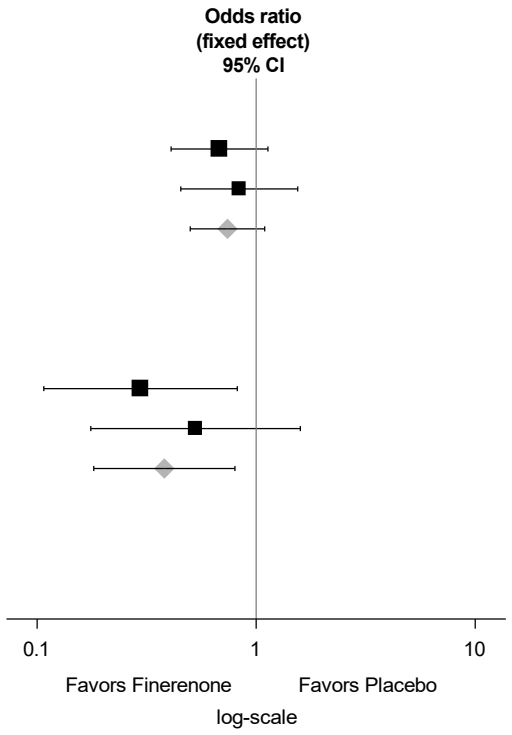
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	23 / 1634	45 / 1657	57.9	0.51 [0.31,0.85]	
FIGARO-DKD	20 / 1010	25 / 989	42.1	0.78 [0.43,1.41]	
Total	43 / 2644	70 / 2646		0.61 [0.41,0.89]	Z=-2.54, p=0.0110
Heterogeneity:	Q=1.11 (df=1)	p=0.2912	I^2=10.2%		
Black					
FIDELIO-DKD	1 / 129	1 / 115	100.0	0.89 [0.06,14.40]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,2E297]	
Total	1 / 172	4 / 186		0.31 [0.03,2.84]	Z=-1.04, p=0.2991
Heterogeneity:	Q=0.56 (df=1)	p=0.4554	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 678	6 / 677	72.7	0.50 [0.12,2.00]	
FIGARO-DKD	1 / 252	3 / 251	27.3	0.33 [0.03,3.19]	
Total	4 / 930	9 / 928		0.44 [0.14,1.44]	Z=-1.36, p=0.1744
Heterogeneity:	Q=0.09 (df=1)	p=0.7617	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 176	1 / 161	50.6	2.77 [0.29,26.95]	
FIGARO-DKD	3 / 52	1 / 45	49.4	2.69 [0.27,26.86]	
Total	6 / 228	2 / 206		2.73 [0.54,13.77]	Z=1.22, p=0.2226
Heterogeneity:	Q=0.00 (df=1)	p=0.9857	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.95 (df=3)	p=0.2674	I^2=24.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.114.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

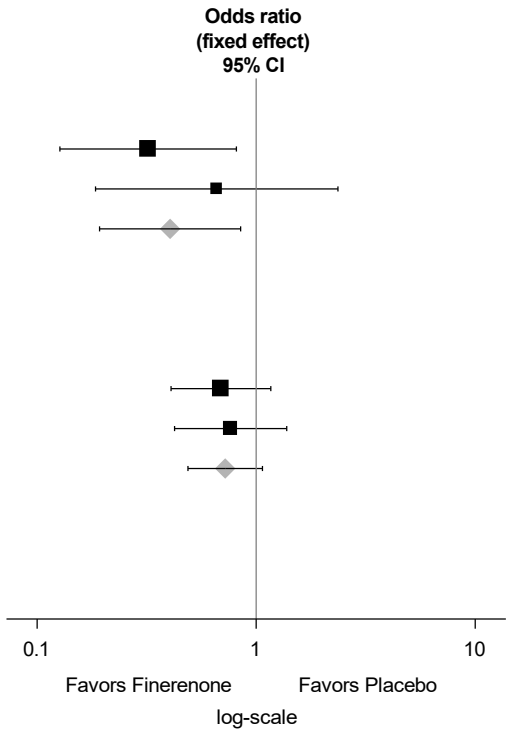
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	25 / 1797	38 / 1870	59.3	0.68 [0.41,1.13]	
FIGARO-DKD	19 / 917	23 / 933	40.7	0.84 [0.45,1.55]	
Total	44 / 2714	61 / 2803		0.74 [0.50,1.09]	Z=-1.51, p=0.1309
Heterogeneity:	Q=0.26 (df=1)	p=0.6100	I^2=0.0%		
Female					
FIDELIO-DKD	5 / 820	15 / 740	54.0	0.30 [0.11,0.82]	
FIGARO-DKD	5 / 440	9 / 423	46.0	0.53 [0.18,1.59]	
Total	10 / 1260	24 / 1163		0.38 [0.18,0.80]	Z=-2.55, p=0.0108
Heterogeneity:	Q=0.57 (df=1)	p=0.4489	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.40 (df=1)	p=0.1211	I^2=58.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.114.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

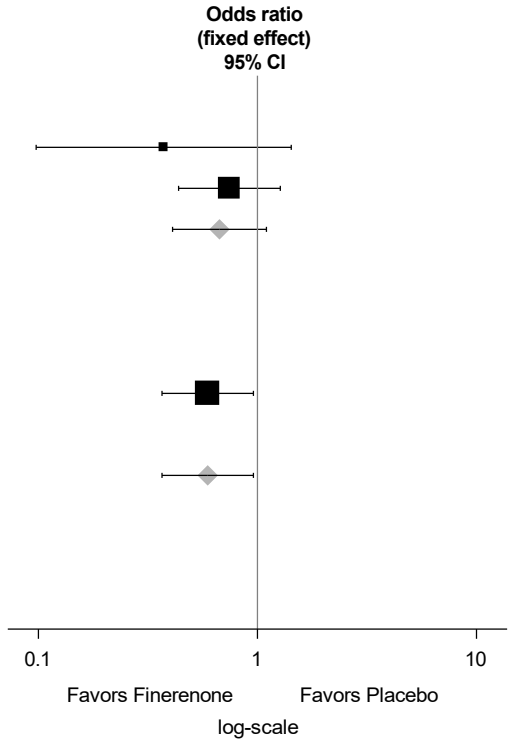
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	6 / 1103	18 / 1075	65.4	0.32 [0.13,0.81]	
FIGARO-DKD	4 / 336	6 / 335	34.6	0.66 [0.18,2.36]	
Total	10 / 1439	24 / 1410		0.40 [0.19,0.85]	Z=-2.39, p=0.0168
Heterogeneity:	Q=0.81 (df=1)	p=0.3691	I^2=0.0%		
>= 65					
FIDELIO-DKD	24 / 1514	35 / 1535	55.8	0.69 [0.41,1.17]	
FIGARO-DKD	20 / 1021	26 / 1021	44.2	0.76 [0.42,1.38]	
Total	44 / 2535	61 / 2556		0.72 [0.49,1.07]	Z=-1.63, p=0.1032
Heterogeneity:	Q=0.06 (df=1)	p=0.7995	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1758	I^2=45.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.114.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

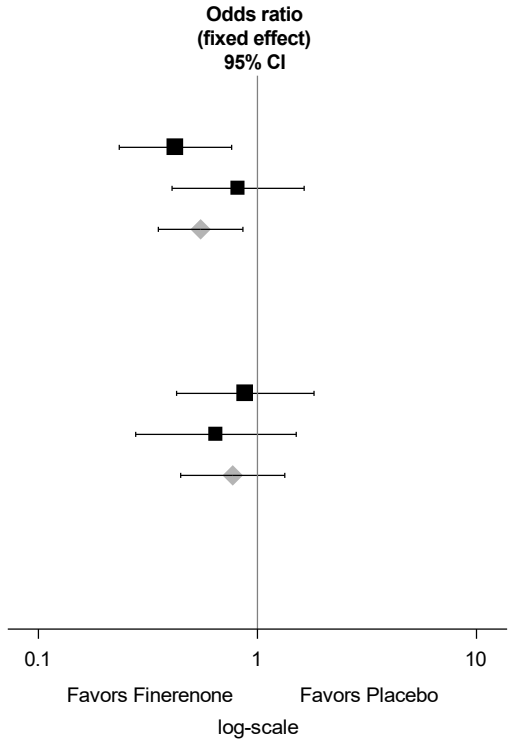
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	8 / 213	13.7	0.37 [0.10,1.43]	
FIGARO-DKD	24 / 1357	32 / 1356	86.3	0.74 [0.44,1.27]	
Total	27 / 1566	40 / 1569		0.67 [0.41,1.10]	Z=-1.59, p=0.1129
Heterogeneity:	Q=0.88 (df=1)	p=0.3476	I^2=0.0%		
Very High					
FIDELIO-DKD	27 / 2408	45 / 2397	100.0	0.59 [0.37,0.96]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	27 / 2408	45 / 2397		0.59 [0.37,0.96]	Z=-2.13, p=0.0329
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=1)	p=0.7241	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.114.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Syncope (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

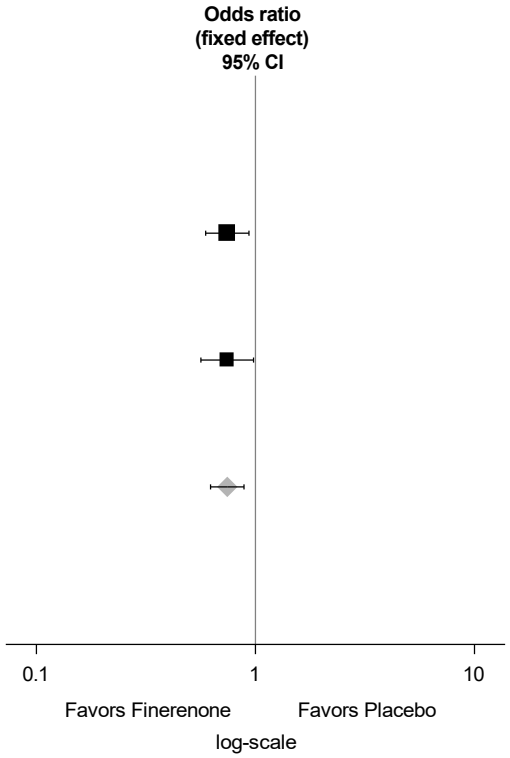
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	16 / 1556	37 / 1541	58.0	0.42 [0.23,0.76]	
FIGARO-DKD	15 / 637	18 / 627	42.0	0.82 [0.41,1.63]	
Total	31 / 2193	55 / 2168		0.55 [0.35,0.86]	Z=-2.63, p=0.0084
Heterogeneity:	Q=2.01 (df=1)	p=0.1565	I^2=50.2%		
45 - < 60					
FIDELIO-DKD	14 / 1061	16 / 1069	57.7	0.88 [0.43,1.81]	
FIGARO-DKD	9 / 720	14 / 729	42.3	0.65 [0.28,1.50]	
Total	23 / 1781	30 / 1798		0.77 [0.45,1.33]	Z=-0.93, p=0.3519
Heterogeneity:	Q=0.30 (df=1)	p=0.5863	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.88 (df=1)	p=0.3481	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

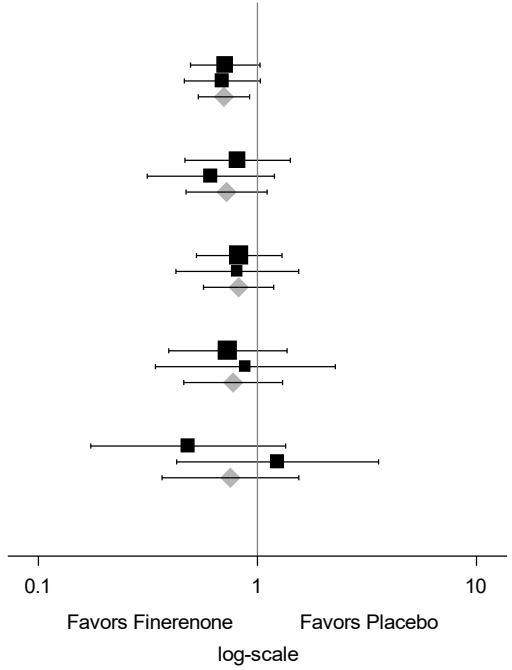
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	139 / 2617	183 / 2610	59.7	0.74 [0.59,0.93]	
FIGARO-DKD	96 / 1357	126 / 1356	40.3	0.74 [0.56,0.98]	
Total	235 / 3974	309 / 3966		0.74 [0.62,0.89]	Z=-3.30, p=0.0010
Heterogeneity:	Q=0.00 (df=1)	p=0.9956	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.115.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

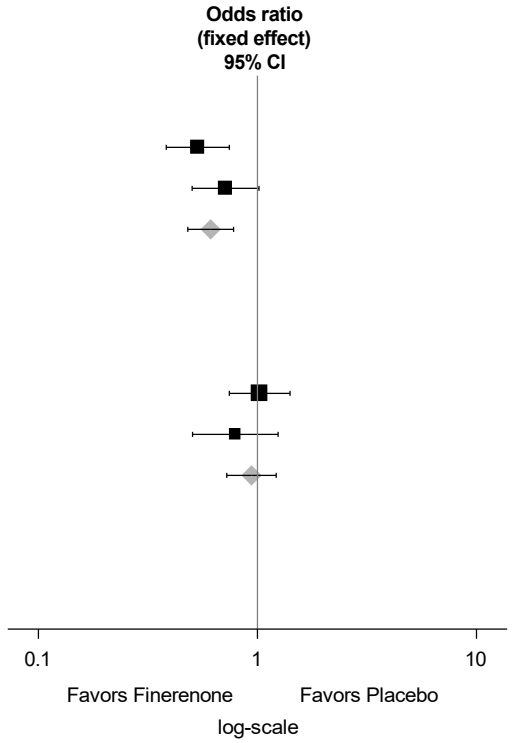
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	53 / 1075	72 / 1062	54.4	0.71 [0.49,1.03]	
FIGARO-DKD	45 / 638	63 / 637	45.6	0.69 [0.46,1.03]	
Total	98 / 1713	135 / 1699		0.70 [0.54,0.92]	Z=-2.56, p=0.0104
Heterogeneity:	Q=0.01 (df=1)	p=0.9111	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 424	30 / 436	59.3	0.81 [0.47,1.41]	
FIGARO-DKD	15 / 267	24 / 271	40.7	0.61 [0.31,1.20]	
Total	39 / 691	54 / 707		0.72 [0.47,1.11]	Z=-1.49, p=0.1355
Heterogeneity:	Q=0.40 (df=1)	p=0.5248	I^2=0.0%		
Asia					
FIDELIO-DKD	37 / 751	44 / 745	67.3	0.83 [0.53,1.29]	
FIGARO-DKD	18 / 289	22 / 290	32.7	0.81 [0.42,1.54]	
Total	55 / 1040	66 / 1035		0.82 [0.57,1.19]	Z=-1.05, p=0.2921
Heterogeneity:	Q=0.00 (df=1)	p=0.9599	I^2=0.0%		
Latin America					
FIDELIO-DKD	19 / 273	25 / 270	69.8	0.73 [0.39,1.37]	
FIGARO-DKD	9 / 102	10 / 101	30.2	0.88 [0.34,2.27]	
Total	28 / 375	35 / 371		0.77 [0.46,1.30]	Z=-0.96, p=0.3349
Heterogeneity:	Q=0.10 (df=1)	p=0.7508	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 94	12 / 97	51.8	0.48 [0.17,1.35]	
FIGARO-DKD	9 / 61	7 / 57	48.2	1.24 [0.43,3.57]	
Total	15 / 155	19 / 154		0.75 [0.37,1.54]	Z=-0.77, p=0.4387
Heterogeneity:	Q=1.56 (df=1)	p=0.2116	I^2=35.9%		
Subgroup Heterogeneity:	Q=0.48 (df=4)	p=0.9755	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	58 / 1213	104 / 1210	52.9	0.53 [0.38,0.74]	
FIGARO-DKD	59 / 862	79 / 848	47.1	0.72 [0.50,1.02]	
Total	117 / 2075	183 / 2058		0.61 [0.48,0.78]	Z=-4.01, p=<.0001
Heterogeneity:	Q=1.40 (df=1)	p=0.2360	I^2=28.8%		
Absent					
FIDELIO-DKD	81 / 1404	79 / 1400	66.5	1.02 [0.74,1.41]	
FIGARO-DKD	37 / 495	47 / 508	33.5	0.79 [0.51,1.24]	
Total	118 / 1899	126 / 1908		0.94 [0.72,1.22]	Z=-0.47, p=0.6363
Heterogeneity:	Q=0.83 (df=1)	p=0.3626	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.64 (df=1)	p=0.0176	I^2=82.3%		

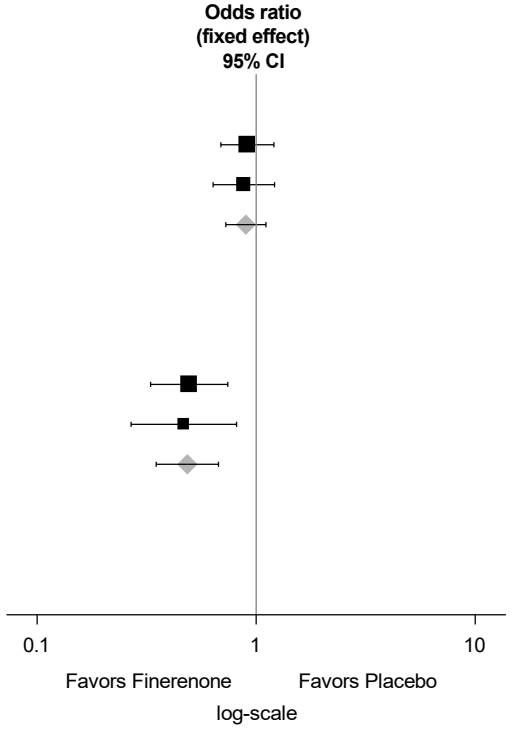


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

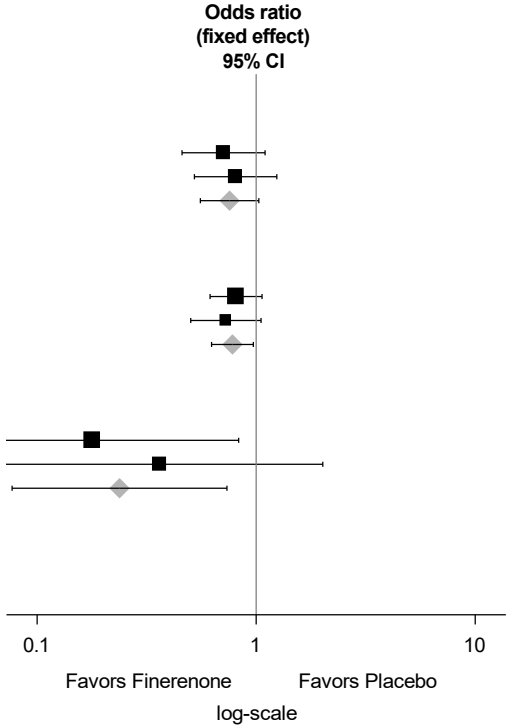
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	102 / 1735	109 / 1700	57.3	0.91 [0.69,1.20]	
FIGARO-DKD	76 / 924	86 / 929	42.7	0.88 [0.64,1.21]	
Total	178 / 2659	195 / 2629		0.90 [0.73,1.11]	Z=-1.01, p=0.3145
Heterogeneity:	Q=0.03 (df=1)	p=0.8647	I^2=0.0%		
> 4.5					
FIDELIO-DKD	37 / 882	74 / 910	65.1	0.49 [0.33,0.74]	
FIGARO-DKD	20 / 433	40 / 426	34.9	0.47 [0.27,0.81]	
Total	57 / 1315	114 / 1336		0.48 [0.35,0.67]	Z=-4.33, p=<.0001
Heterogeneity:	Q=0.03 (df=1)	p=0.8711	I^2=0.0%		
Subgroup Heterogeneity:	Q=9.59 (df=1)	p=0.0020	I^2=89.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

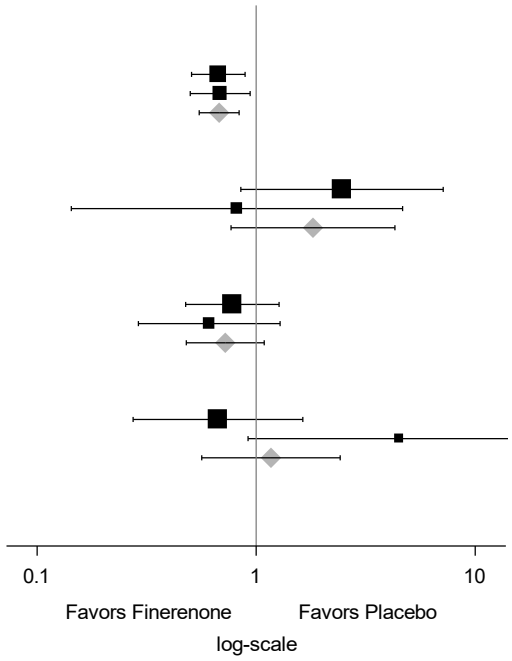
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	37 / 724	51 / 723	49.6	0.71 [0.46,1.10]	
FIGARO-DKD	41 / 494	50 / 495	50.4	0.81 [0.52,1.24]	
Total	78 / 1218	101 / 1218		0.76 [0.56,1.03]	Z=-1.78, p=0.0747
Heterogeneity:	Q=0.16 (df=1)	p=0.6863	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	100 / 1759	122 / 1760	64.7	0.81 [0.62,1.06]	
FIGARO-DKD	53 / 829	71 / 827	35.3	0.73 [0.50,1.05]	
Total	153 / 2588	193 / 2587		0.78 [0.63,0.97]	Z=-2.23, p=0.0260
Heterogeneity:	Q=0.21 (df=1)	p=0.6484	I^2=0.0%		
>= 160					
FIDELIO-DKD	2 / 133	10 / 127	55.4	0.18 [0.04,0.83]	
FIGARO-DKD	2 / 34	5 / 34	44.6	0.36 [0.07,2.01]	
Total	4 / 167	15 / 161		0.24 [0.08,0.74]	Z=-2.49, p=0.0127
Heterogeneity:	Q=0.37 (df=1)	p=0.5457	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.09 (df=2)	p=0.1291	I^2=51.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

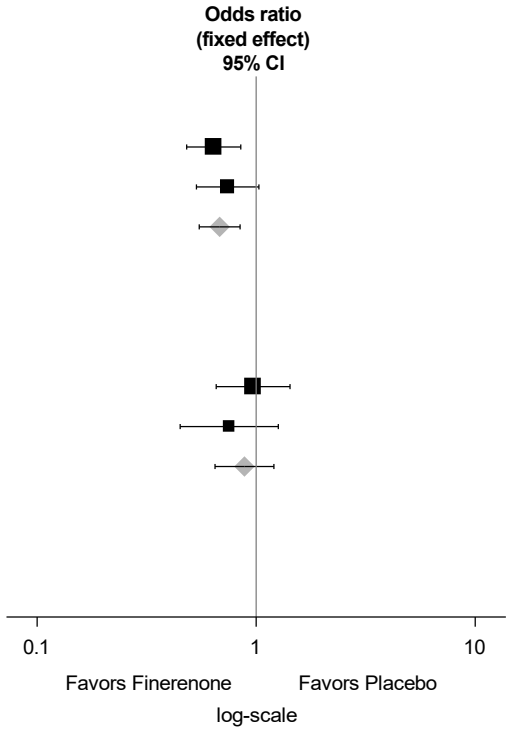
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	87 / 1634	128 / 1657	55.6	0.67 [0.51,0.89]	
FIGARO-DKD	73 / 1010	101 / 989	44.4	0.68 [0.50,0.94]	
Total	160 / 2644	229 / 2646		0.68 [0.55,0.84]	Z=-3.64, p=0.0003
Heterogeneity:	Q=0.01 (df=1)	p=0.9280	I^2=0.0%		
Black					
FIDELIO-DKD	13 / 129	5 / 115	72.8	2.47 [0.85,7.14]	
FIGARO-DKD	2 / 43	4 / 71	27.2	0.82 [0.14,4.66]	
Total	15 / 172	9 / 186		1.82 [0.77,4.30]	Z=1.36, p=0.1742
Heterogeneity:	Q=1.13 (df=1)	p=0.2888	I^2=11.1%		
Asian					
FIDELIO-DKD	30 / 678	38 / 677	69.7	0.78 [0.48,1.27]	
FIGARO-DKD	12 / 252	19 / 251	30.3	0.61 [0.29,1.29]	
Total	42 / 930	57 / 928		0.72 [0.48,1.09]	Z=-1.56, p=0.1198
Heterogeneity:	Q=0.29 (df=1)	p=0.5933	I^2=0.0%		
Others					
FIDELIO-DKD	9 / 176	12 / 161	76.0	0.67 [0.27,1.63]	
FIGARO-DKD	9 / 52	2 / 45	24.0	4.50 [0.92,22.05]	
Total	18 / 228	14 / 206		1.17 [0.56,2.42]	Z=0.42, p=0.6753
Heterogeneity:	Q=4.26 (df=1)	p=0.0389	I^2=76.6%		
Subgroup Heterogeneity:	Q=6.38 (df=3)	p=0.0945	I^2=53.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.115.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

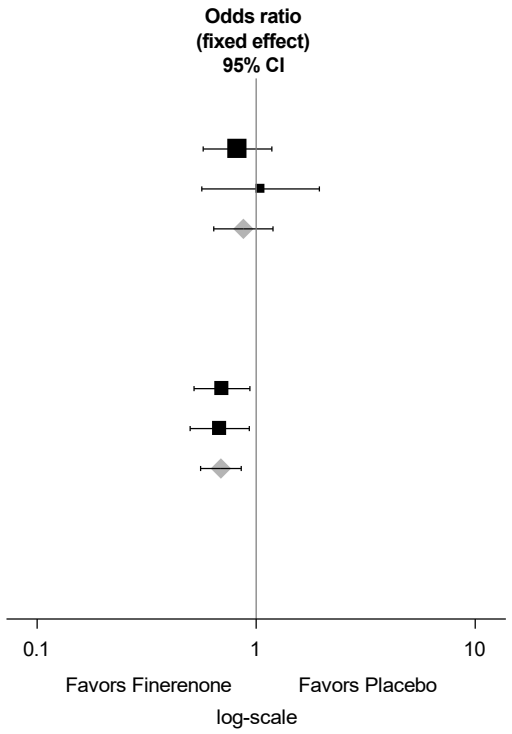
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	82 / 1797	130 / 1870	57.1	0.64 [0.48,0.85]	
FIGARO-DKD	68 / 917	91 / 933	42.9	0.74 [0.53,1.03]	
Total	150 / 2714	221 / 2803		0.68 [0.55,0.84]	Z=-3.50, p=0.0005
Heterogeneity:	Q=0.44 (df=1)	p=0.5079	I^2=0.0%		
Female					
FIDELIO-DKD	57 / 820	53 / 740	63.9	0.97 [0.66,1.43]	
FIGARO-DKD	28 / 440	35 / 423	36.1	0.75 [0.45,1.26]	
Total	85 / 1260	88 / 1163		0.88 [0.65,1.20]	Z=-0.78, p=0.4354
Heterogeneity:	Q=0.58 (df=1)	p=0.4460	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.84 (df=1)	p=0.1747	I^2=45.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.115.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

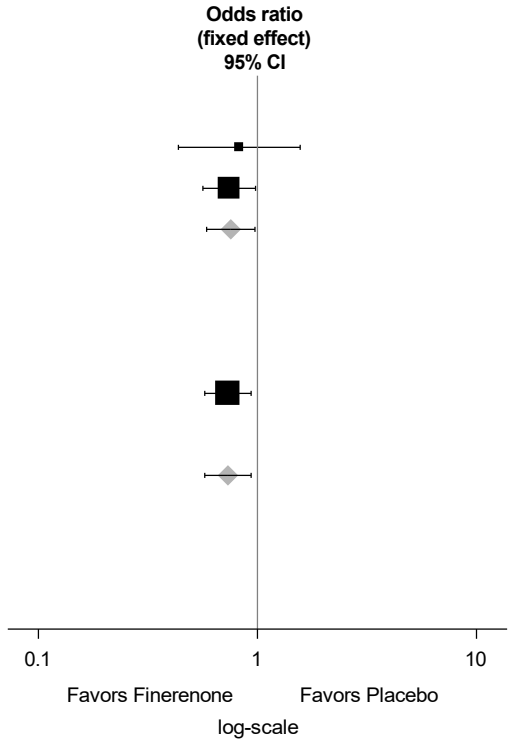
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	58 / 1103	68 / 1075	74.6	0.82 [0.57,1.18]	
FIGARO-DKD	22 / 336	21 / 335	25.4	1.05 [0.56,1.94]	
Total	80 / 1439	89 / 1410		0.87 [0.64,1.19]	Z=-0.85, p=0.3970
Heterogeneity:	Q=0.44 (df=1)	p=0.5064	I^2=0.0%		
>= 65					
FIDELIO-DKD	81 / 1514	115 / 1535	52.9	0.70 [0.52,0.94]	
FIGARO-DKD	74 / 1021	105 / 1021	47.1	0.68 [0.50,0.93]	
Total	155 / 2535	220 / 2556		0.69 [0.56,0.85]	Z=-3.40, p=0.0007
Heterogeneity:	Q=0.01 (df=1)	p=0.9140	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.50 (df=1)	p=0.2201	I^2=33.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.115.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

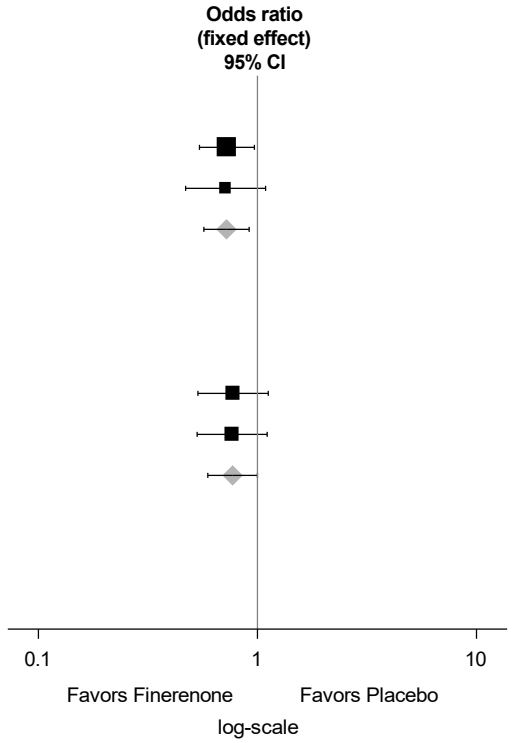
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	19 / 209	23 / 213	15.8	0.83 [0.44,1.57]	
FIGARO-DKD	96 / 1357	126 / 1356	84.2	0.74 [0.56,0.98]	
Total	115 / 1566	149 / 1569		0.76 [0.59,0.97]	Z=-2.16, p=0.0307
Heterogeneity:	Q=0.09 (df=1)	p=0.7663	I^2=0.0%		
Very High					
FIDELIO-DKD	120 / 2408	160 / 2397	100.0	0.73 [0.57,0.94]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	120 / 2408	160 / 2397		0.73 [0.57,0.94]	Z=-2.49, p=0.0126
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.03 (df=1)	p=0.8673	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.115.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Psychiatric Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

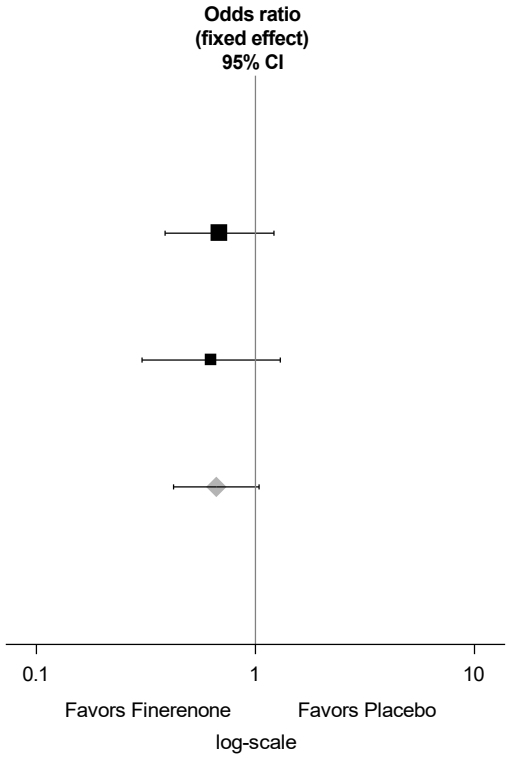
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	86 / 1556	115 / 1541	67.9	0.73 [0.54,0.97]	
FIGARO-DKD	41 / 637	55 / 627	32.1	0.72 [0.47,1.09]	
Total	127 / 2193	170 / 2168		0.72 [0.57,0.92]	Z=-2.68, p=0.0074
Heterogeneity:	Q=0.00 (df=1)	p=0.9574	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	53 / 1061	68 / 1069	49.8	0.77 [0.53,1.12]	
FIGARO-DKD	55 / 720	71 / 729	50.2	0.77 [0.53,1.11]	
Total	108 / 1781	139 / 1798		0.77 [0.59,1.00]	Z=-1.96, p=0.0498
Heterogeneity:	Q=0.00 (df=1)	p=0.9708	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.13 (df=1)	p=0.7210	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.116: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Anxiety (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

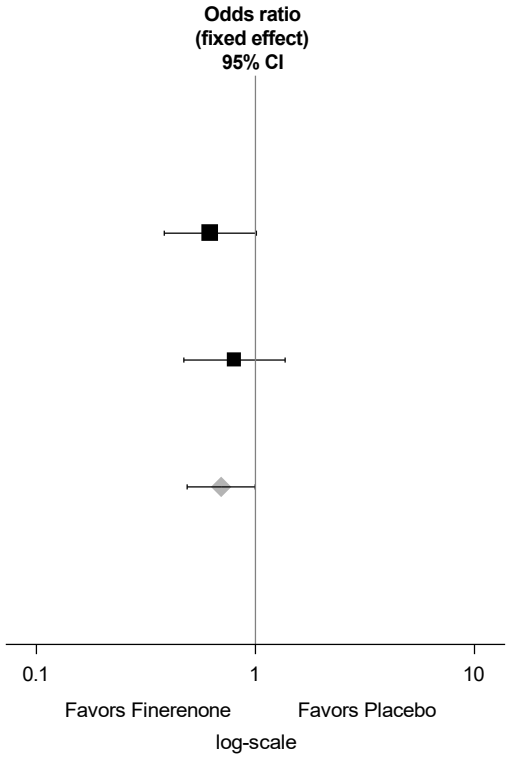
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	29 / 2610	61.7	0.69 [0.39,1.21]	
FIGARO-DKD	12 / 1357	19 / 1356	38.3	0.63 [0.30,1.30]	
Total	32 / 3974	48 / 3966		0.66 [0.42,1.04]	Z=-1.79, p=0.0728
Heterogeneity:	Q=0.03 (df=1)	p=0.8525	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.117: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

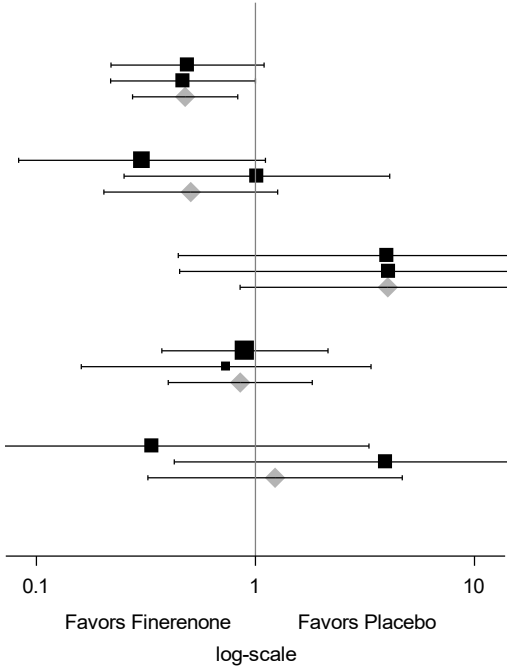
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	43 / 2610	54.7	0.62 [0.38,1.01]	
FIGARO-DKD	25 / 1357	31 / 1356	45.3	0.80 [0.47,1.37]	
Total	52 / 3974	74 / 3966		0.70 [0.49,1.00]	Z=-1.98, p=0.0481
Heterogeneity:	Q=0.48 (df=1)	p=0.4892	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.117.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

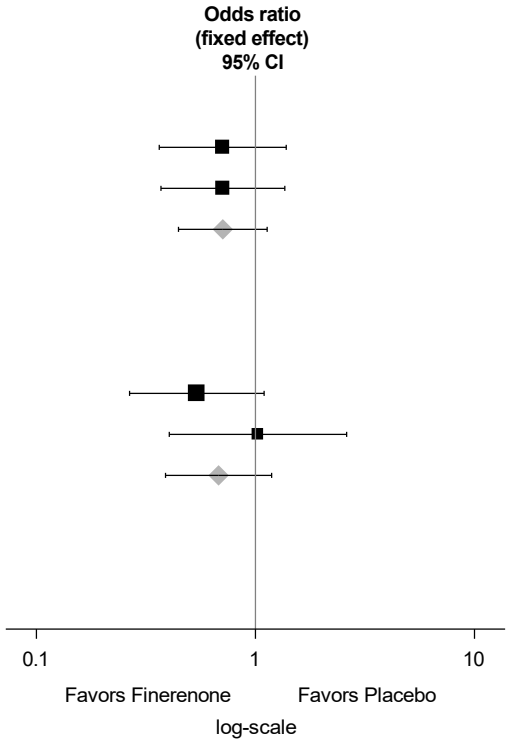
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	18 / 1062	47.2	0.49 [0.22,1.09]	
FIGARO-DKD	10 / 638	21 / 637	52.8	0.47 [0.22,1.00]	
Total	19 / 1713	39 / 1699		0.48 [0.27,0.83]	Z=-2.62, p=0.0088
Heterogeneity:	Q=0.01 (df=1)	p=0.9334	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	10 / 436	53.7	0.30 [0.08,1.11]	
FIGARO-DKD	4 / 267	4 / 271	46.3	1.02 [0.25,4.10]	
Total	7 / 691	14 / 707		0.51 [0.20,1.26]	Z=-1.46, p=0.1445
Heterogeneity:	Q=1.55 (df=1)	p=0.2130	I^2=35.5%		
Asia					
FIDELIO-DKD	4 / 751	1 / 745	50.1	3.98 [0.44,35.73]	
FIGARO-DKD	4 / 289	1 / 290	49.9	4.06 [0.45,36.51]	
Total	8 / 1040	2 / 1035		4.02 [0.85,18.99]	Z=1.76, p=0.0790
Heterogeneity:	Q=0.00 (df=1)	p=0.9910	I^2=0.0%		
Latin America					
FIDELIO-DKD	10 / 273	11 / 270	75.3	0.90 [0.37,2.14]	
FIGARO-DKD	3 / 102	4 / 101	24.7	0.73 [0.16,3.37]	
Total	13 / 375	15 / 371		0.85 [0.40,1.82]	Z=-0.41, p=0.6790
Heterogeneity:	Q=0.05 (df=1)	p=0.8255	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	48.7	0.34 [0.03,3.30]	
FIGARO-DKD	4 / 61	1 / 57	51.3	3.93 [0.43,36.26]	
Total	5 / 155	4 / 154		1.23 [0.32,4.68]	Z=0.30, p=0.7623
Heterogeneity:	Q=2.29 (df=1)	p=0.1304	I^2=56.3%		
Subgroup Heterogeneity:	Q=8.09 (df=4)	p=0.0882	I^2=50.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.117.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

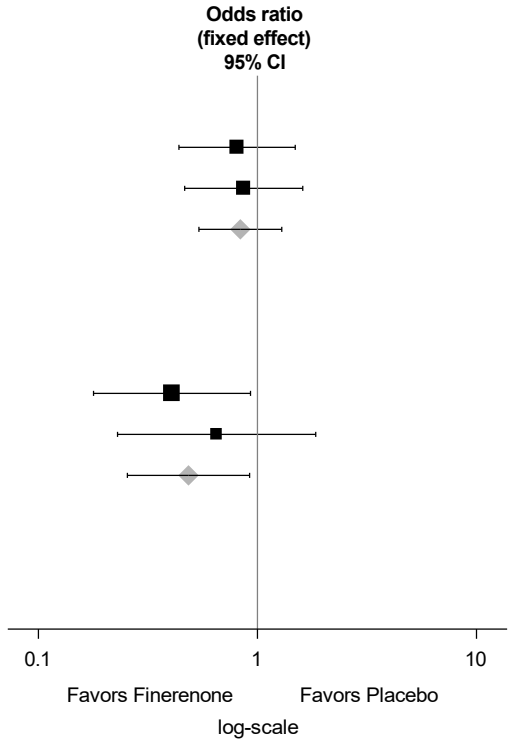
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	15 / 1213	21 / 1210	48.8	0.71 [0.36,1.38]	
FIGARO-DKD	16 / 862	22 / 848	51.2	0.71 [0.37,1.36]	
Total	31 / 2075	43 / 2058		0.71 [0.45,1.13]	Z=-1.44, p=0.1490
Heterogeneity:	Q=0.00 (df=1)	p=0.9973	I^2=0.0%		
Absent					
FIDELIO-DKD	12 / 1404	22 / 1400	63.5	0.54 [0.27,1.10]	
FIGARO-DKD	9 / 495	9 / 508	36.5	1.03 [0.40,2.61]	
Total	21 / 1899	31 / 1908		0.68 [0.39,1.19]	Z=-1.36, p=0.1730
Heterogeneity:	Q=1.16 (df=1)	p=0.2817	I^2=13.7%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9043	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.117.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

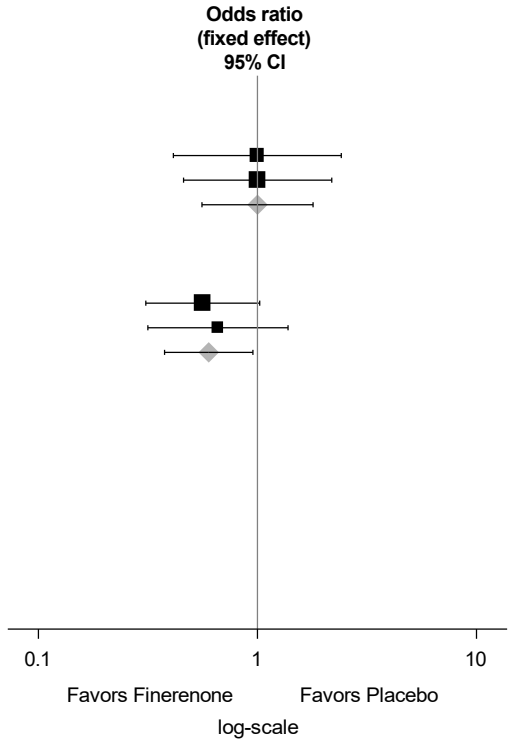
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 1735	23 / 1700	50.8	0.81 [0.44,1.49]	
FIGARO-DKD	19 / 924	22 / 929	49.2	0.87 [0.47,1.61]	
Total	38 / 2659	45 / 2629		0.84 [0.54,1.29]	Z=-0.81, p=0.4184
Heterogeneity:	Q=0.02 (df=1)	p=0.8755	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	20 / 910	61.4	0.41 [0.18,0.93]	
FIGARO-DKD	6 / 433	9 / 426	38.6	0.65 [0.23,1.85]	
Total	14 / 1315	29 / 1336		0.48 [0.25,0.92]	Z=-2.21, p=0.0270
Heterogeneity:	Q=0.48 (df=1)	p=0.4889	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.89 (df=1)	p=0.1686	I^2=47.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.117.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

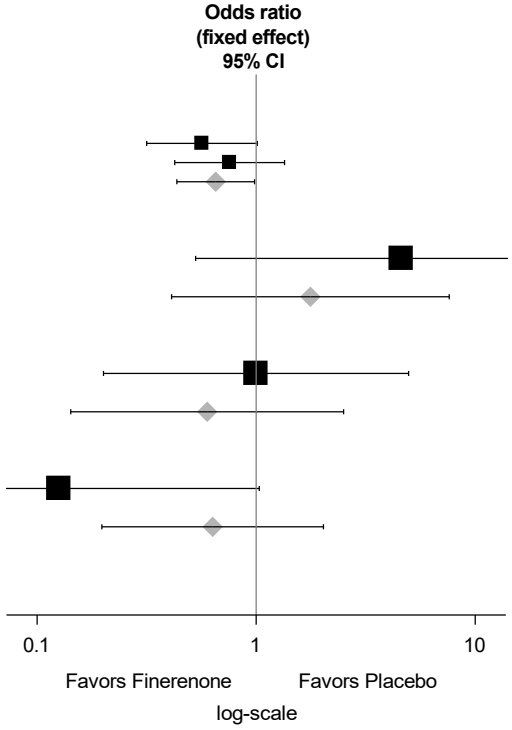
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	10 / 724	10 / 723	43.8	1.00 [0.41,2.41]	
FIGARO-DKD	13 / 494	13 / 495	56.2	1.00 [0.46,2.18]	
Total	23 / 1218	23 / 1218		1.00 [0.56,1.79]	Z=0.00, p=0.9985
Heterogeneity:	Q=0.00 (df=1)	p=0.9954	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	17 / 1759	30 / 1760	60.2	0.56 [0.31,1.02]	
FIGARO-DKD	12 / 829	18 / 827	39.8	0.66 [0.32,1.38]	
Total	29 / 2588	48 / 2587		0.60 [0.38,0.95]	Z=-2.16, p=0.0306
Heterogeneity:	Q=0.11 (df=1)	p=0.7418	I^2=0.0%		
>= 160					
FIDELIO-DKD	0 / 133	3 / 127	0.0	0.00 [0.00,13E296]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	0 / 167	3 / 161		0.00 [0.00,65E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=1.81 (df=2)	p=0.4038	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.117.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

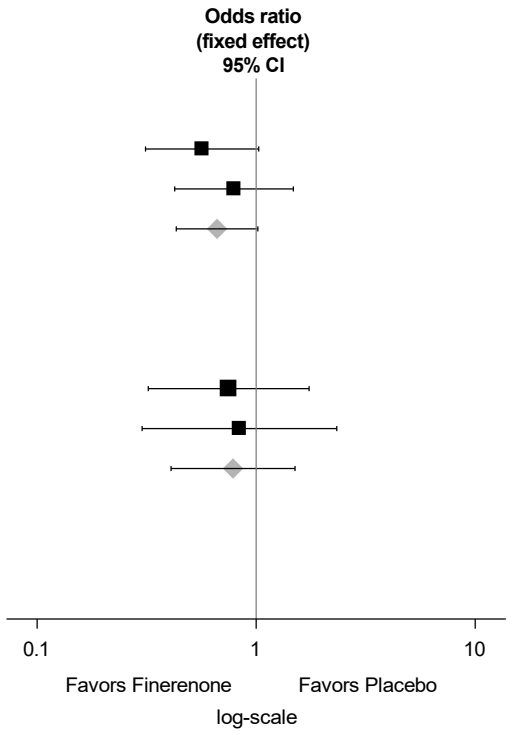
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	18 / 1634	32 / 1657	49.6	0.57 [0.32,1.01]	
FIGARO-DKD	21 / 1010	27 / 989	50.4	0.76 [0.42,1.35]	
Total	39 / 2644	59 / 2646		0.65 [0.43,0.98]	Z=-2.04, p=0.0412
Heterogeneity:	Q=0.48 (df=1)	p=0.4866	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	1 / 115	100.0	4.60 [0.53,39.94]	
FIGARO-DKD	0 / 43	2 / 71	0.0	0.00 [0.00,1E297]	
Total	5 / 172	3 / 186		1.77 [0.41,7.61]	Z=0.77, p=0.4440
Heterogeneity:	Q=0.75 (df=1)	p=0.3865	I^2=0.0%		
Asian					
FIDELIO-DKD	3 / 678	3 / 677	100.0	1.00 [0.20,4.96]	
FIGARO-DKD	0 / 252	2 / 251	0.0	0.00 [0.00,15E296]	
Total	3 / 930	5 / 928		0.60 [0.14,2.51]	Z=-0.70, p=0.4815
Heterogeneity:	Q=0.39 (df=1)	p=0.5302	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 176	7 / 161	100.0	0.13 [0.02,1.03]	
FIGARO-DKD	4 / 52	0 / 45	0.0	174E9 [174E9,174E9]	
Total	5 / 228	7 / 206		0.63 [0.20,2.03]	Z=-0.77, p=0.4413
Heterogeneity:	Q=2.26 (df=1)	p=0.1326	I^2=55.8%		
Subgroup Heterogeneity:	Q=1.72 (df=3)	p=0.6314	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.117.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

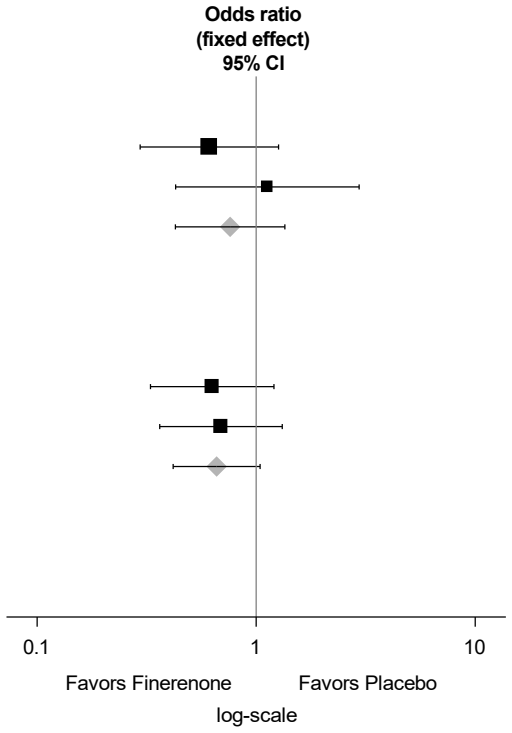
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	17 / 1797	31 / 1870	52.3	0.57 [0.31,1.03]	
FIGARO-DKD	18 / 917	23 / 933	47.7	0.79 [0.42,1.48]	
Total	35 / 2714	54 / 2803		0.66 [0.43,1.02]	Z=-1.88, p=0.0602
Heterogeneity:	Q=0.58 (df=1)	p=0.4459	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	12 / 740	59.4	0.75 [0.32,1.74]	
FIGARO-DKD	7 / 440	8 / 423	40.6	0.84 [0.30,2.33]	
Total	17 / 1260	20 / 1163		0.78 [0.41,1.50]	Z=-0.73, p=0.4643
Heterogeneity:	Q=0.03 (df=1)	p=0.8674	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.18 (df=1)	p=0.6732	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.117.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

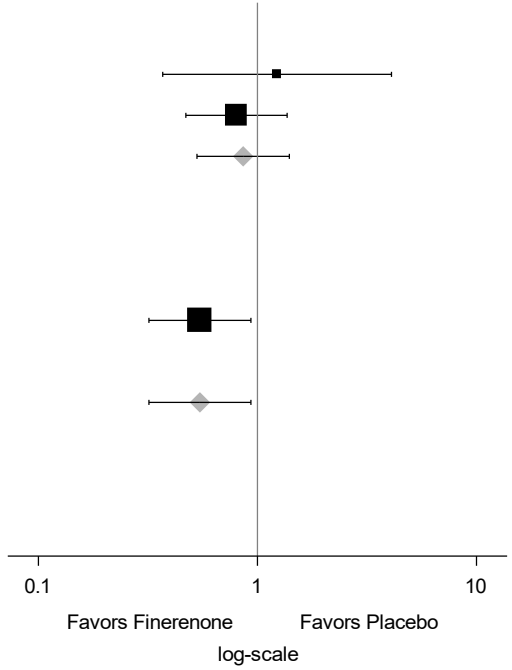
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	12 / 1103	19 / 1075	63.7	0.61 [0.30,1.27]	
FIGARO-DKD	9 / 336	8 / 335	36.3	1.12 [0.43,2.95]	
Total	21 / 1439	27 / 1410		0.76 [0.43,1.35]	Z=-0.93, p=0.3508
Heterogeneity:	Q=0.98 (df=1)	p=0.3225	I^2=0.0%		
>= 65					
FIDELIO-DKD	15 / 1514	24 / 1535	49.6	0.63 [0.33,1.21]	
FIGARO-DKD	16 / 1021	23 / 1021	50.4	0.69 [0.36,1.32]	
Total	31 / 2535	47 / 2556		0.66 [0.42,1.04]	Z=-1.78, p=0.0745
Heterogeneity:	Q=0.04 (df=1)	p=0.8434	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.14 (df=1)	p=0.7051	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.117.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

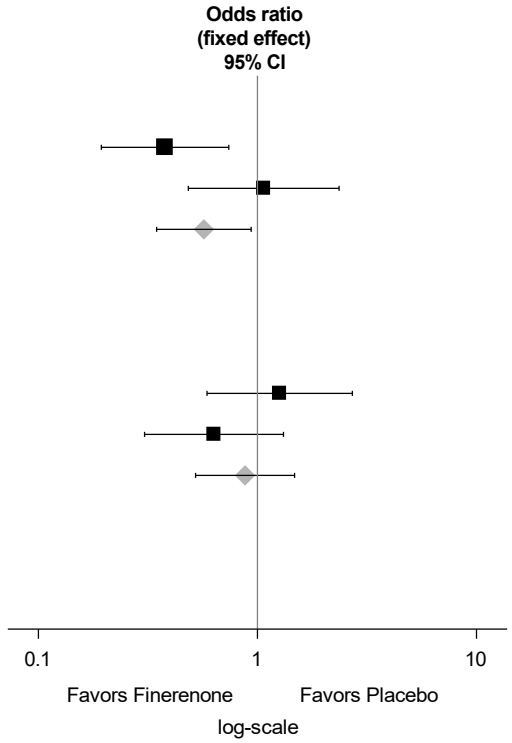
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	6 / 209	5 / 213	16.4	1.23 [0.37,4.09]	
FIGARO-DKD	25 / 1357	31 / 1356	83.6	0.80 [0.47,1.37]	
Total	31 / 1566	36 / 1569		0.86 [0.53,1.40]	Z=-0.61, p=0.5441
Heterogeneity:	Q=0.41 (df=1)	p=0.5245	I^2=0.0%		
Very High					
FIDELIO-DKD	21 / 2408	38 / 2397	100.0	0.55 [0.32,0.93]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	21 / 2408	38 / 2397		0.55 [0.32,0.93]	Z=-2.21, p=0.0270
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.52 (df=1)	p=0.2179	I^2=34.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.117.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Depression (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

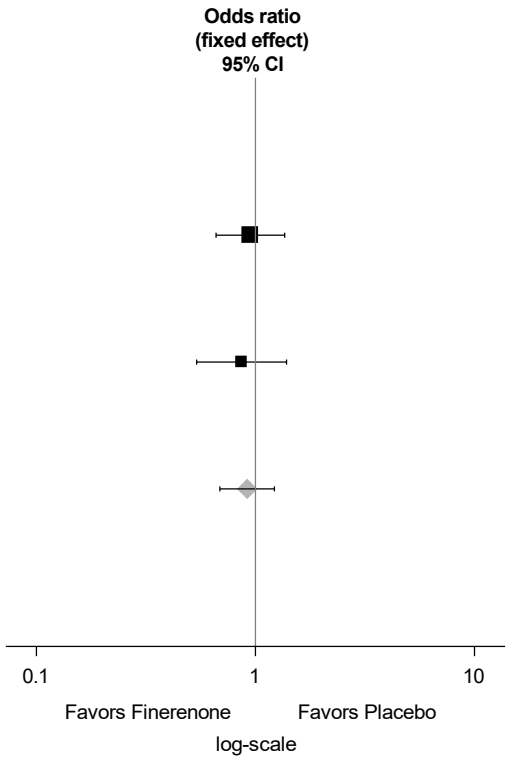
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	12 / 1556	31 / 1541	58.3	0.38 [0.19,0.74]	
FIGARO-DKD	13 / 637	12 / 627	41.7	1.07 [0.48,2.36]	
Total	25 / 2193	43 / 2168		0.57 [0.35,0.94]	Z=-2.22, p=0.0263
Heterogeneity:	Q=3.84 (df=1)	p=0.0500	I^2=74.0%		
45 - < 60					
FIDELIO-DKD	15 / 1061	12 / 1069	47.7	1.26 [0.59,2.71]	
FIGARO-DKD	12 / 720	19 / 729	52.3	0.63 [0.31,1.31]	
Total	27 / 1781	31 / 1798		0.88 [0.52,1.48]	Z=-0.49, p=0.6237
Heterogeneity:	Q=1.64 (df=1)	p=0.2004	I^2=39.0%		
Subgroup Heterogeneity:	Q=1.39 (df=1)	p=0.2383	I^2=28.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.118: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Insomnia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

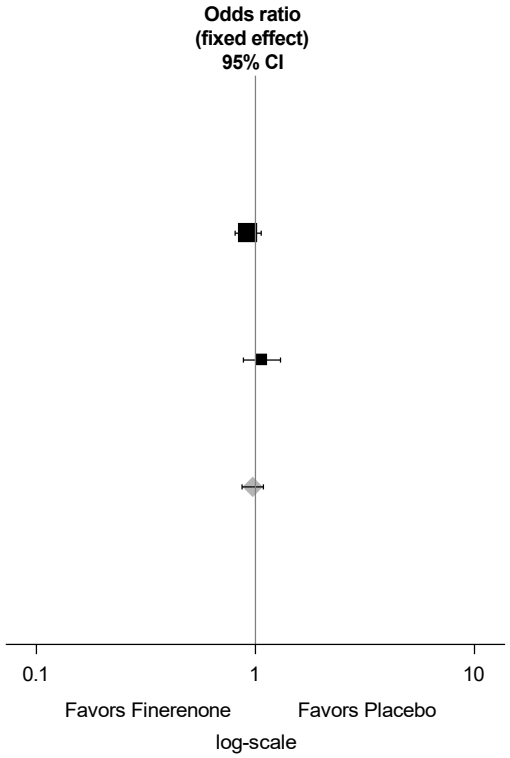
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	59 / 2617	62 / 2610	63.2	0.95 [0.66,1.36]	
FIGARO-DKD	33 / 1357	38 / 1356	36.8	0.86 [0.54,1.39]	
Total	92 / 3974	100 / 3966		0.92 [0.69,1.22]	Z=-0.60, p=0.5498
Heterogeneity:	Q=0.09 (df=1)	p=0.7614	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.119: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

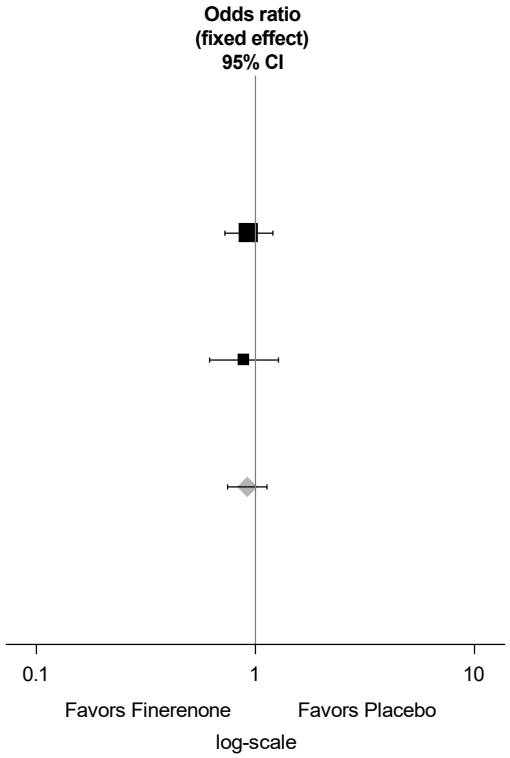
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	494 / 2617	524 / 2610	67.0	0.93 [0.81,1.06]	
FIGARO-DKD	254 / 1357	240 / 1356	33.0	1.07 [0.88,1.30]	
Total	748 / 3974	764 / 3966		0.97 [0.87,1.09]	Z=-0.50, p=0.6160
Heterogeneity:	Q=1.42 (df=1)	p=0.2333	I^2=29.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.120: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

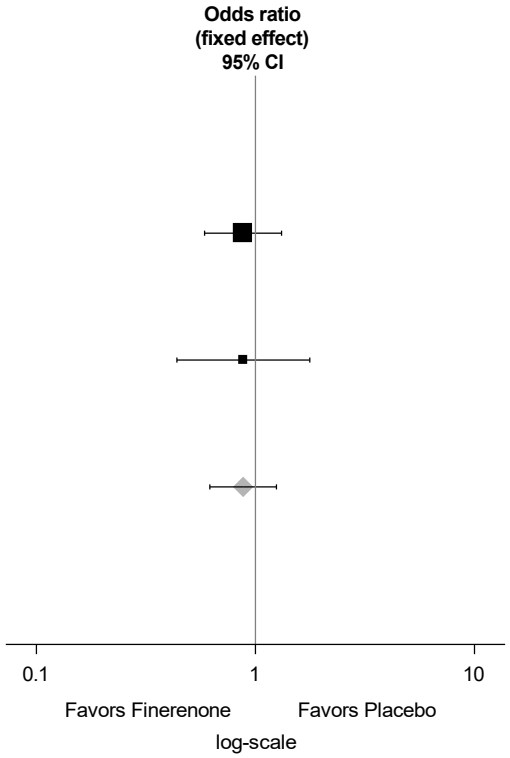
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	123 / 2617	131 / 2610	67.3	0.93 [0.73,1.20]	
FIGARO-DKD	58 / 1357	65 / 1356	32.7	0.89 [0.62,1.27]	
Total	181 / 3974	196 / 3966		0.92 [0.75,1.13]	Z=-0.81, p=0.4170
Heterogeneity:	Q=0.05 (df=1)	p=0.8206	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.121: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic kidney disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

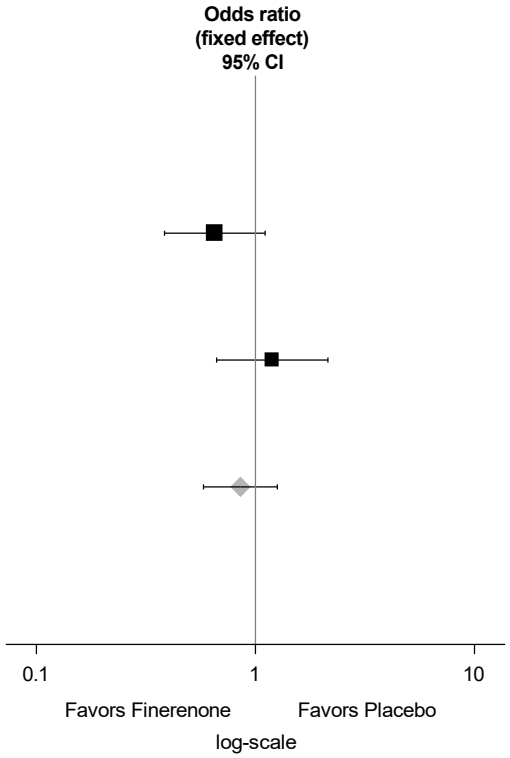
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	51 / 2610	74.9	0.88 [0.59,1.32]	
FIGARO-DKD	15 / 1357	17 / 1356	25.1	0.88 [0.44,1.77]	
Total	60 / 3974	68 / 3966		0.88 [0.62,1.25]	Z=-0.73, p=0.4684
Heterogeneity:	Q=0.00 (df=1)	p=0.9945	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.122: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Haematuria (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

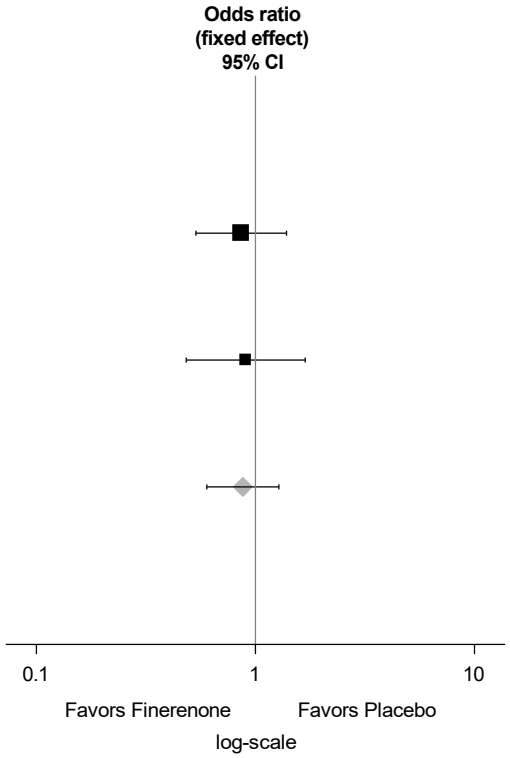
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	35 / 2610	55.0	0.65 [0.38,1.11]	
FIGARO-DKD	25 / 1357	21 / 1356	45.0	1.19 [0.66,2.14]	
Total	48 / 3974	56 / 3966		0.85 [0.58,1.26]	Z=-0.80, p=0.4246
Heterogeneity:	Q=2.25 (df=1)	p=0.1335	I^2=55.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.123: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Nephrolithiasis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

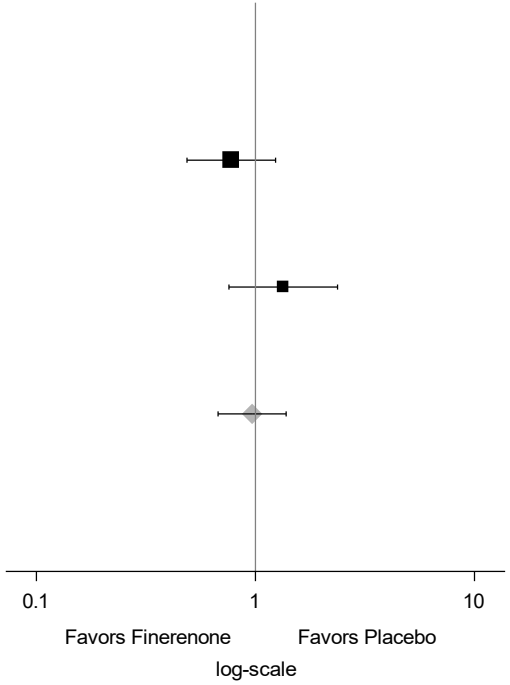
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	37 / 2610	63.3	0.86 [0.53,1.39]	
FIGARO-DKD	19 / 1357	21 / 1356	36.7	0.90 [0.48,1.69]	
Total	51 / 3974	58 / 3966		0.88 [0.60,1.28]	Z=-0.68, p=0.4933
Heterogeneity:	Q=0.01 (df=1)	p=0.9057	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.124: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal cyst (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

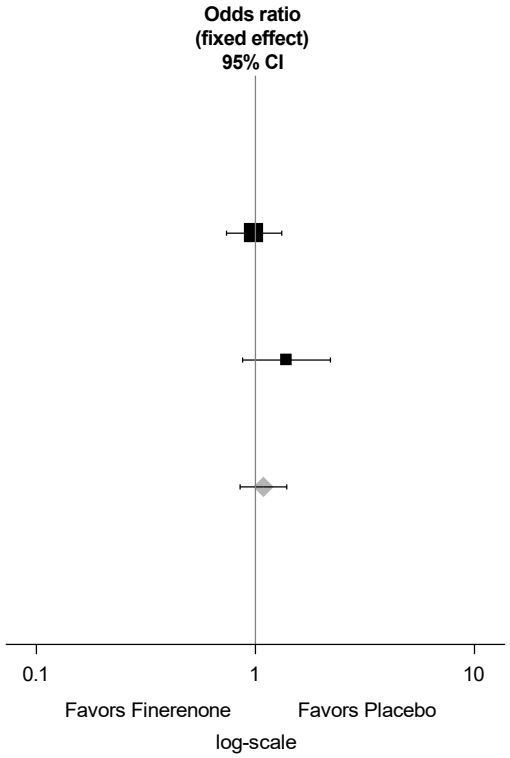
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	32 / 2617	41 / 2610	60.1	0.78 [0.49,1.24]	
FIGARO-DKD	28 / 1357	21 / 1356	39.9	1.34 [0.76,2.37]	
Total	60 / 3974	62 / 3966		0.97 [0.68,1.38]	Z=-0.19, p=0.8469
Heterogeneity:	Q=2.11 (df=1)	p=0.1461	I^2=52.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.125: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Renal impairment (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

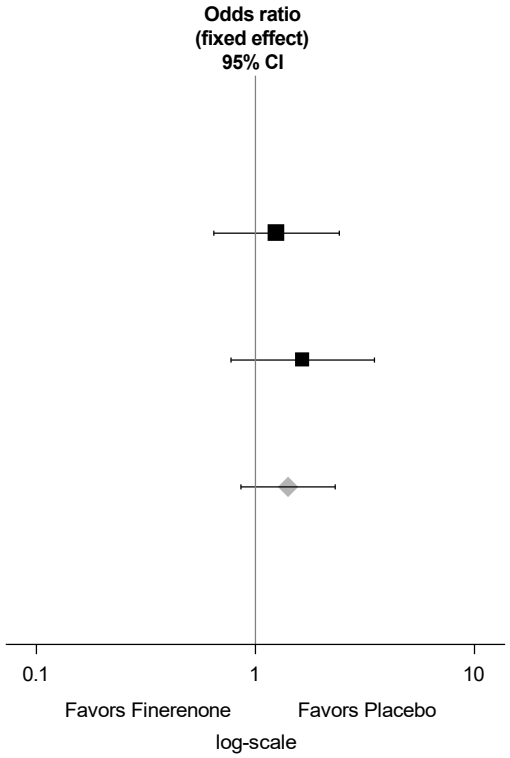
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2617	95 / 2610	71.6	0.99 [0.74,1.32]	
FIGARO-DKD	44 / 1357	32 / 1356	28.4	1.39 [0.87,2.20]	
Total	138 / 3974	127 / 3966		1.09 [0.85,1.39]	Z=0.67, p=0.5030
Heterogeneity:	Q=1.50 (df=1)	p=0.2211	I^2=33.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.126: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Urinary incontinence (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

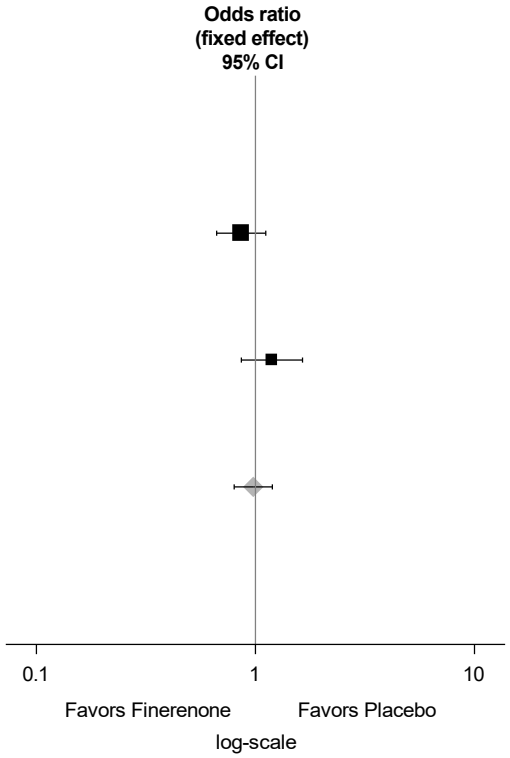
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	16 / 2610	56.6	1.25 [0.65,2.41]	
FIGARO-DKD	18 / 1357	11 / 1356	43.4	1.64 [0.77,3.49]	
Total	38 / 3974	27 / 3966		1.41 [0.86,2.31]	Z=1.36, p=0.1750
Heterogeneity:	Q=0.29 (df=1)	p=0.5906	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.127: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Reproductive System And Breast Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

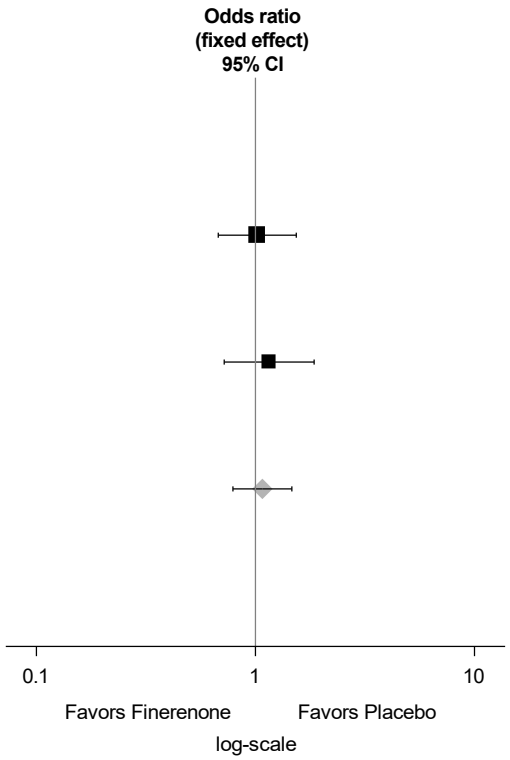
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2617	130 / 2610	60.8	0.86 [0.67,1.11]	
FIGARO-DKD	86 / 1357	73 / 1356	39.2	1.19 [0.86,1.64]	
Total	199 / 3974	203 / 3966		0.98 [0.80,1.19]	Z=-0.22, p=0.8224
Heterogeneity:	Q=2.36 (df=1)	p=0.1245	I^2=57.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.128: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Benign prostatic hyperplasia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

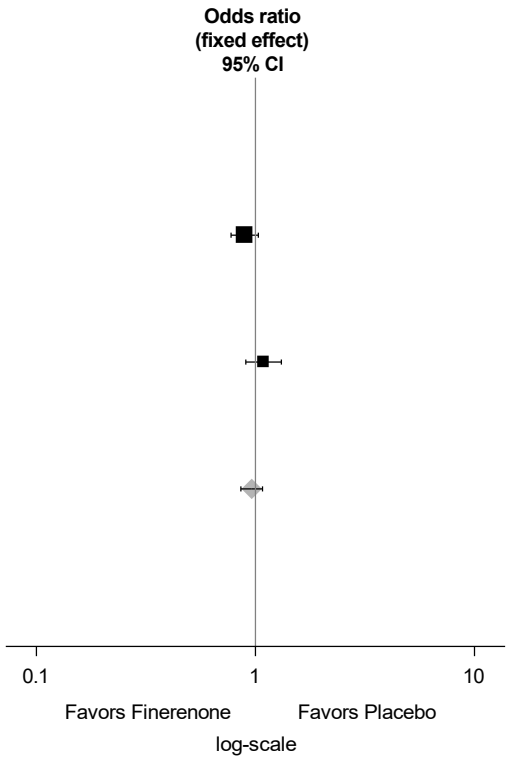
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	47 / 2617	46 / 2610	57.0	1.02 [0.68,1.54]	
FIGARO-DKD	38 / 1357	33 / 1356	43.0	1.16 [0.72,1.85]	
Total	85 / 3974	79 / 3966		1.08 [0.79,1.47]	Z=0.46, p=0.6443
Heterogeneity:	Q=0.15 (df=1)	p=0.6955	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.129: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

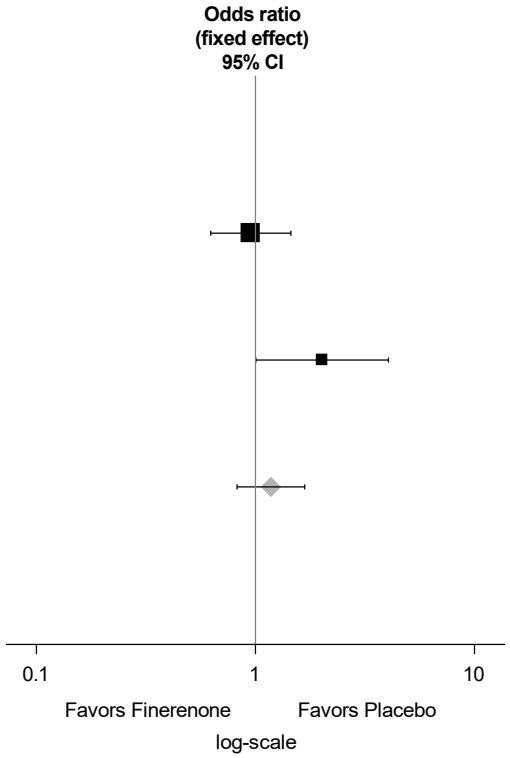
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	432 / 2617	473 / 2610	62.9	0.89 [0.77,1.03]	
FIGARO-DKD	286 / 1357	267 / 1356	37.1	1.09 [0.90,1.31]	
Total	718 / 3974	740 / 3966		0.96 [0.86,1.08]	Z=-0.68, p=0.4970
Heterogeneity:	Q=2.72 (df=1)	p=0.0990	I^2=63.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.130: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Chronic obstructive pulmonary disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

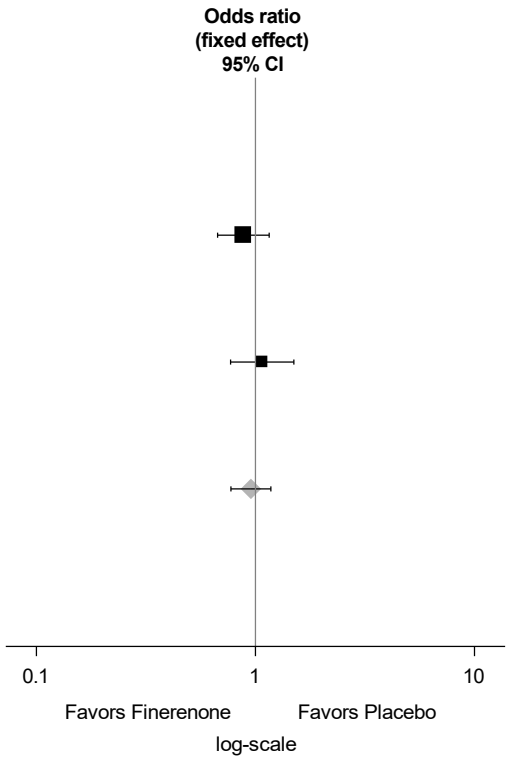
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	43 / 2617	45 / 2610	73.2	0.95 [0.62,1.45]	
FIGARO-DKD	24 / 1357	12 / 1356	26.8	2.02 [1.00,4.05]	
Total	67 / 3974	57 / 3966		1.18 [0.82,1.68]	Z=0.89, p=0.3722
Heterogeneity:	Q=3.26 (df=1)	p=0.0709	I^2=69.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.131: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cough (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

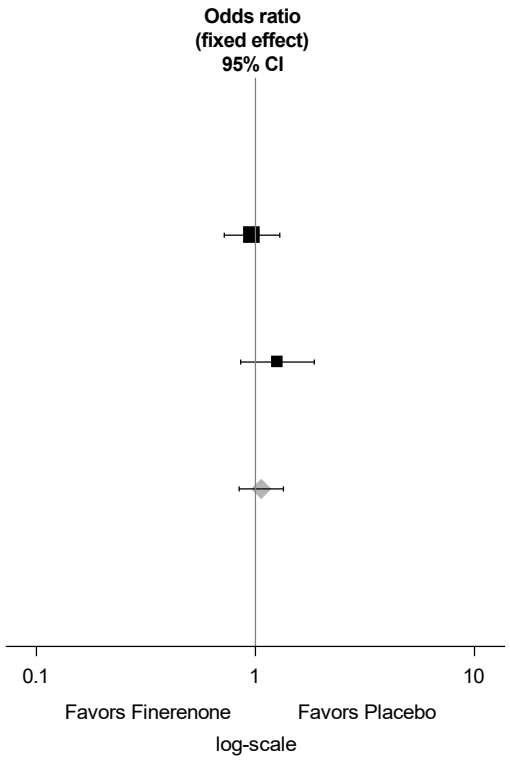
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	103 / 2617	116 / 2610	60.1	0.88 [0.67,1.16]	
FIGARO-DKD	76 / 1357	71 / 1356	39.9	1.07 [0.77,1.50]	
Total	179 / 3974	187 / 3966		0.95 [0.77,1.18]	Z=-0.45, p=0.6550
Heterogeneity:	Q=0.82 (df=1)	p=0.3657	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.132: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspnoea (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

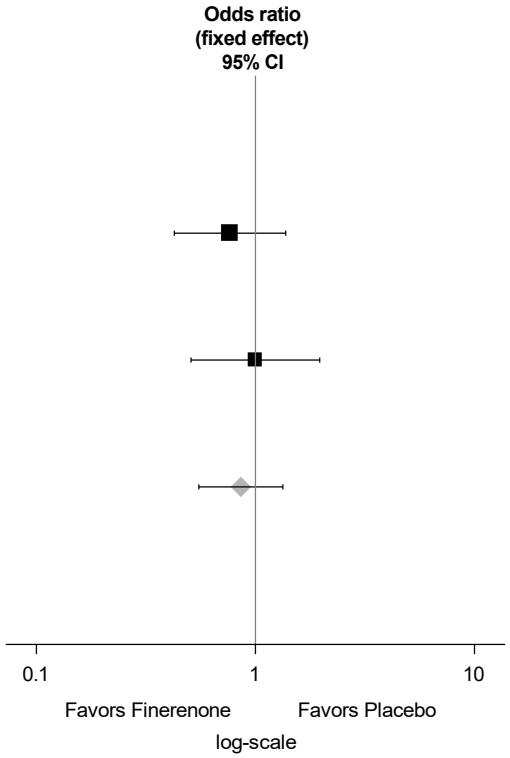
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	92 / 2617	95 / 2610	63.8	0.96 [0.72,1.29]	
FIGARO-DKD	60 / 1357	48 / 1356	36.2	1.26 [0.86,1.86]	
Total	152 / 3974	143 / 3966		1.06 [0.84,1.34]	Z=0.52, p=0.6053
Heterogeneity:	Q=1.17 (df=1)	p=0.2794	I^2=14.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.133: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Dyspnoea exertional (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

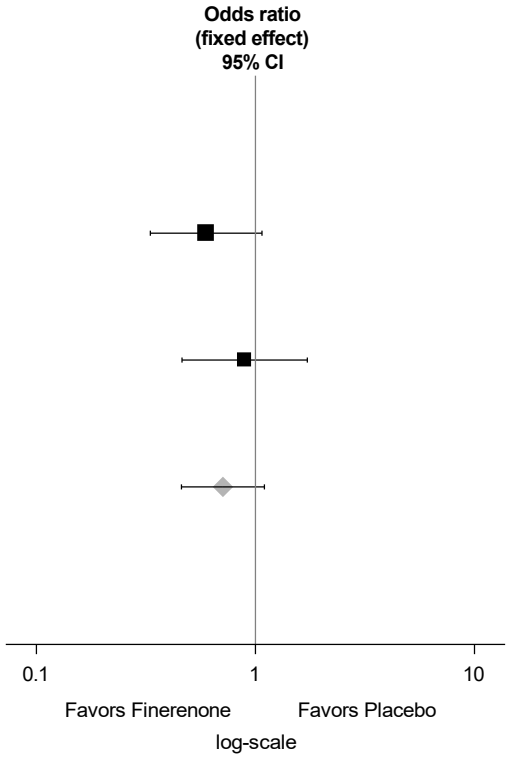
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	26 / 2610	57.2	0.77 [0.43,1.37]	
FIGARO-DKD	17 / 1357	17 / 1356	42.8	1.00 [0.51,1.97]	
Total	37 / 3974	43 / 3966		0.86 [0.55,1.33]	Z=-0.68, p=0.4952
Heterogeneity:	Q=0.34 (df=1)	p=0.5591	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.134: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Sleep apnoea syndrome (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

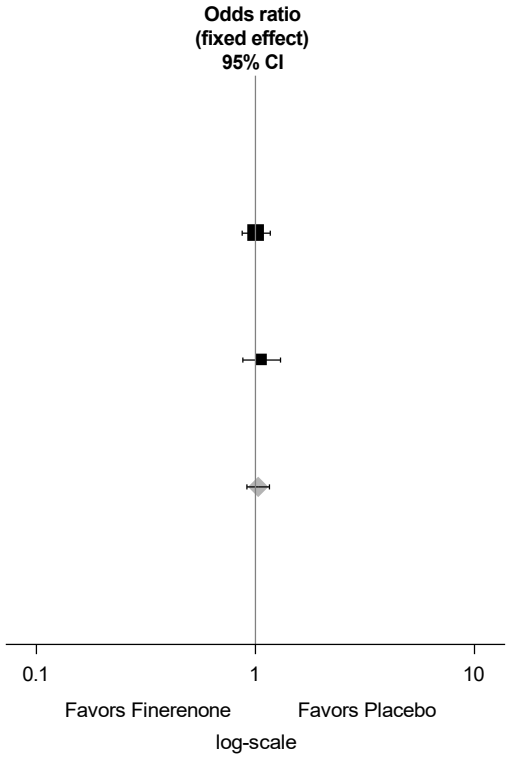
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	30 / 2610	55.7	0.60 [0.33,1.07]	
FIGARO-DKD	17 / 1357	19 / 1356	44.3	0.89 [0.46,1.73]	
Total	35 / 3974	49 / 3966		0.71 [0.46,1.10]	Z=-1.54, p=0.1242
Heterogeneity:	Q=0.81 (df=1)	p=0.3686	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.135: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

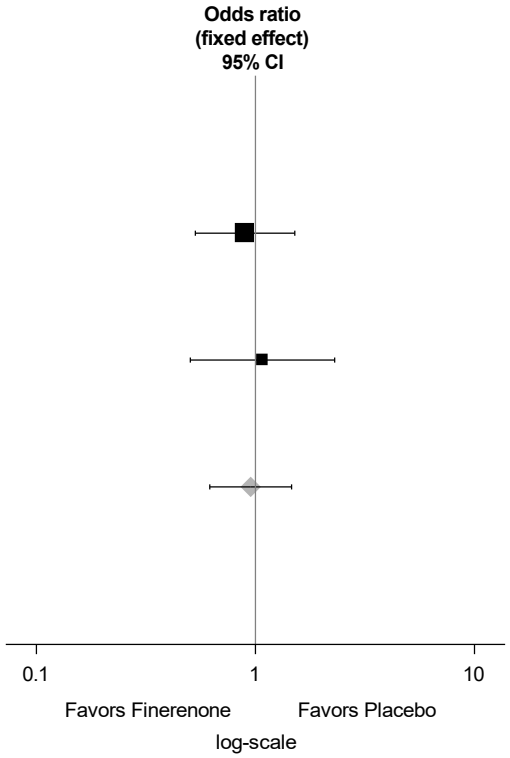
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	422 / 2617	418 / 2610	64.3	1.01 [0.87,1.17]	
FIGARO-DKD	244 / 1357	231 / 1356	35.7	1.07 [0.88,1.30]	
Total	666 / 3974	649 / 3966		1.03 [0.91,1.16]	Z=0.47, p=0.6355
Heterogeneity:	Q=0.21 (df=1)	p=0.6493	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.136: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Diabetic foot (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

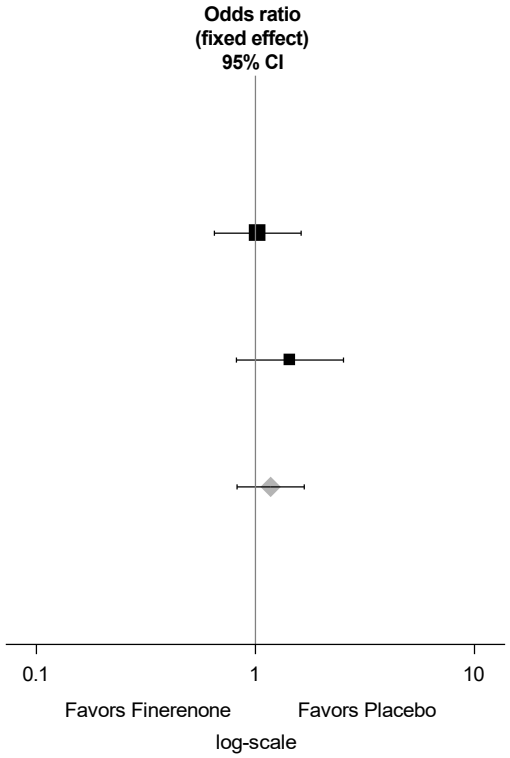
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	30 / 2610	67.8	0.90 [0.53,1.51]	
FIGARO-DKD	14 / 1357	13 / 1356	32.2	1.08 [0.50,2.30]	
Total	41 / 3974	43 / 3966		0.95 [0.62,1.46]	Z=-0.23, p=0.8190
Heterogeneity:	Q=0.15 (df=1)	p=0.6965	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.137: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Eczema (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

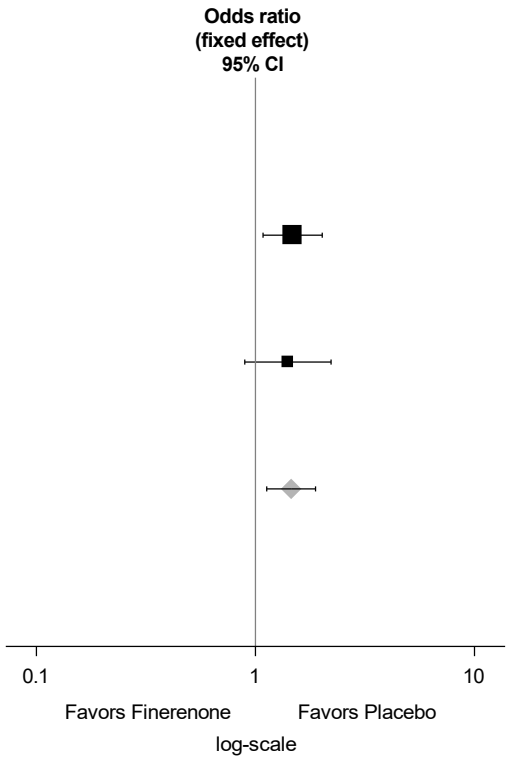
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	37 / 2610	60.4	1.02 [0.65,1.62]	
FIGARO-DKD	30 / 1357	21 / 1356	39.6	1.44 [0.82,2.52]	
Total	68 / 3974	58 / 3966		1.17 [0.82,1.67]	Z=0.89, p=0.3753
Heterogeneity:	Q=0.84 (df=1)	p=0.3599	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.138: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

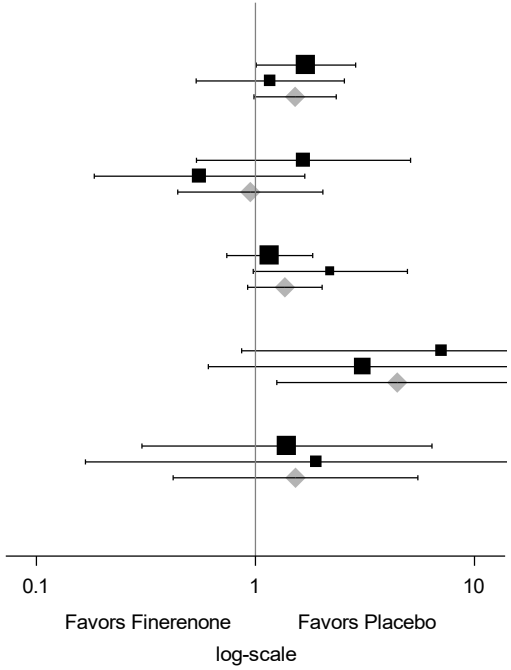
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	101 / 2617	69 / 2610	68.0	1.48 [1.08,2.02]	
FIGARO-DKD	46 / 1357	33 / 1356	32.0	1.41 [0.89,2.21]	
Total	147 / 3974	102 / 3966		1.46 [1.13,1.88]	Z=2.87, p=0.0042
Heterogeneity:	Q=0.03 (df=1)	p=0.8595	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.138.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

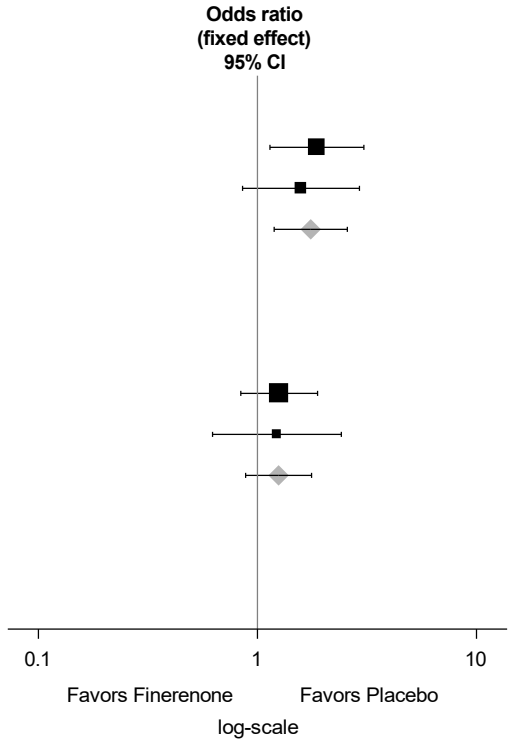
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	39 / 1075	23 / 1062	69.0	1.70 [1.01,2.87]	
FIGARO-DKD	14 / 638	12 / 637	31.0	1.17 [0.54,2.55]	
Total	53 / 1713	35 / 1699		1.52 [0.98,2.34]	Z=1.89, p=0.0589
Heterogeneity:	Q=0.61 (df=1)	p=0.4330	I^2=0.0%		
North America					
FIDELIO-DKD	8 / 424	5 / 436	49.2	1.66 [0.54,5.11]	
FIGARO-DKD	5 / 267	9 / 271	50.8	0.56 [0.18,1.68]	
Total	13 / 691	14 / 707		0.95 [0.44,2.03]	Z=-0.14, p=0.8895
Heterogeneity:	Q=1.84 (df=1)	p=0.1746	I^2=45.7%		
Asia					
FIDELIO-DKD	43 / 751	37 / 745	76.3	1.16 [0.74,1.83]	
FIGARO-DKD	19 / 289	9 / 290	23.7	2.20 [0.98,4.94]	
Total	62 / 1040	46 / 1035		1.36 [0.92,2.02]	Z=1.55, p=0.1213
Heterogeneity:	Q=1.81 (df=1)	p=0.1783	I^2=44.8%		
Latin America					
FIDELIO-DKD	7 / 273	1 / 270	37.4	7.08 [0.87,57.93]	
FIGARO-DKD	6 / 102	2 / 101	62.6	3.09 [0.61,15.71]	
Total	13 / 375	3 / 371		4.44 [1.25,15.75]	Z=2.31, p=0.0210
Heterogeneity:	Q=0.38 (df=1)	p=0.5381	I^2=0.0%		
Others					
FIDELIO-DKD	4 / 94	3 / 97	71.7	1.39 [0.30,6.40]	
FIGARO-DKD	2 / 61	1 / 57	28.3	1.90 [0.17,21.52]	
Total	6 / 155	4 / 154		1.52 [0.42,5.52]	Z=0.64, p=0.5210
Heterogeneity:	Q=0.04 (df=1)	p=0.8323	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.33 (df=4)	p=0.3628	I^2=7.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.138.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

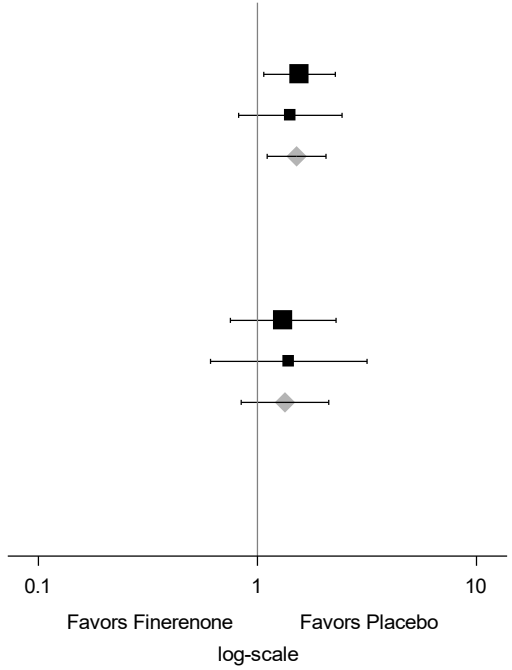
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	46 / 1213	25 / 1210	60.8	1.87 [1.14,3.06]	
FIGARO-DKD	27 / 862	17 / 848	39.2	1.58 [0.86,2.92]	
Total	73 / 2075	42 / 2058		1.75 [1.19,2.57]	Z=2.86, p=0.0043
Heterogeneity:	Q=0.17 (df=1)	p=0.6775	I^2=0.0%		
Absent					
FIDELIO-DKD	55 / 1404	44 / 1400	73.8	1.26 [0.84,1.88]	
FIGARO-DKD	19 / 495	16 / 508	26.2	1.23 [0.62,2.42]	
Total	74 / 1899	60 / 1908		1.25 [0.88,1.77]	Z=1.26, p=0.2089
Heterogeneity:	Q=0.00 (df=1)	p=0.9536	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.64 (df=1)	p=0.2006	I^2=39.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.138.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

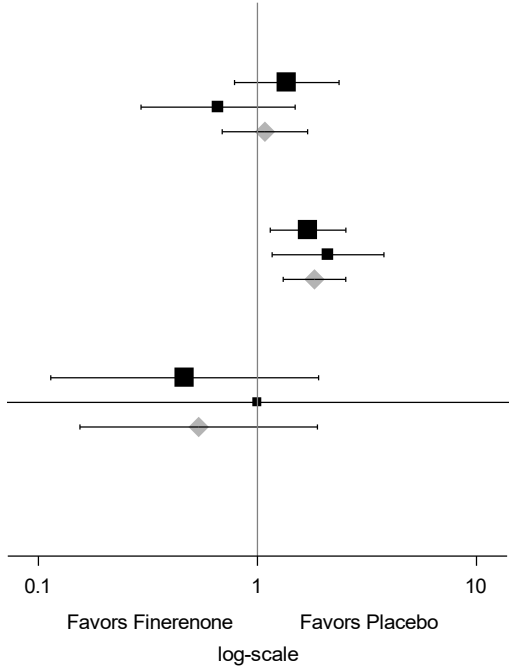
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	72 / 1735	46 / 1700	67.6	1.56 [1.07,2.27]	
FIGARO-DKD	32 / 924	23 / 929	32.4	1.41 [0.82,2.43]	
Total	104 / 2659	69 / 2629		1.51 [1.11,2.06]	Z=2.61, p=0.0091
Heterogeneity:	Q=0.08 (df=1)	p=0.7742	I^2=0.0%		
> 4.5					
FIDELIO-DKD	29 / 882	23 / 910	68.7	1.31 [0.75,2.28]	
FIGARO-DKD	14 / 433	10 / 426	31.3	1.39 [0.61,3.16]	
Total	43 / 1315	33 / 1336		1.34 [0.84,2.12]	Z=1.23, p=0.2180
Heterogeneity:	Q=0.01 (df=1)	p=0.9082	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.19 (df=1)	p=0.6656	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.138.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

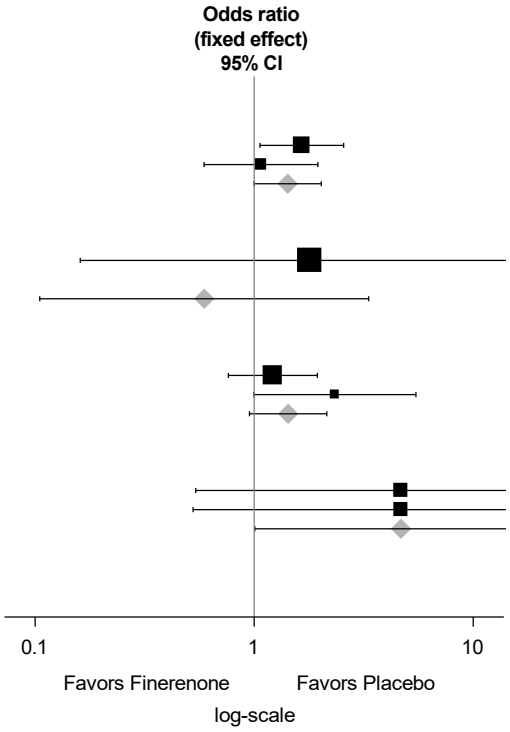
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	31 / 724	23 / 723	68.5	1.36 [0.79,2.36]	
FIGARO-DKD	10 / 494	15 / 495	31.5	0.66 [0.29,1.49]	
Total	41 / 1218	38 / 1218		1.08 [0.69,1.69]	Z=0.34, p=0.7324
Heterogeneity:	Q=2.09 (df=1)	p=0.1481	I^2=52.2%		
130 - < 160					
FIDELIO-DKD	67 / 1759	40 / 1760	68.6	1.70 [1.14,2.53]	
FIGARO-DKD	35 / 829	17 / 827	31.4	2.10 [1.17,3.78]	
Total	102 / 2588	57 / 2587		1.82 [1.31,2.53]	Z=3.57, p=0.0004
Heterogeneity:	Q=0.34 (df=1)	p=0.5620	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 133	6 / 127	80.0	0.47 [0.11,1.90]	
FIGARO-DKD	1 / 34	1 / 34	20.0	1.00 [0.06,16.67]	
Total	4 / 167	7 / 161		0.54 [0.15,1.88]	Z=-0.97, p=0.3320
Heterogeneity:	Q=0.23 (df=1)	p=0.6336	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.90 (df=2)	p=0.0524	I^2=66.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.138.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

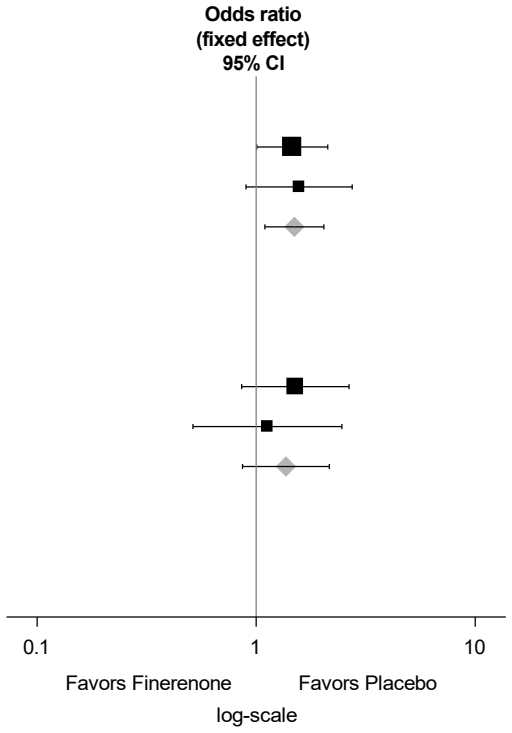
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	53 / 1634	33 / 1657	64.9	1.65 [1.06,2.56]	
FIGARO-DKD	23 / 1010	21 / 989	35.1	1.07 [0.59,1.95]	
Total	76 / 2644	54 / 2646		1.42 [1.00,2.03]	Z=1.96, p=0.0504
Heterogeneity:	Q=1.28 (df=1)	p=0.2574	I^2=22.0%		
Black					
FIDELIO-DKD	2 / 129	1 / 115	100.0	1.80 [0.16,20.06]	
FIGARO-DKD	0 / 43	3 / 71	0.0	0.00 [0.00,2E297]	
Total	2 / 172	4 / 186		0.59 [0.10,3.33]	Z=-0.60, p=0.5518
Heterogeneity:	Q=0.81 (df=1)	p=0.3673	I^2=0.0%		
Asian					
FIDELIO-DKD	41 / 678	34 / 677	76.8	1.22 [0.76,1.94]	
FIGARO-DKD	18 / 252	8 / 251	23.2	2.34 [1.00,5.48]	
Total	59 / 930	42 / 928		1.43 [0.95,2.15]	Z=1.72, p=0.0853
Heterogeneity:	Q=1.73 (df=1)	p=0.1882	I^2=42.2%		
Others					
FIDELIO-DKD	5 / 176	1 / 161	50.6	4.68 [0.54,40.48]	
FIGARO-DKD	5 / 52	1 / 45	49.4	4.68 [0.53,41.66]	
Total	10 / 228	2 / 206		4.68 [1.01,21.73]	Z=1.97, p=0.0489
Heterogeneity:	Q=0.00 (df=1)	p=0.9997	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.28 (df=3)	p=0.3498	I^2=8.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.138.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

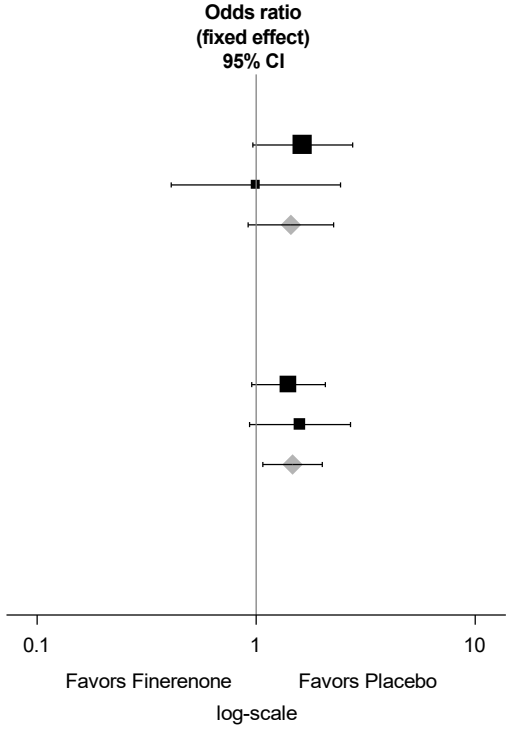
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	68 / 1797	49 / 1870	69.1	1.46 [1.01,2.12]	
FIGARO-DKD	32 / 917	21 / 933	30.9	1.57 [0.90,2.74]	
Total	100 / 2714	70 / 2803		1.49 [1.10,2.04]	Z=2.54, p=0.0111
Heterogeneity:	Q=0.04 (df=1)	p=0.8341	I^2=0.0%		
Female					
FIDELIO-DKD	33 / 820	20 / 740	65.8	1.51 [0.86,2.65]	
FIGARO-DKD	14 / 440	12 / 423	34.2	1.13 [0.51,2.46]	
Total	47 / 1260	32 / 1163		1.37 [0.87,2.16]	Z=1.34, p=0.1794
Heterogeneity:	Q=0.36 (df=1)	p=0.5512	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.10 (df=1)	p=0.7518	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.138.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

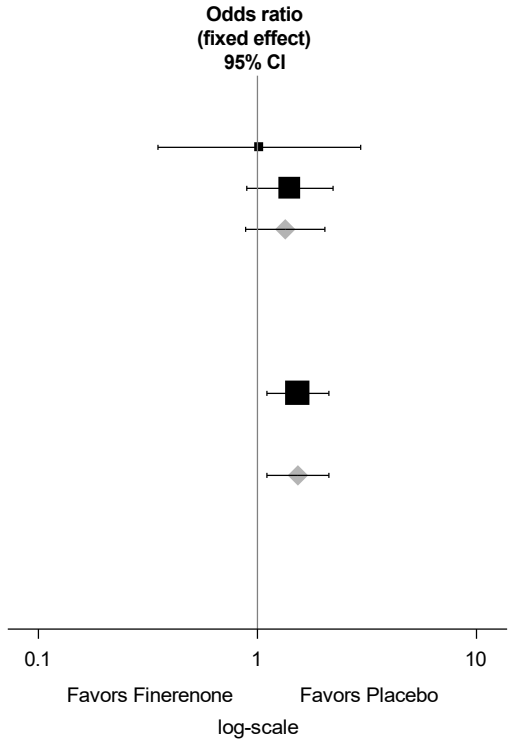
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	38 / 1103	23 / 1075	74.2	1.63 [0.97,2.76]	
FIGARO-DKD	10 / 336	10 / 335	25.8	1.00 [0.41,2.43]	
Total	48 / 1439	33 / 1410		1.44 [0.92,2.26]	Z=1.59, p=0.1116
Heterogeneity:	Q=0.87 (df=1)	p=0.3497	I^2=0.0%		
>= 65					
FIDELIO-DKD	63 / 1514	46 / 1535	65.3	1.41 [0.95,2.07]	
FIGARO-DKD	36 / 1021	23 / 1021	34.7	1.59 [0.93,2.70]	
Total	99 / 2535	69 / 2556		1.47 [1.07,2.00]	Z=2.40, p=0.0164
Heterogeneity:	Q=0.13 (df=1)	p=0.7184	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9494	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.138.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

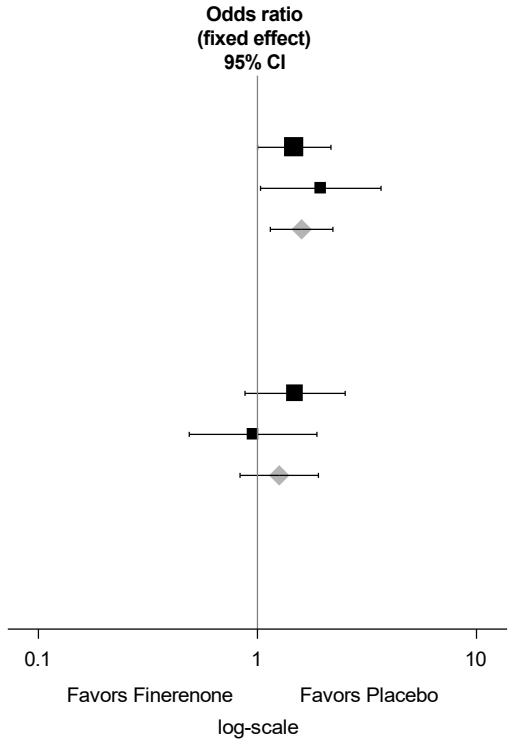
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	7 / 213	15.3	1.02 [0.35,2.96]	
FIGARO-DKD	46 / 1357	33 / 1356	84.7	1.41 [0.89,2.21]	
Total	53 / 1566	40 / 1569		1.34 [0.88,2.03]	Z=1.37, p=0.1691
Heterogeneity:	Q=0.30 (df=1)	p=0.5862	I^2=0.0%		
Very High					
FIDELIO-DKD	94 / 2408	62 / 2397	100.0	1.53 [1.10,2.12]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	94 / 2408	62 / 2397		1.53 [1.10,2.12]	Z=2.56, p=0.0105
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6223	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.138.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pruritus (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

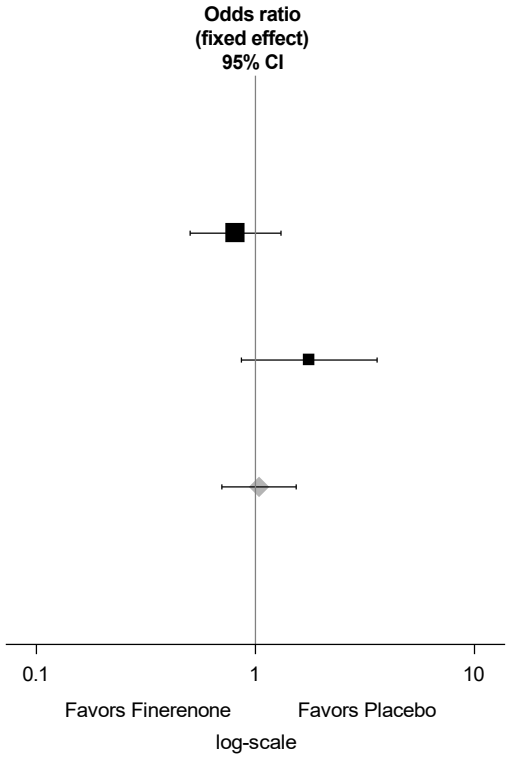
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	66 / 1556	45 / 1541	73.0	1.47 [1.00,2.17]	
FIGARO-DKD	29 / 637	15 / 627	27.0	1.95 [1.03,3.67]	
Total	95 / 2193	60 / 2168		1.59 [1.15,2.21]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.54 (df=1)	p=0.4611	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	24 / 1069	61.9	1.49 [0.88,2.51]	
FIGARO-DKD	17 / 720	18 / 729	38.1	0.96 [0.49,1.87]	
Total	52 / 1781	42 / 1798		1.26 [0.83,1.90]	Z=1.09, p=0.2762
Heterogeneity:	Q=1.03 (df=1)	p=0.3103	I^2=2.8%		
Subgroup Heterogeneity:	Q=0.77 (df=1)	p=0.3815	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.139: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Rash (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

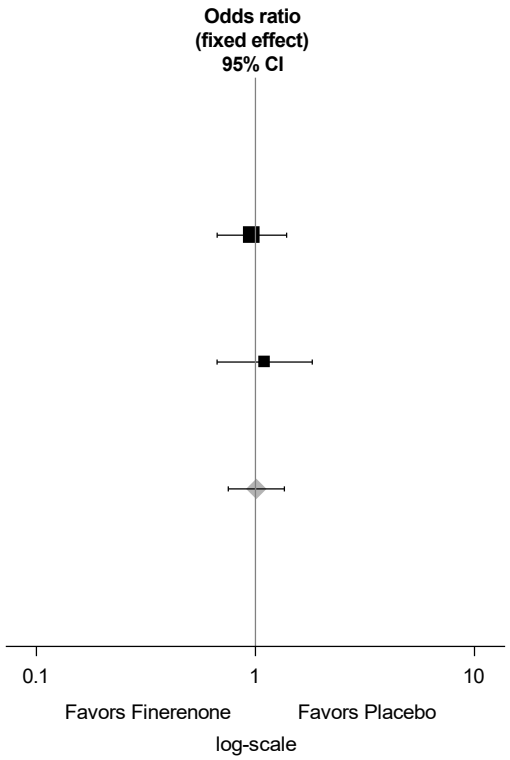
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	38 / 2610	69.1	0.81 [0.50,1.31]	
FIGARO-DKD	21 / 1357	12 / 1356	30.9	1.76 [0.86,3.59]	
Total	52 / 3974	50 / 3966		1.04 [0.70,1.53]	Z=0.19, p=0.8502
Heterogeneity:	Q=3.13 (df=1)	p=0.0769	I^2=68.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.140: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Skin ulcer (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

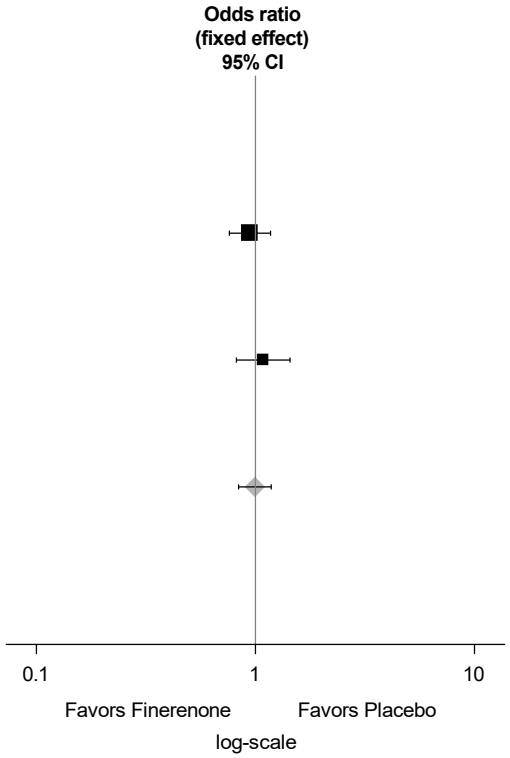
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	58 / 2617	60 / 2610	65.3	0.96 [0.67,1.39]	
FIGARO-DKD	33 / 1357	30 / 1356	34.7	1.10 [0.67,1.82]	
Total	91 / 3974	90 / 3966		1.01 [0.75,1.36]	Z=0.06, p=0.9509
Heterogeneity:	Q=0.18 (df=1)	p=0.6709	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.141: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

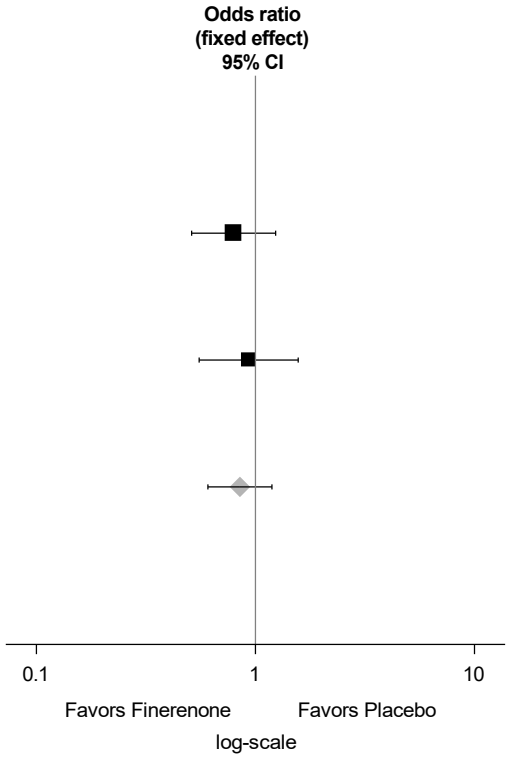
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	172 / 2617	181 / 2610	63.0	0.94 [0.76,1.17]	
FIGARO-DKD	109 / 1357	101 / 1356	37.0	1.09 [0.82,1.44]	
Total	281 / 3974	282 / 3966		0.99 [0.84,1.18]	Z=-0.07, p=0.9460
Heterogeneity:	Q=0.59 (df=1)	p=0.4417	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.142: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Cataract operation (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

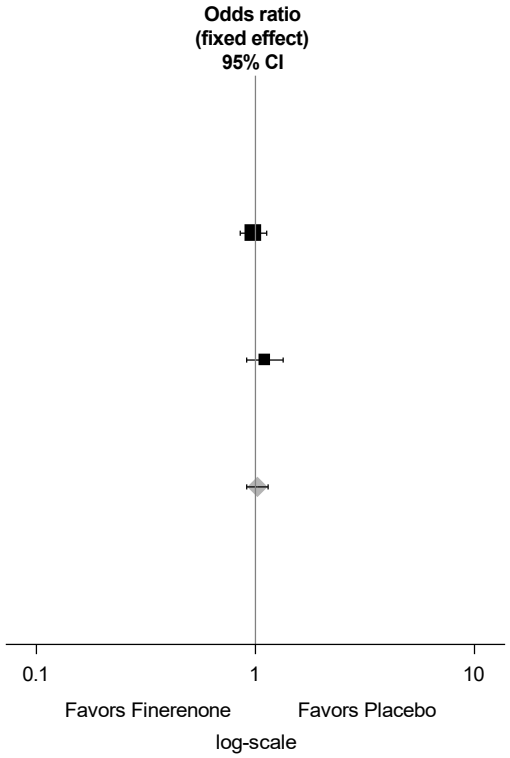
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	45 / 2610	58.1	0.80 [0.51,1.24]	
FIGARO-DKD	28 / 1357	30 / 1356	41.9	0.93 [0.55,1.57]	
Total	64 / 3974	75 / 3966		0.85 [0.61,1.19]	Z=-0.95, p=0.3413
Heterogeneity:	Q=0.21 (df=1)	p=0.6499	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.143: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

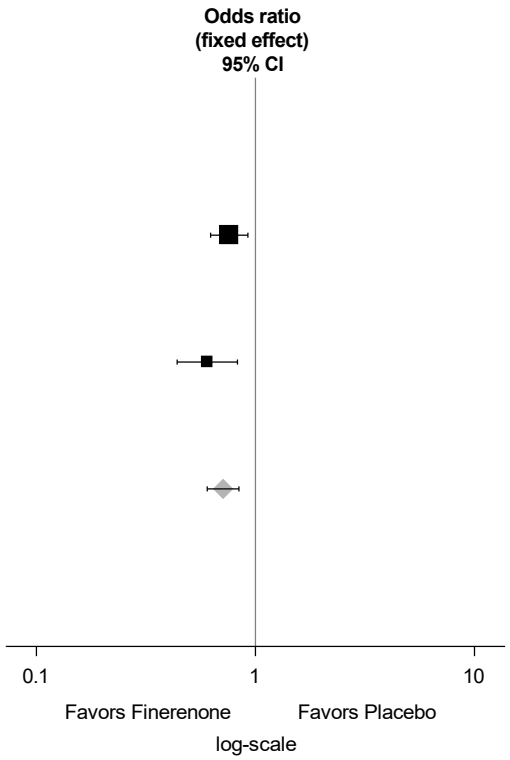
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	485 / 2617	492 / 2610	65.5	0.98 [0.85,1.13]	
FIGARO-DKD	269 / 1357	248 / 1356	34.5	1.10 [0.91,1.34]	
Total	754 / 3974	740 / 3966		1.02 [0.91,1.14]	Z=0.36, p=0.7196
Heterogeneity:	Q=0.99 (df=1)	p=0.3191	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.144: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

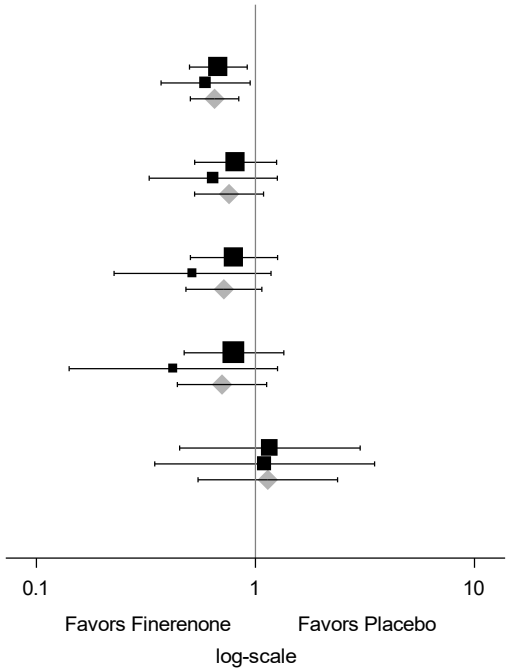
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	194 / 2617	249 / 2610	72.3	0.76 [0.62,0.92]	
FIGARO-DKD	66 / 1357	106 / 1356	27.7	0.60 [0.44,0.83]	
Total	260 / 3974	355 / 3966		0.71 [0.60,0.84]	Z=-4.00, p=<.0001
Heterogeneity:	Q=1.47 (df=1)	p=0.2254	I^2=32.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.144.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

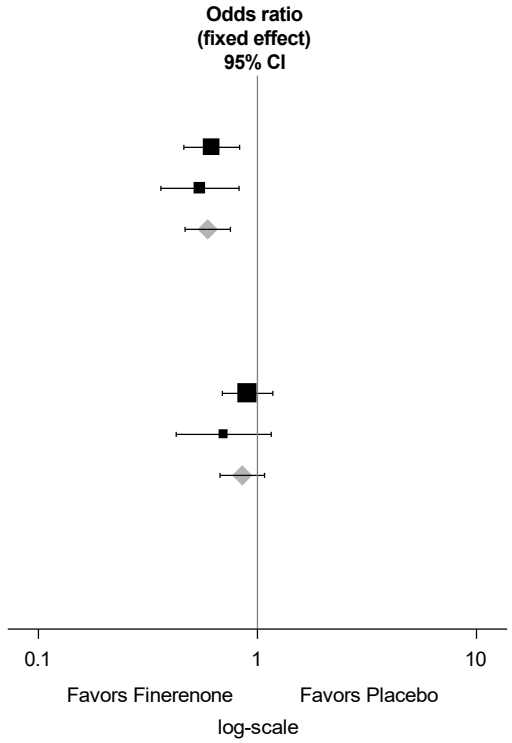
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	78 / 1075	110 / 1062	70.4	0.68 [0.50,0.92]	
FIGARO-DKD	30 / 638	49 / 637	29.6	0.59 [0.37,0.95]	
Total	108 / 1713	159 / 1699		0.65 [0.50,0.84]	Z=-3.31, p=0.0009
Heterogeneity:	Q=0.22 (df=1)	p=0.6376	I^2=0.0%		
North America					
FIDELIO-DKD	42 / 424	52 / 436	71.0	0.81 [0.53,1.25]	
FIGARO-DKD	15 / 267	23 / 271	29.0	0.64 [0.33,1.26]	
Total	57 / 691	75 / 707		0.76 [0.53,1.09]	Z=-1.50, p=0.1336
Heterogeneity:	Q=0.33 (df=1)	p=0.5644	I^2=0.0%		
Asia					
FIDELIO-DKD	35 / 751	43 / 745	76.4	0.80 [0.50,1.26]	
FIGARO-DKD	9 / 289	17 / 290	23.6	0.52 [0.23,1.18]	
Total	44 / 1040	60 / 1035		0.72 [0.48,1.07]	Z=-1.63, p=0.1030
Heterogeneity:	Q=0.82 (df=1)	p=0.3654	I^2=0.0%		
Latin America					
FIDELIO-DKD	29 / 273	35 / 270	81.4	0.80 [0.47,1.35]	
FIGARO-DKD	5 / 102	11 / 101	18.6	0.42 [0.14,1.26]	
Total	34 / 375	46 / 371		0.70 [0.44,1.13]	Z=-1.47, p=0.1421
Heterogeneity:	Q=1.06 (df=1)	p=0.3031	I^2=5.7%		
Others					
FIDELIO-DKD	10 / 94	9 / 97	59.7	1.16 [0.45,3.01]	
FIGARO-DKD	7 / 61	6 / 57	40.3	1.10 [0.35,3.50]	
Total	17 / 155	15 / 154		1.14 [0.55,2.37]	Z=0.35, p=0.7287
Heterogeneity:	Q=0.01 (df=1)	p=0.9426	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.17 (df=4)	p=0.7037	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.144.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

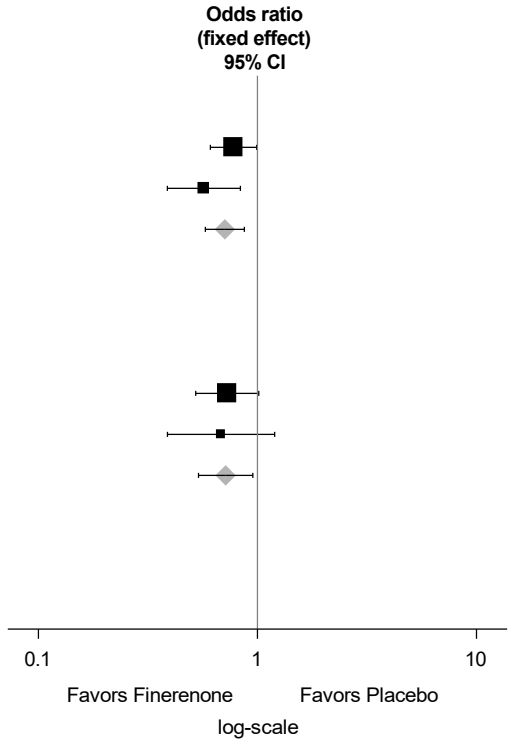
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	80 / 1213	124 / 1210	66.3	0.62 [0.46,0.83]	
FIGARO-DKD	38 / 862	66 / 848	33.7	0.55 [0.36,0.82]	
Total	118 / 2075	190 / 2058		0.59 [0.47,0.75]	Z=-4.30, p=<.0001
Heterogeneity:	Q=0.23 (df=1)	p=0.6308	I^2=0.0%		
Absent					
FIDELIO-DKD	114 / 1404	125 / 1400	78.0	0.90 [0.69,1.18]	
FIGARO-DKD	28 / 495	40 / 508	22.0	0.70 [0.43,1.16]	
Total	142 / 1899	165 / 1908		0.85 [0.67,1.08]	Z=-1.34, p=0.1814
Heterogeneity:	Q=0.75 (df=1)	p=0.3851	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.54 (df=1)	p=0.0332	I^2=78.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.144.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

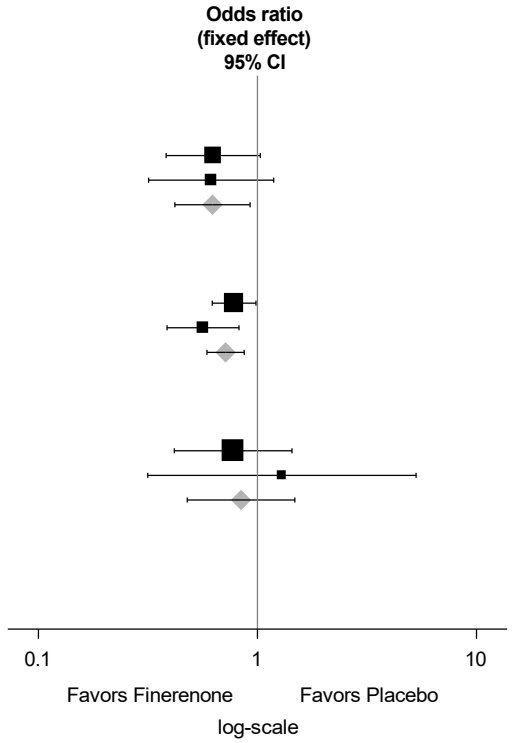
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	128 / 1735	158 / 1700	71.3	0.78 [0.61,0.99]	
FIGARO-DKD	44 / 924	75 / 929	28.7	0.57 [0.39,0.84]	
Total	172 / 2659	233 / 2629		0.71 [0.58,0.87]	Z=-3.28, p=0.0010
Heterogeneity:	Q=1.80 (df=1)	p=0.1793	I^2=44.6%		
> 4.5					
FIDELIO-DKD	66 / 882	91 / 910	74.3	0.73 [0.52,1.01]	
FIGARO-DKD	22 / 433	31 / 426	25.7	0.68 [0.39,1.20]	
Total	88 / 1315	122 / 1336		0.72 [0.54,0.95]	Z=-2.29, p=0.0218
Heterogeneity:	Q=0.04 (df=1)	p=0.8452	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9622	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.144.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

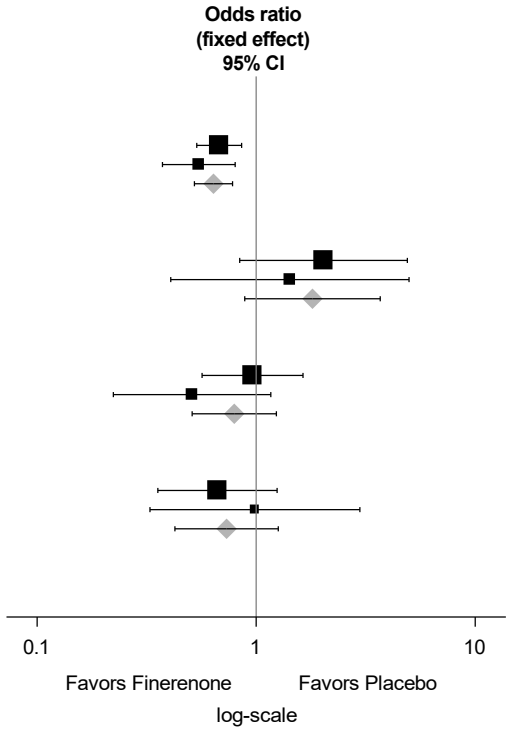
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	27 / 724	42 / 723	63.8	0.63 [0.38,1.03]	
FIGARO-DKD	15 / 494	24 / 495	36.2	0.61 [0.32,1.19]	
Total	42 / 1218	66 / 1218		0.62 [0.42,0.93]	Z=-2.34, p=0.0191
Heterogeneity:	Q=0.00 (df=1)	p=0.9586	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	144 / 1759	180 / 1760	73.0	0.78 [0.62,0.98]	
FIGARO-DKD	46 / 829	78 / 827	27.0	0.56 [0.39,0.82]	
Total	190 / 2588	258 / 2587		0.72 [0.59,0.87]	Z=-3.35, p=0.0008
Heterogeneity:	Q=2.11 (df=1)	p=0.1468	I^2=52.5%		
>= 160					
FIDELIO-DKD	23 / 133	27 / 127	83.9	0.77 [0.42,1.44]	
FIGARO-DKD	5 / 34	4 / 34	16.1	1.29 [0.32,5.30]	
Total	28 / 167	31 / 161		0.84 [0.48,1.48]	Z=-0.60, p=0.5498
Heterogeneity:	Q=0.43 (df=1)	p=0.5141	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.77 (df=2)	p=0.6807	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.144.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

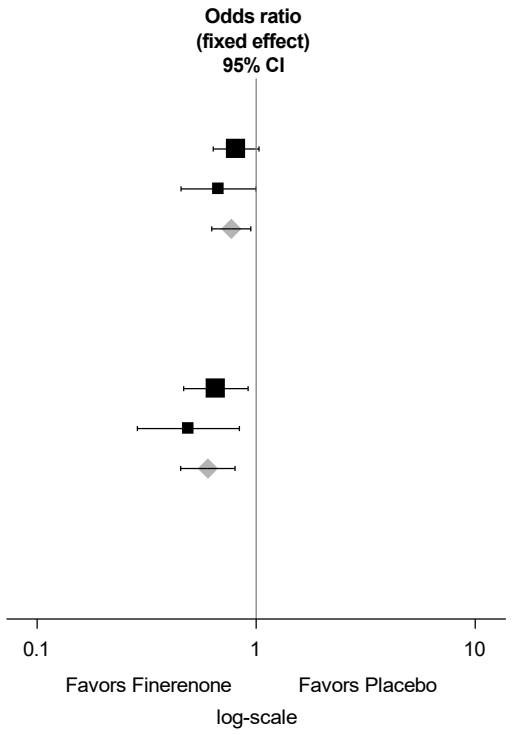
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	129 / 1634	186 / 1657	72.4	0.68 [0.54,0.86]	
FIGARO-DKD	44 / 1010	76 / 989	27.6	0.55 [0.37,0.80]	
Total	173 / 2644	262 / 2646		0.64 [0.52,0.78]	Z=-4.39, p=<.0001
Heterogeneity:	Q=0.87 (df=1)	p=0.3498	I^2=0.0%		
Black					
FIDELIO-DKD	17 / 129	8 / 115	66.9	2.03 [0.84,4.90]	
FIGARO-DKD	5 / 43	6 / 71	33.1	1.43 [0.41,4.99]	
Total	22 / 172	14 / 186		1.81 [0.89,3.68]	Z=1.63, p=0.1033
Heterogeneity:	Q=0.20 (df=1)	p=0.6508	I^2=0.0%		
Asian					
FIDELIO-DKD	28 / 678	29 / 677	70.9	0.96 [0.57,1.64]	
FIGARO-DKD	9 / 252	17 / 251	29.1	0.51 [0.22,1.17]	
Total	37 / 930	46 / 928		0.79 [0.51,1.24]	Z=-1.02, p=0.3080
Heterogeneity:	Q=1.61 (df=1)	p=0.2050	I^2=37.7%		
Others					
FIDELIO-DKD	20 / 176	26 / 161	75.6	0.67 [0.36,1.25]	
FIGARO-DKD	8 / 52	7 / 45	24.4	0.99 [0.33,2.98]	
Total	28 / 228	33 / 206		0.73 [0.43,1.26]	Z=-1.12, p=0.2620
Heterogeneity:	Q=0.37 (df=1)	p=0.5430	I^2=0.0%		
Subgroup Heterogeneity:	Q=7.95 (df=3)	p=0.0470	I^2=62.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.144.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

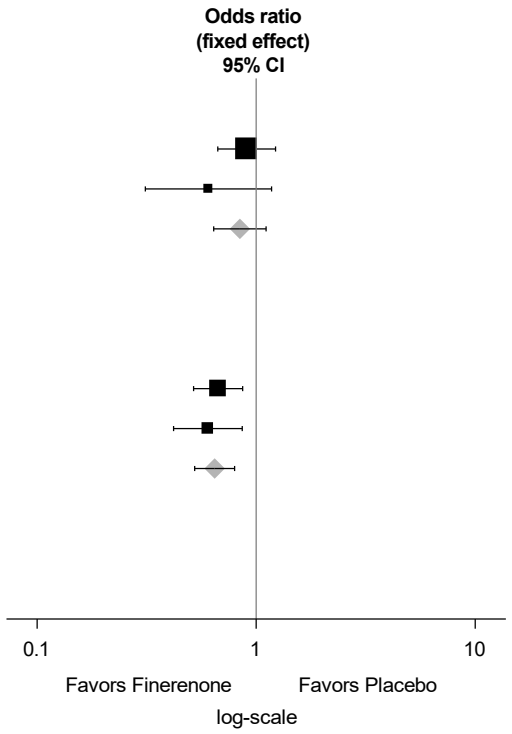
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	129 / 1797	163 / 1870	72.8	0.81 [0.64,1.03]	
FIGARO-DKD	44 / 917	65 / 933	27.2	0.67 [0.45,1.00]	
Total	173 / 2714	228 / 2803		0.77 [0.63,0.95]	Z=-2.50, p=0.0125
Heterogeneity:	Q=0.62 (df=1)	p=0.4319	I^2=0.0%		
Female					
FIDELIO-DKD	65 / 820	86 / 740	71.5	0.65 [0.47,0.92]	
FIGARO-DKD	22 / 440	41 / 423	28.5	0.49 [0.29,0.84]	
Total	87 / 1260	127 / 1163		0.60 [0.45,0.80]	Z=-3.48, p=0.0005
Heterogeneity:	Q=0.80 (df=1)	p=0.3717	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.88 (df=1)	p=0.1701	I^2=46.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.144.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

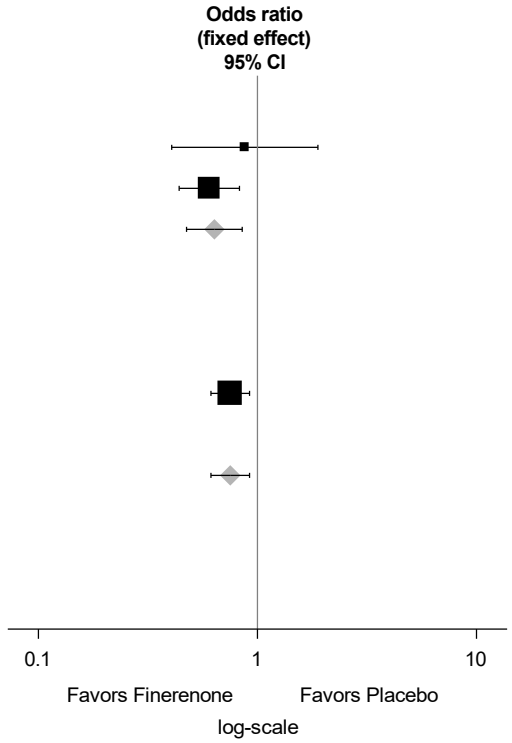
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	88 / 1103	94 / 1075	82.7	0.90 [0.67,1.23]	
FIGARO-DKD	15 / 336	24 / 335	17.3	0.61 [0.31,1.18]	
Total	103 / 1439	118 / 1410		0.84 [0.64,1.11]	Z=-1.22, p=0.2231
Heterogeneity:	Q=1.16 (df=1)	p=0.2808	I^2=14.0%		
>= 65					
FIDELIO-DKD	106 / 1514	155 / 1535	66.2	0.67 [0.52,0.87]	
FIGARO-DKD	51 / 1021	82 / 1021	33.8	0.60 [0.42,0.86]	
Total	157 / 2535	237 / 2556		0.65 [0.52,0.80]	Z=-4.08, p=<.0001
Heterogeneity:	Q=0.22 (df=1)	p=0.6354	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.26 (df=1)	p=0.1329	I^2=55.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.144.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

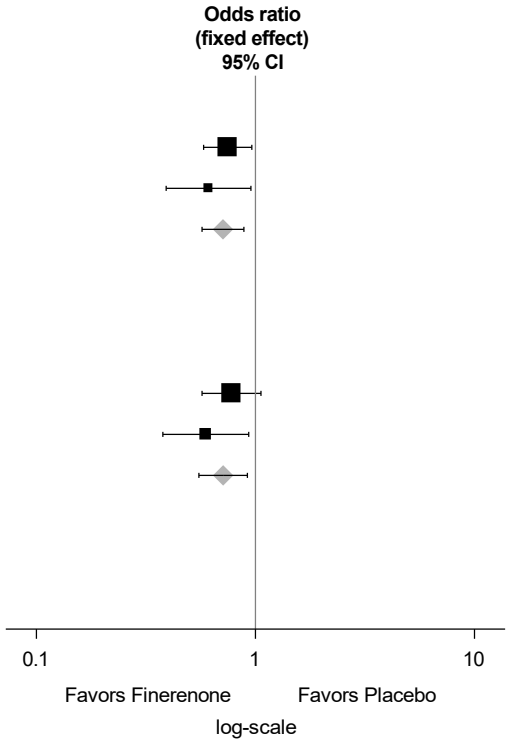
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	13 / 209	15 / 213	14.5	0.88 [0.41,1.89]	
FIGARO-DKD	66 / 1357	106 / 1356	85.5	0.60 [0.44,0.83]	
Total	79 / 1566	121 / 1569		0.64 [0.47,0.85]	Z=-3.03, p=0.0024
Heterogeneity:	Q=0.77 (df=1)	p=0.3790	I^2=0.0%		
Very High					
FIDELIO-DKD	181 / 2408	234 / 2397	100.0	0.75 [0.61,0.92]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	181 / 2408	234 / 2397		0.75 [0.61,0.92]	Z=-2.76, p=0.0057
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.84 (df=1)	p=0.3584	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.144.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypertension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

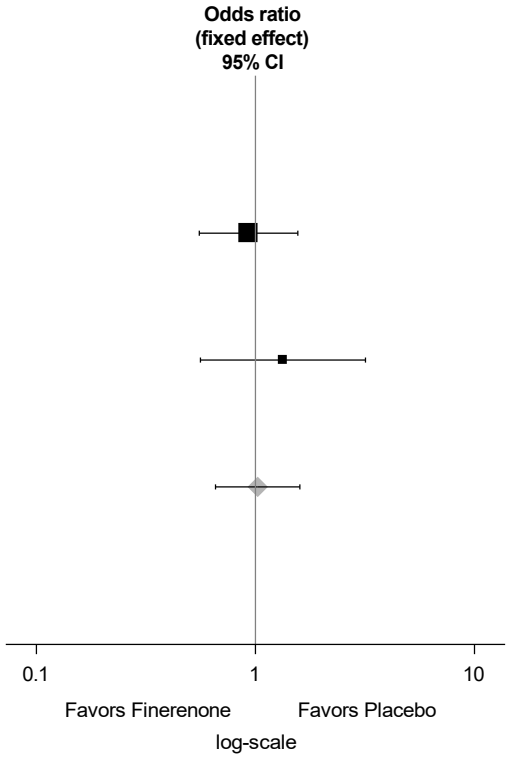
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	116 / 1556	150 / 1541	75.6	0.75 [0.58,0.96]	
FIGARO-DKD	34 / 637	53 / 627	24.4	0.61 [0.39,0.95]	
Total	150 / 2193	203 / 2168		0.71 [0.57,0.89]	Z=-3.04, p=0.0023
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	78 / 1061	99 / 1069	68.0	0.78 [0.57,1.06]	
FIGARO-DKD	32 / 720	53 / 729	32.0	0.59 [0.38,0.93]	
Total	110 / 1781	152 / 1798		0.71 [0.55,0.92]	Z=-2.61, p=0.0090
Heterogeneity:	Q=0.94 (df=1)	p=0.3329	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9914	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.145: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypertensive crisis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

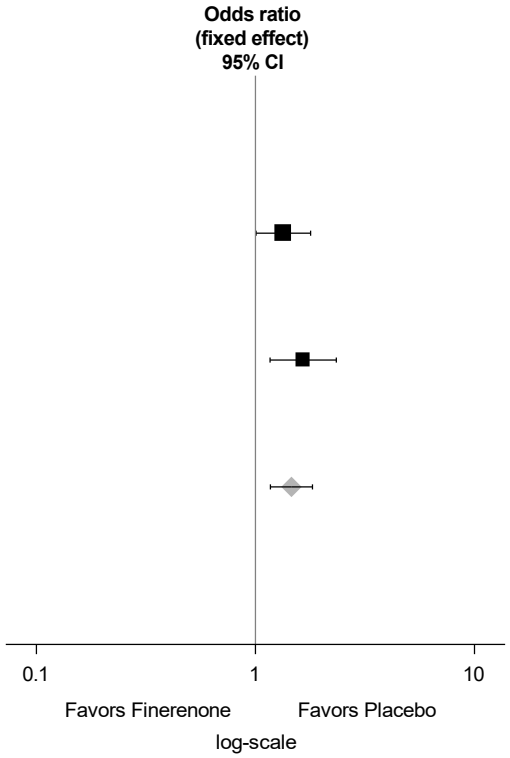
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	28 / 2617	30 / 2610	73.7	0.93 [0.55,1.56]	
FIGARO-DKD	12 / 1357	9 / 1356	26.3	1.34 [0.56,3.18]	
Total	40 / 3974	39 / 3966		1.02 [0.66,1.59]	Z=0.10, p=0.9176
Heterogeneity:	Q=0.49 (df=1)	p=0.4830	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.146: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

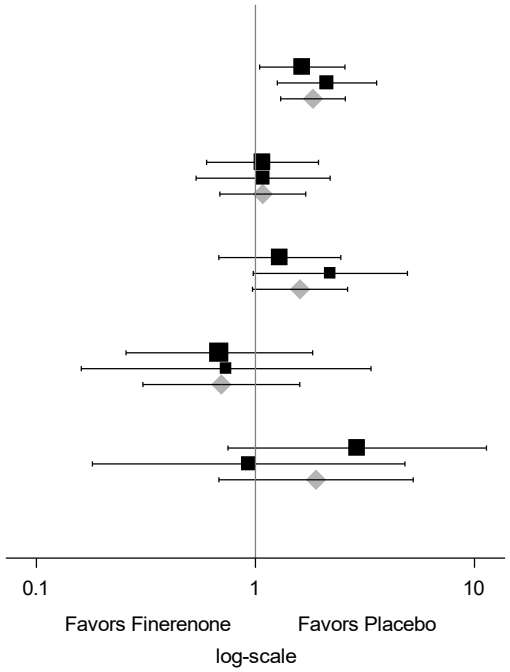
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	113 / 2617	85 / 2610	59.6	1.34 [1.01,1.79]	
FIGARO-DKD	87 / 1357	54 / 1356	40.4	1.65 [1.17,2.34]	
Total	200 / 3974	139 / 3966		1.46 [1.17,1.82]	Z=3.35, p=0.0008
Heterogeneity:	Q=0.82 (df=1)	p=0.3645	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.146.1: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Region - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

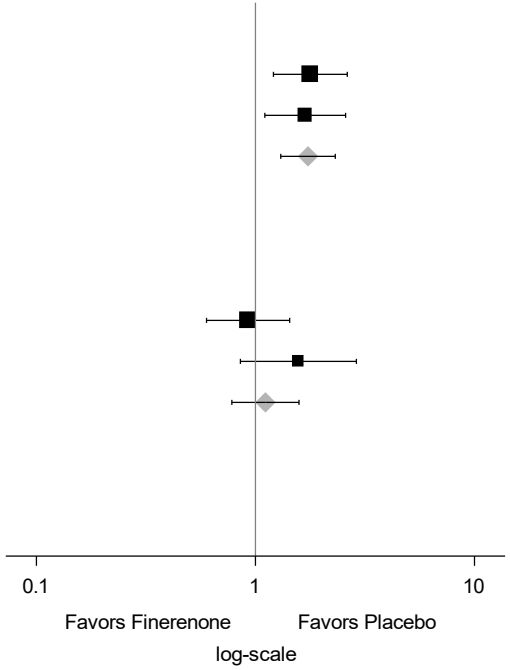
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	52 / 1075	32 / 1062	57.5	1.64 [1.04,2.56]	
FIGARO-DKD	45 / 638	22 / 637	42.5	2.12 [1.26,3.58]	
Total	97 / 1713	54 / 1699		1.83 [1.30,2.57]	Z=3.49, p=0.0005
Heterogeneity:	Q=0.55 (df=1)	p=0.4597	I^2=0.0%		
North America					
FIDELIO-DKD	24 / 424	23 / 436	58.9	1.08 [0.60,1.94]	
FIGARO-DKD	17 / 267	16 / 271	41.1	1.08 [0.54,2.19]	
Total	41 / 691	39 / 707		1.08 [0.69,1.70]	Z=0.33, p=0.7383
Heterogeneity:	Q=0.00 (df=1)	p=0.9900	I^2=0.0%		
Asia					
FIDELIO-DKD	22 / 751	17 / 745	61.5	1.29 [0.68,2.45]	
FIGARO-DKD	19 / 289	9 / 290	38.5	2.20 [0.98,4.94]	
Total	41 / 1040	26 / 1035		1.60 [0.97,2.63]	Z=1.84, p=0.0662
Heterogeneity:	Q=1.01 (df=1)	p=0.3140	I^2=1.4%		
Latin America					
FIDELIO-DKD	7 / 273	10 / 270	70.7	0.68 [0.26,1.82]	
FIGARO-DKD	3 / 102	4 / 101	29.3	0.73 [0.16,3.37]	
Total	10 / 375	14 / 371		0.70 [0.31,1.59]	Z=-0.85, p=0.3939
Heterogeneity:	Q=0.01 (df=1)	p=0.9384	I^2=0.0%		
Others					
FIDELIO-DKD	8 / 94	3 / 97	59.4	2.91 [0.75,11.34]	
FIGARO-DKD	3 / 61	3 / 57	40.6	0.93 [0.18,4.81]	
Total	11 / 155	6 / 154		1.89 [0.68,5.25]	Z=1.22, p=0.2215
Heterogeneity:	Q=1.10 (df=1)	p=0.2933	I^2=9.4%		
Subgroup Heterogeneity:	Q=6.86 (df=4)	p=0.1436	I^2=41.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.146.2: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by History of CVD - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

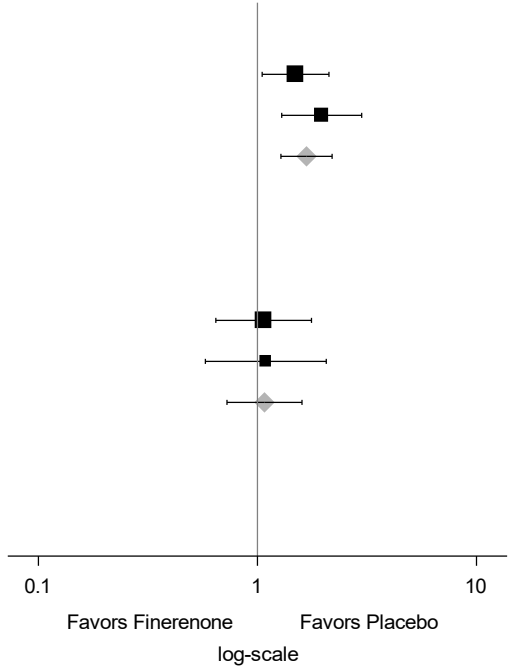
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	73 / 1213	42 / 1210	54.5	1.78 [1.21,2.63]	
FIGARO-DKD	60 / 862	36 / 848	45.5	1.69 [1.10,2.58]	
Total	133 / 2075	78 / 2058		1.74 [1.30,2.31]	Z=3.78, p=0.0002
Heterogeneity:	Q=0.03 (df=1)	p=0.8545	I^2=0.0%		
Absent					
FIDELIO-DKD	40 / 1404	43 / 1400	66.1	0.93 [0.60,1.43]	
FIGARO-DKD	27 / 495	18 / 508	33.9	1.57 [0.85,2.89]	
Total	67 / 1899	61 / 1908		1.11 [0.78,1.58]	Z=0.58, p=0.5609
Heterogeneity:	Q=1.91 (df=1)	p=0.1670	I^2=47.6%		
Subgroup Heterogeneity:	Q=3.73 (df=1)	p=0.0535	I^2=73.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.146.3: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

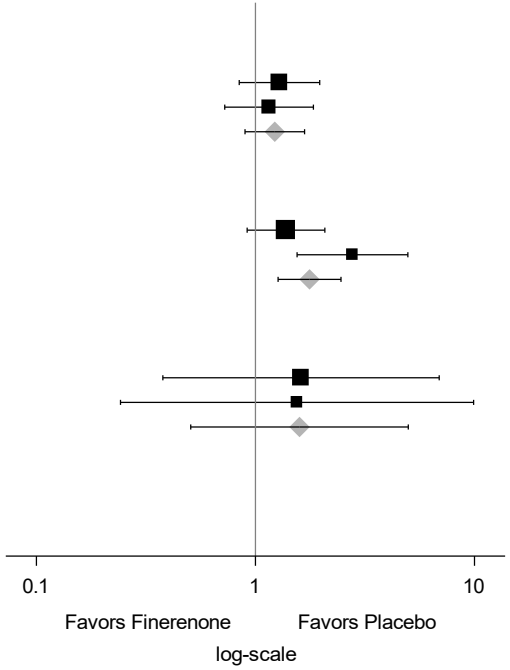
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	81 / 1735	54 / 1700	58.9	1.49 [1.05,2.12]	
FIGARO-DKD	66 / 924	35 / 929	41.1	1.96 [1.29,2.99]	
Total	147 / 2659	89 / 2629		1.67 [1.28,2.19]	Z=3.76, p=0.0002
Heterogeneity:	Q=0.97 (df=1)	p=0.3254	I^2=0.0%		
> 4.5					
FIDELIO-DKD	32 / 882	31 / 910	61.5	1.07 [0.65,1.76]	
FIGARO-DKD	21 / 433	19 / 426	38.5	1.09 [0.58,2.06]	
Total	53 / 1315	50 / 1336		1.08 [0.73,1.60]	Z=0.37, p=0.7130
Heterogeneity:	Q=0.00 (df=1)	p=0.9565	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.29 (df=1)	p=0.0698	I^2=69.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.146.4: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

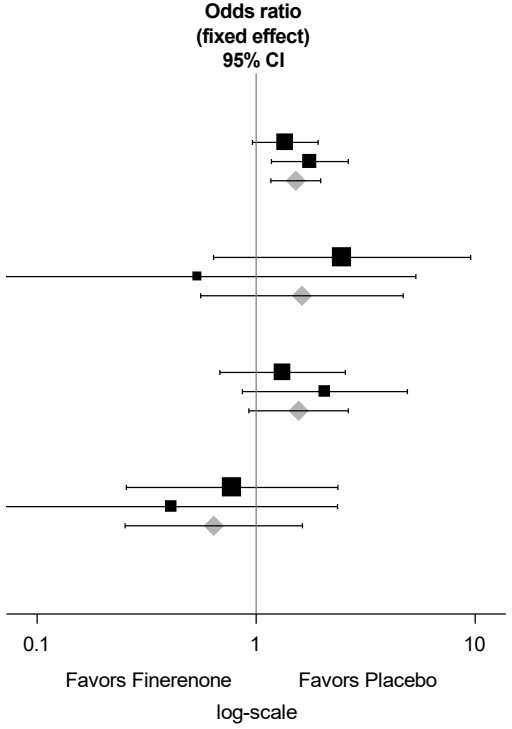
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	52 / 724	41 / 723	54.8	1.29 [0.84,1.96]	
FIGARO-DKD	41 / 494	36 / 495	45.2	1.15 [0.72,1.84]	
Total	93 / 1218	77 / 1218		1.23 [0.90,1.68]	Z=1.27, p=0.2033
Heterogeneity:	Q=0.12 (df=1)	p=0.7338	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	56 / 1759	41 / 1760	67.0	1.38 [0.92,2.07]	
FIGARO-DKD	43 / 829	16 / 827	33.0	2.77 [1.55,4.96]	
Total	99 / 2588	57 / 2587		1.77 [1.27,2.46]	Z=3.37, p=0.0008
Heterogeneity:	Q=3.72 (df=1)	p=0.0538	I^2=73.1%		
>= 160					
FIDELIO-DKD	5 / 133	3 / 127	62.0	1.61 [0.38,6.90]	
FIGARO-DKD	3 / 34	2 / 34	38.0	1.55 [0.24,9.91]	
Total	8 / 167	5 / 161		1.59 [0.51,4.99]	Z=0.79, p=0.4273
Heterogeneity:	Q=0.00 (df=1)	p=0.9722	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.49 (df=2)	p=0.2875	I^2=19.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.146.5: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Race - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

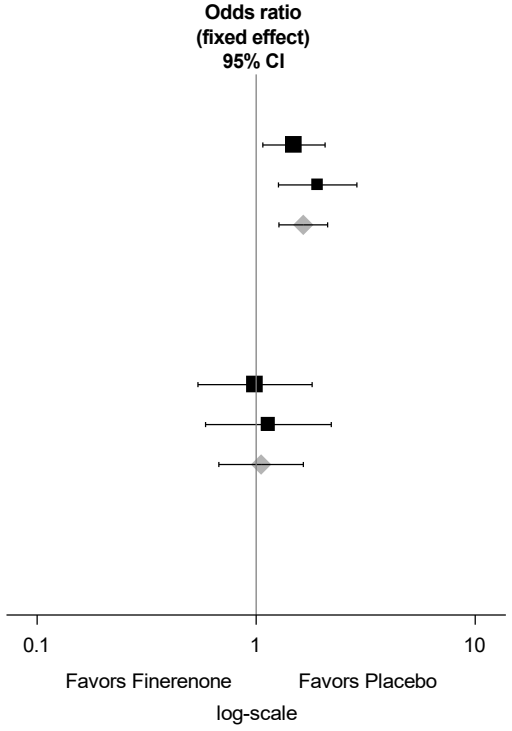
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	78 / 1634	59 / 1657	57.8	1.36 [0.96,1.92]	
FIGARO-DKD	68 / 1010	39 / 989	42.2	1.76 [1.17,2.63]	
Total	146 / 2644	98 / 2646		1.52 [1.17,1.97]	Z=3.12, p=0.0018
Heterogeneity:	Q=0.91 (df=1)	p=0.3401	I^2=0.0%		
Black					
FIDELIO-DKD	8 / 129	3 / 115	74.3	2.47 [0.64,9.54]	
FIGARO-DKD	1 / 43	3 / 71	25.7	0.54 [0.05,5.36]	
Total	9 / 172	6 / 186		1.62 [0.56,4.69]	Z=0.89, p=0.3759
Heterogeneity:	Q=1.25 (df=1)	p=0.2628	I^2=20.3%		
Asian					
FIDELIO-DKD	21 / 678	16 / 677	63.4	1.32 [0.68,2.55]	
FIGARO-DKD	16 / 252	8 / 251	36.6	2.06 [0.87,4.90]	
Total	37 / 930	24 / 928		1.56 [0.93,2.63]	Z=1.67, p=0.0944
Heterogeneity:	Q=0.64 (df=1)	p=0.4239	I^2=0.0%		
Others					
FIDELIO-DKD	6 / 176	7 / 161	71.2	0.78 [0.26,2.36]	
FIGARO-DKD	2 / 52	4 / 45	28.8	0.41 [0.07,2.35]	
Total	8 / 228	11 / 206		0.64 [0.25,1.63]	Z=-0.94, p=0.3488
Heterogeneity:	Q=0.37 (df=1)	p=0.5454	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.18 (df=3)	p=0.3643	I^2=5.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.146.6: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Sex - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

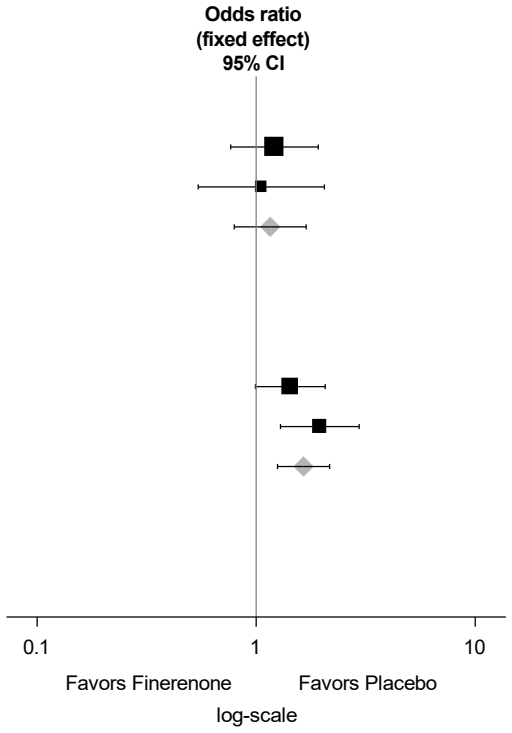
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	90 / 1797	64 / 1870	61.3	1.49 [1.07,2.06]	
FIGARO-DKD	67 / 917	37 / 933	38.7	1.91 [1.26,2.88]	
Total	157 / 2714	101 / 2803		1.64 [1.27,2.12]	Z=3.79, p=0.0001
Heterogeneity:	Q=0.86 (df=1)	p=0.3535	I^2=0.0%		
Female					
FIDELIO-DKD	23 / 820	21 / 740	54.8	0.99 [0.54,1.80]	
FIGARO-DKD	20 / 440	17 / 423	45.2	1.14 [0.59,2.20]	
Total	43 / 1260	38 / 1163		1.05 [0.68,1.64]	Z=0.23, p=0.8196
Heterogeneity:	Q=0.10 (df=1)	p=0.7575	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.87 (df=1)	p=0.0900	I^2=65.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.146.7: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Age Group (years) - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

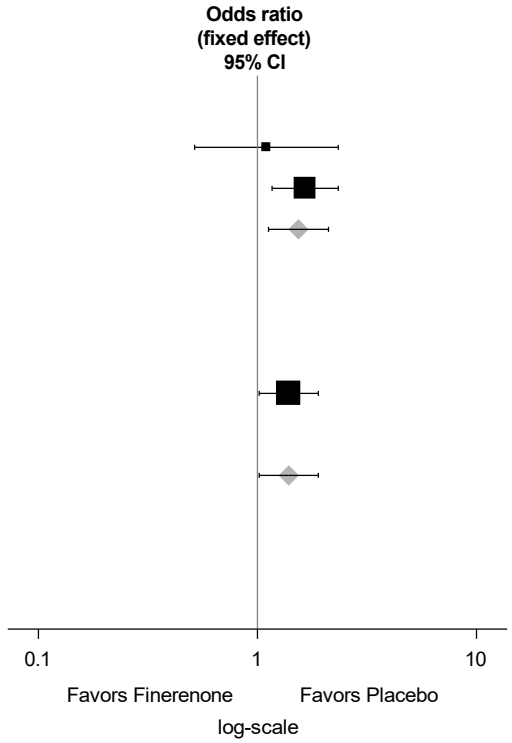
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	42 / 1103	34 / 1075	67.5	1.21 [0.76,1.92]	
FIGARO-DKD	19 / 336	18 / 335	32.5	1.06 [0.54,2.05]	
Total	61 / 1439	52 / 1410		1.16 [0.79,1.69]	Z=0.77, p=0.4442
Heterogeneity:	Q=0.11 (df=1)	p=0.7372	I^2=0.0%		
>= 65					
FIDELIO-DKD	71 / 1514	51 / 1535	56.0	1.43 [0.99,2.07]	
FIGARO-DKD	68 / 1021	36 / 1021	44.0	1.95 [1.29,2.95]	
Total	139 / 2535	87 / 2556		1.65 [1.25,2.16]	Z=3.56, p=0.0004
Heterogeneity:	Q=1.21 (df=1)	p=0.2716	I^2=17.3%		
Subgroup Heterogeneity:	Q=2.17 (df=1)	p=0.1409	I^2=53.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.146.8: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by Type of Albuminuria at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

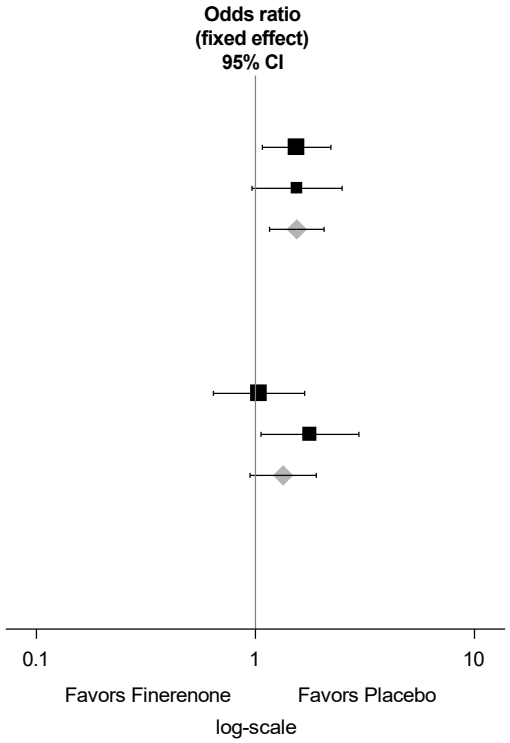
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	15 / 209	14 / 213	17.6	1.10 [0.52,2.34]	
FIGARO-DKD	87 / 1357	54 / 1356	82.4	1.65 [1.17,2.34]	
Total	102 / 1566	68 / 1569		1.54 [1.12,2.11]	Z=2.68, p=0.0073
Heterogeneity:	Q=0.92 (df=1)	p=0.3367	I^2=0.0%		
Very High					
FIDELIO-DKD	98 / 2408	71 / 2397	100.0	1.39 [1.02,1.90]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	98 / 2408	71 / 2397		1.39 [1.02,1.90]	Z=2.08, p=0.0379
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.20 (df=1)	p=0.6507	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.146.9: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hypotension (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

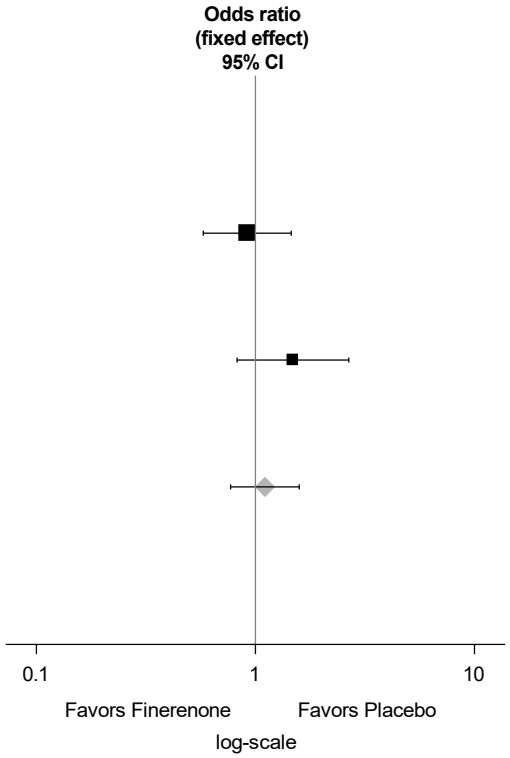
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	78 / 1556	51 / 1541	63.4	1.54 [1.08,2.21]	
FIGARO-DKD	46 / 637	30 / 627	36.6	1.55 [0.96,2.49]	
Total	124 / 2193	81 / 2168		1.54 [1.16,2.06]	Z=2.97, p=0.0030
Heterogeneity:	Q=0.00 (df=1)	p=0.9880	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	35 / 1061	34 / 1069	53.5	1.04 [0.64,1.68]	
FIGARO-DKD	41 / 720	24 / 729	46.5	1.77 [1.06,2.97]	
Total	76 / 1781	58 / 1798		1.34 [0.94,1.90]	Z=1.64, p=0.1012
Heterogeneity:	Q=2.22 (df=1)	p=0.1358	I^2=55.1%		
Subgroup Heterogeneity:	Q=0.39 (df=1)	p=0.5336	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.147: Forest Plot for Odds Ratio of Proportion of Subjects with TEAEs - Peripheral arterial occlusive disease (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

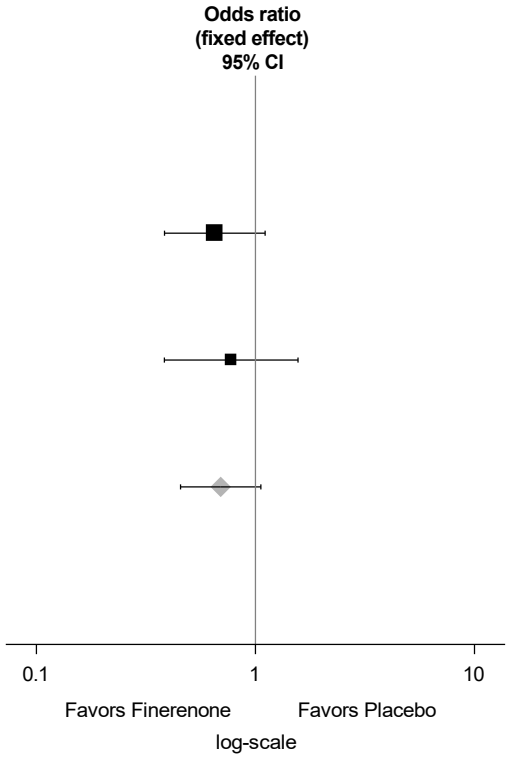
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	35 / 2617	38 / 2610	61.7	0.92 [0.58,1.46]	
FIGARO-DKD	28 / 1357	19 / 1356	38.3	1.48 [0.82,2.67]	
Total	63 / 3974	57 / 3966		1.10 [0.77,1.59]	Z=0.54, p=0.5884
Heterogeneity:	Q=1.58 (df=1)	p=0.2084	I^2=36.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.148: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Blood and lymphatic system disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

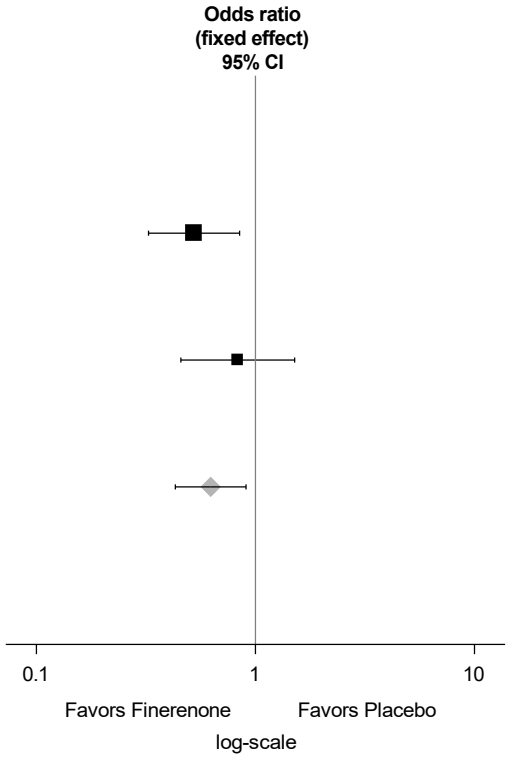
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	23 / 2617	35 / 2610	63.8	0.65 [0.38,1.11]	
FIGARO-DKD	14 / 1357	18 / 1356	36.2	0.77 [0.38,1.56]	
Total	37 / 3974	53 / 3966		0.69 [0.45,1.06]	Z=-1.70, p=0.0898
Heterogeneity:	Q=0.15 (df=1)	p=0.7012	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.149: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

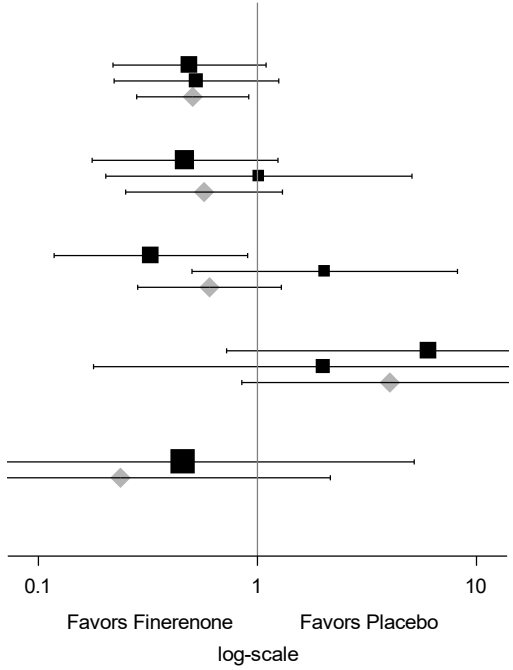
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	49 / 2610	61.0	0.52 [0.32,0.85]	
FIGARO-DKD	20 / 1357	24 / 1356	39.0	0.83 [0.46,1.51]	
Total	46 / 3974	73 / 3966		0.62 [0.43,0.91]	Z=-2.48, p=0.0130
Heterogeneity:	Q=1.38 (df=1)	p=0.2399	I^2=27.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.149.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

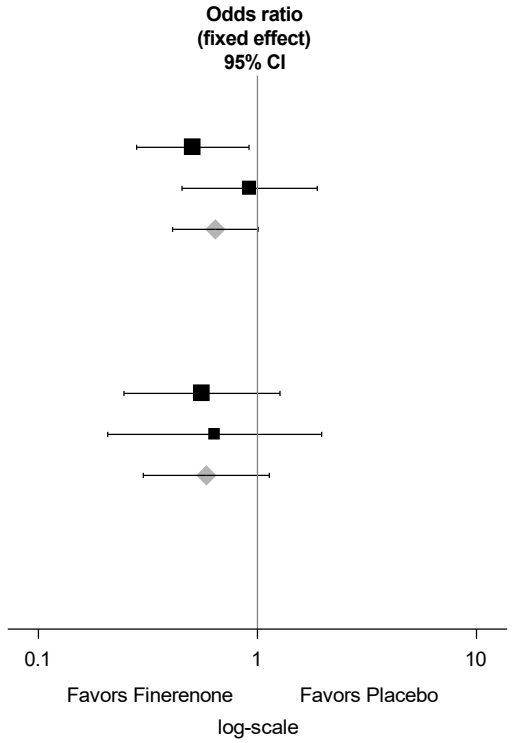
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	9 / 1075	18 / 1062	53.6	0.49 [0.22,1.09]	
FIGARO-DKD	8 / 638	15 / 637	46.4	0.53 [0.22,1.25]	
Total	17 / 1713	33 / 1699		0.51 [0.28,0.91]	Z=-2.26, p=0.0236
Heterogeneity:	Q=0.01 (df=1)	p=0.9041	I^2=0.0%		
North America					
FIDELIO-DKD	6 / 424	13 / 436	73.1	0.47 [0.18,1.24]	
FIGARO-DKD	3 / 267	3 / 271	26.9	1.02 [0.20,5.08]	
Total	9 / 691	16 / 707		0.57 [0.25,1.30]	Z=-1.33, p=0.1820
Heterogeneity:	Q=0.65 (df=1)	p=0.4188	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 751	15 / 745	65.3	0.33 [0.12,0.90]	
FIGARO-DKD	6 / 289	3 / 290	34.7	2.03 [0.50,8.19]	
Total	11 / 1040	18 / 1035		0.60 [0.28,1.29]	Z=-1.31, p=0.1909
Heterogeneity:	Q=4.30 (df=1)	p=0.0380	I^2=76.8%		
Latin America					
FIDELIO-DKD	6 / 273	1 / 270	56.4	6.04 [0.72,50.55]	
FIGARO-DKD	2 / 102	1 / 101	43.6	2.00 [0.18,22.41]	
Total	8 / 375	2 / 371		4.02 [0.85,19.07]	Z=1.75, p=0.0796
Heterogeneity:	Q=0.46 (df=1)	p=0.4965	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	2 / 97	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	1 / 61	2 / 57	100.0	0.46 [0.04,5.20]	
Total	1 / 155	4 / 154		0.24 [0.03,2.15]	Z=-1.28, p=0.2008
Heterogeneity:	Q=0.28 (df=1)	p=0.5943	I^2=0.0%		
Subgroup Heterogeneity:	Q=6.76 (df=4)	p=0.1494	I^2=40.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.149.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

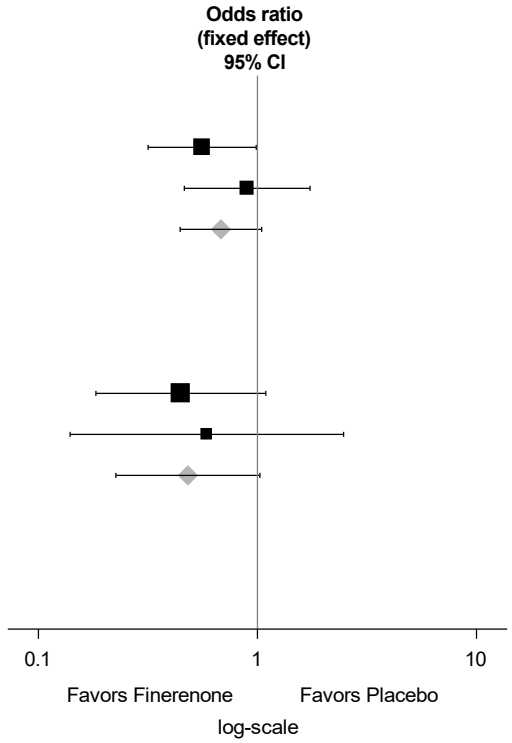
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	17 / 1213	33 / 1210	59.2	0.51 [0.28,0.92]	
FIGARO-DKD	15 / 862	16 / 848	40.8	0.92 [0.45,1.87]	
Total	32 / 2075	49 / 2058		0.64 [0.41,1.01]	Z=-1.93, p=0.0538
Heterogeneity:	Q=1.60 (df=1)	p=0.2055	I^2=37.6%		
Absent					
FIDELIO-DKD	9 / 1404	16 / 1400	65.3	0.56 [0.25,1.27]	
FIGARO-DKD	5 / 495	8 / 508	34.7	0.64 [0.21,1.96]	
Total	14 / 1899	24 / 1908		0.58 [0.30,1.13]	Z=-1.59, p=0.1117
Heterogeneity:	Q=0.04 (df=1)	p=0.8509	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.05 (df=1)	p=0.8162	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.149.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	19 / 1735	33 / 1700	57.5	0.56 [0.32,0.99]	
FIGARO-DKD	17 / 924	19 / 929	42.5	0.90 [0.46,1.74]	
Total	36 / 2659	52 / 2629		0.68 [0.44,1.05]	Z=-1.76, p=0.0790
Heterogeneity:	Q=1.13 (df=1)	p=0.2873	I^2=11.7%		
> 4.5					
FIDELIO-DKD	7 / 882	16 / 910	72.2	0.45 [0.18,1.09]	
FIGARO-DKD	3 / 433	5 / 426	27.8	0.59 [0.14,2.47]	
Total	10 / 1315	21 / 1336		0.48 [0.23,1.03]	Z=-1.89, p=0.0583
Heterogeneity:	Q=0.10 (df=1)	p=0.7517	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4338	I^2=0.0%		

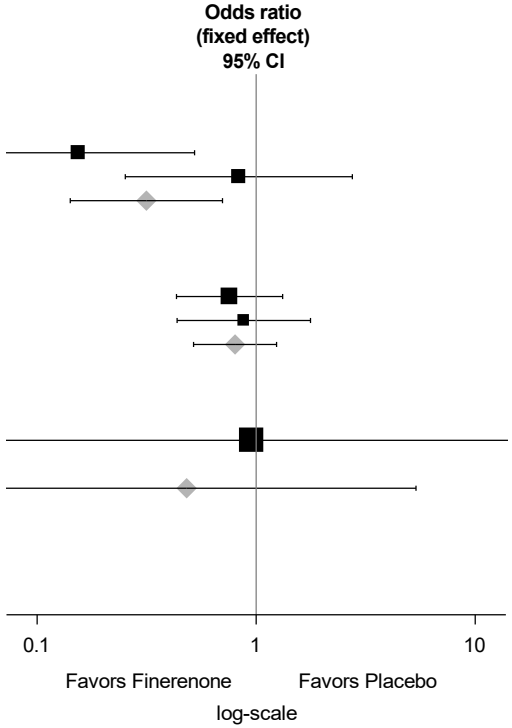


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.149.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Cardiac Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

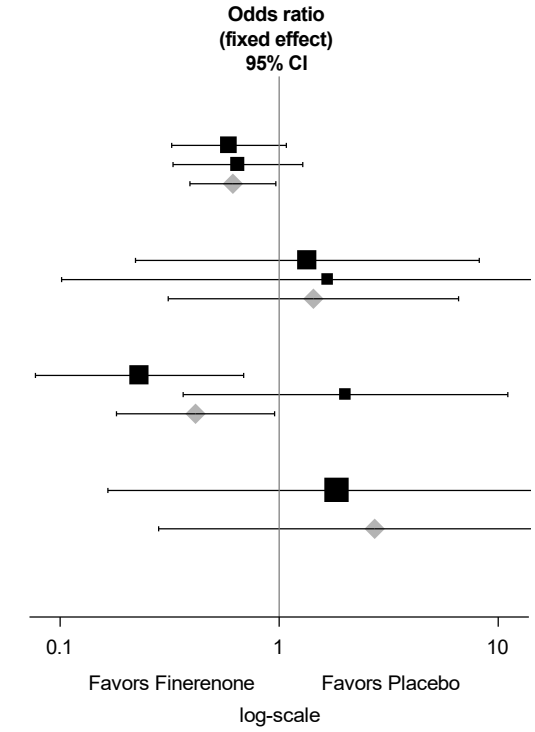
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	3 / 724	19 / 723	48.8	0.15 [0.05,0.52]	
FIGARO-DKD	5 / 494	6 / 495	51.2	0.83 [0.25,2.75]	
Total	8 / 1218	25 / 1218		0.32 [0.14,0.70]	Z=-2.83, p=0.0047
Heterogeneity:	Q=3.86 (df=1)	p=0.0493	I^2=74.1%		
130 - < 160					
FIDELIO-DKD	22 / 1759	29 / 1760	61.2	0.76 [0.43,1.32]	
FIGARO-DKD	15 / 829	17 / 827	38.8	0.88 [0.44,1.77]	
Total	37 / 2588	46 / 2587		0.80 [0.52,1.24]	Z=-1.00, p=0.3189
Heterogeneity:	Q=0.11 (df=1)	p=0.7435	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	1 / 127	100.0	0.95 [0.06,15.43]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,1E297]	
Total	1 / 167	2 / 161		0.48 [0.04,5.37]	Z=-0.59, p=0.5524
Heterogeneity:	Q=0.23 (df=1)	p=0.6297	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.07 (df=2)	p=0.1304	I^2=50.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.149.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

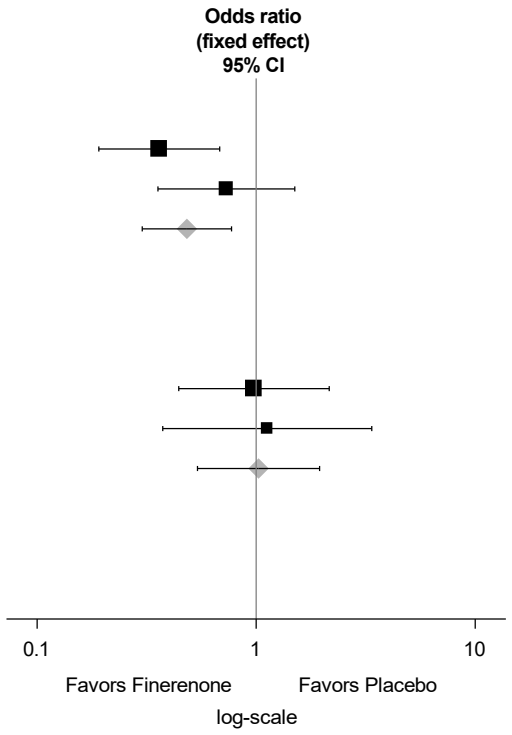
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	17 / 1634	29 / 1657	56.2	0.59 [0.32,1.08]	
FIGARO-DKD	14 / 1010	21 / 989	43.8	0.65 [0.33,1.28]	
Total	31 / 2644	50 / 2646		0.61 [0.39,0.97]	Z=-2.11, p=0.0346
Heterogeneity:	Q=0.04 (df=1)	p=0.8407	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 129	2 / 115	70.6	1.35 [0.22,8.20]	
FIGARO-DKD	1 / 43	1 / 71	29.4	1.67 [0.10,27.36]	
Total	4 / 172	3 / 186		1.43 [0.31,6.59]	Z=0.46, p=0.6440
Heterogeneity:	Q=0.02 (df=1)	p=0.8997	I^2=0.0%		
Asian					
FIDELIO-DKD	4 / 678	17 / 677	70.9	0.23 [0.08,0.69]	
FIGARO-DKD	4 / 252	2 / 251	29.1	2.01 [0.36,11.06]	
Total	8 / 930	19 / 928		0.42 [0.18,0.95]	Z=-2.07, p=0.0381
Heterogeneity:	Q=4.39 (df=1)	p=0.0362	I^2=77.2%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.84 [0.17,20.48]	
FIGARO-DKD	1 / 52	0 / 45	0.0	111E9 [111E9,111E9]	
Total	3 / 228	1 / 206		2.73 [0.28,26.45]	Z=0.87, p=0.3862
Heterogeneity:	Q=0.10 (df=1)	p=0.7481	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.69 (df=3)	p=0.2970	I^2=18.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.149.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

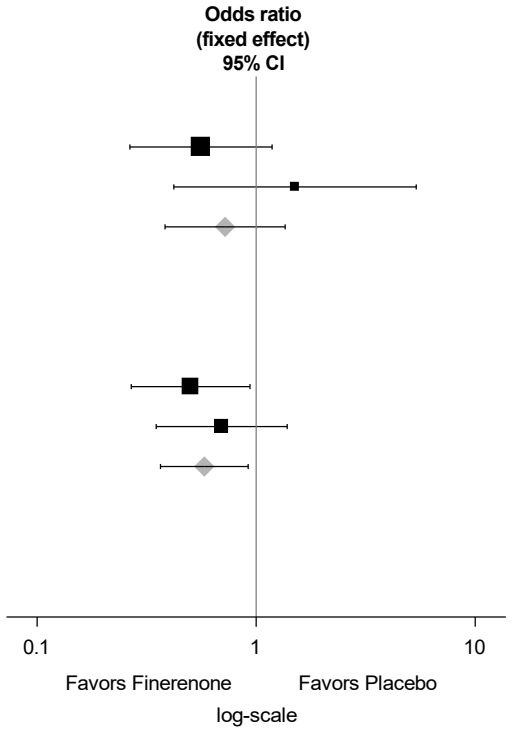
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	13 / 1797	37 / 1870	56.2	0.36 [0.19,0.68]	
FIGARO-DKD	13 / 917	18 / 933	43.8	0.73 [0.36,1.50]	
Total	26 / 2714	55 / 2803		0.48 [0.30,0.77]	Z=-3.04, p=0.0024
Heterogeneity:	Q=2.08 (df=1)	p=0.1490	I^2=52.0%		
Female					
FIDELIO-DKD	13 / 820	12 / 740	65.9	0.98 [0.44,2.16]	
FIGARO-DKD	7 / 440	6 / 423	34.1	1.12 [0.37,3.37]	
Total	20 / 1260	18 / 1163		1.03 [0.54,1.95]	Z=0.08, p=0.9397
Heterogeneity:	Q=0.04 (df=1)	p=0.8400	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.44 (df=1)	p=0.0634	I^2=71.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.149.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

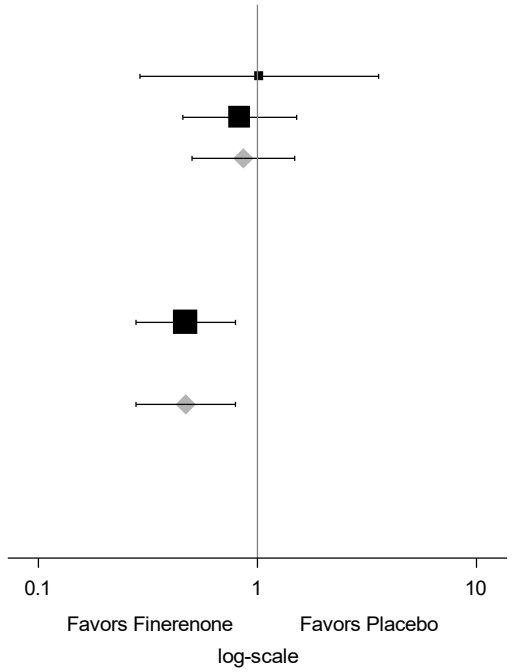
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1103	19 / 1075	74.4	0.56 [0.27,1.18]	
FIGARO-DKD	6 / 336	4 / 335	25.6	1.50 [0.42,5.38]	
Total	17 / 1439	23 / 1410		0.72 [0.38,1.36]	Z=-1.01, p=0.3101
Heterogeneity:	Q=1.72 (df=1)	p=0.1897	I^2=41.9%		
>= 65					
FIDELIO-DKD	15 / 1514	30 / 1535	54.9	0.50 [0.27,0.94]	
FIGARO-DKD	14 / 1021	20 / 1021	45.1	0.70 [0.35,1.39]	
Total	29 / 2535	50 / 2556		0.58 [0.37,0.92]	Z=-2.32, p=0.0204
Heterogeneity:	Q=0.47 (df=1)	p=0.4909	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5841	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.149.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

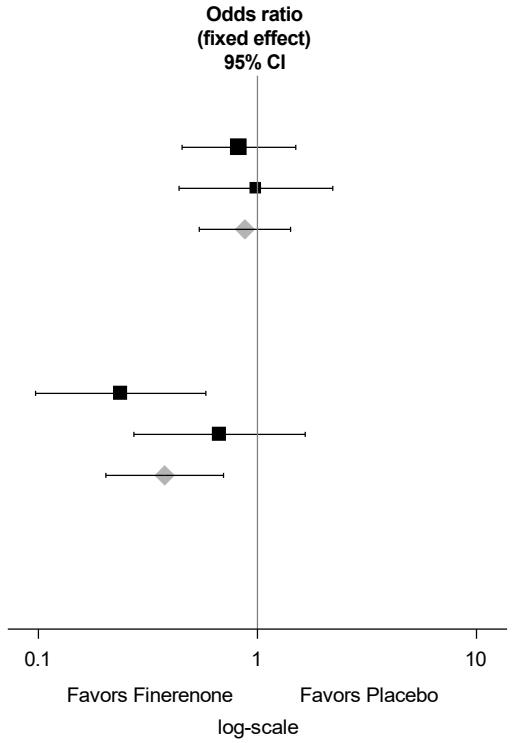
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	5 / 209	5 / 213	18.5	1.02 [0.29,3.57]	
FIGARO-DKD	20 / 1357	24 / 1356	81.5	0.83 [0.46,1.51]	
Total	25 / 1566	29 / 1569		0.86 [0.50,1.48]	Z=-0.54, p=0.5906
Heterogeneity:	Q=0.08 (df=1)	p=0.7720	I^2=0.0%		
Very High					
FIDELIO-DKD	21 / 2408	44 / 2397	100.0	0.47 [0.28,0.79]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	21 / 2408	44 / 2397		0.47 [0.28,0.79]	Z=-2.83, p=0.0047
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.50 (df=1)	p=0.1140	I^2=60.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.149.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

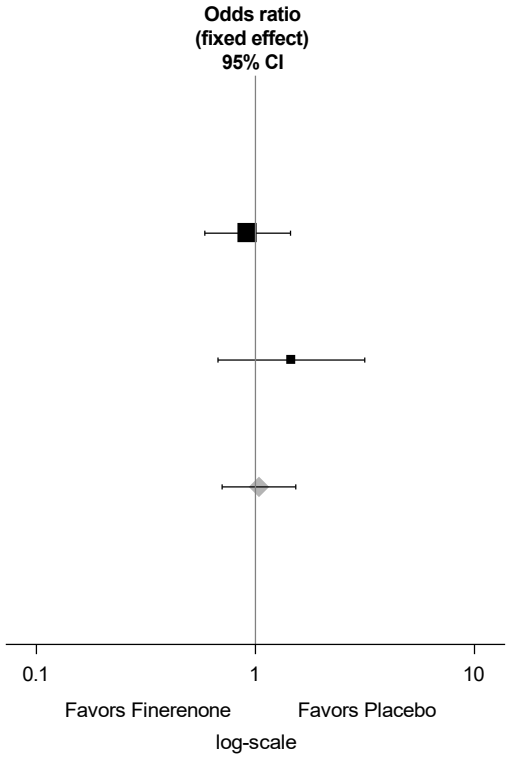
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	20 / 1556	24 / 1541	64.6	0.82 [0.45,1.50]	
FIGARO-DKD	12 / 637	12 / 627	35.4	0.98 [0.44,2.21]	
Total	32 / 2193	36 / 2168		0.88 [0.54,1.42]	Z=-0.54, p=0.5907
Heterogeneity:	Q=0.12 (df=1)	p=0.7275	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	6 / 1061	25 / 1069	50.3	0.24 [0.10,0.58]	
FIGARO-DKD	8 / 720	12 / 729	49.7	0.67 [0.27,1.65]	
Total	14 / 1781	37 / 1798		0.38 [0.20,0.70]	Z=-3.09, p=0.0020
Heterogeneity:	Q=2.60 (df=1)	p=0.1068	I^2=61.5%		
Subgroup Heterogeneity:	Q=4.46 (df=1)	p=0.0347	I^2=77.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.150: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Eye Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

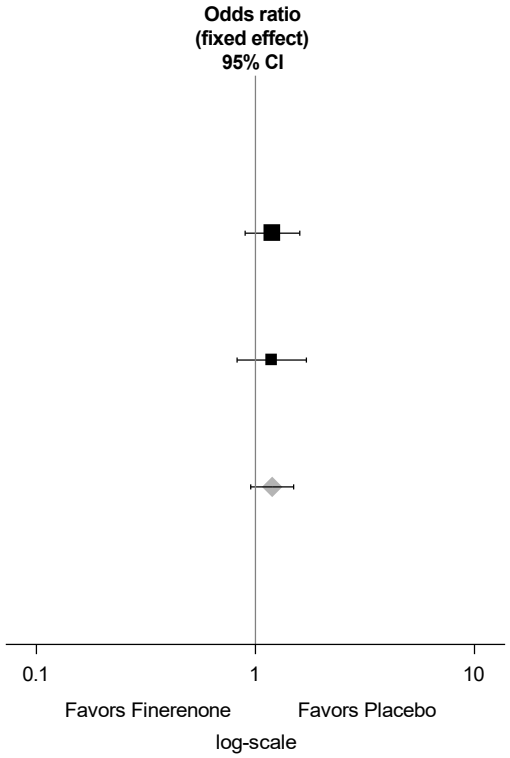
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	37 / 2617	40 / 2610	74.6	0.92 [0.59,1.45]	
FIGARO-DKD	16 / 1357	11 / 1356	25.4	1.46 [0.67,3.16]	
Total	53 / 3974	51 / 3966		1.04 [0.70,1.53]	Z=0.19, p=0.8522
Heterogeneity:	Q=1.02 (df=1)	p=0.3133	I^2=1.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.151: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

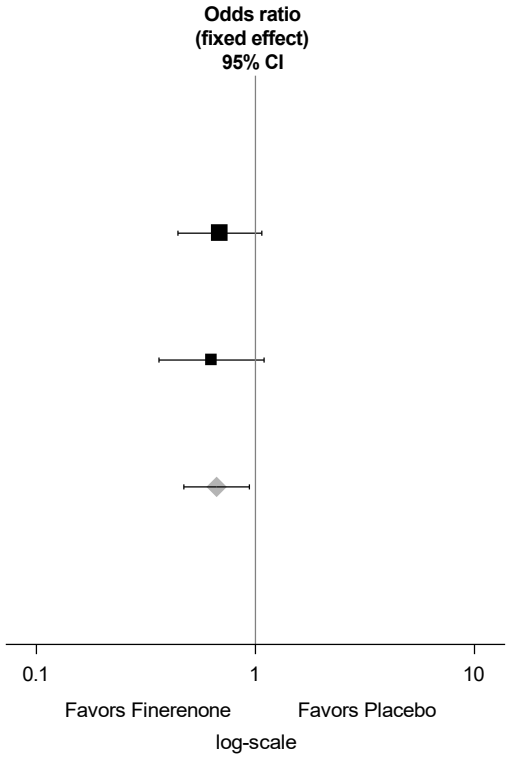
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	106 / 2617	89 / 2610	61.7	1.20 [0.90,1.59]	
FIGARO-DKD	66 / 1357	56 / 1356	38.3	1.19 [0.82,1.71]	
Total	172 / 3974	145 / 3966		1.19 [0.95,1.49]	Z=1.53, p=0.1264
Heterogeneity:	Q=0.00 (df=1)	p=0.9746	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.152: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

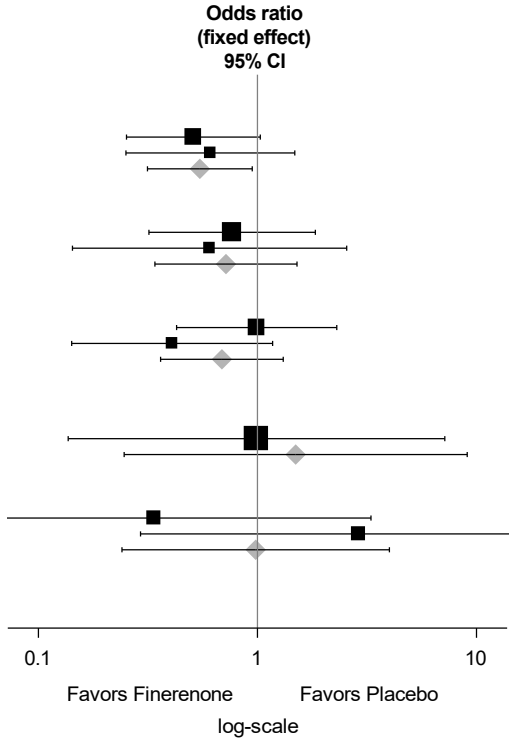
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	34 / 2617	49 / 2610	61.1	0.69 [0.44,1.07]	
FIGARO-DKD	21 / 1357	33 / 1356	38.9	0.63 [0.36,1.09]	
Total	55 / 3974	82 / 3966		0.66 [0.47,0.94]	Z=-2.32, p=0.0202
Heterogeneity:	Q=0.06 (df=1)	p=0.8077	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.152.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 1075	23 / 1062	61.4	0.51 [0.25,1.03]	
FIGARO-DKD	8 / 638	13 / 637	38.6	0.61 [0.25,1.48]	
Total	20 / 1713	36 / 1699		0.55 [0.31,0.95]	Z=-2.16, p=0.0311
Heterogeneity:	Q=0.10 (df=1)	p=0.7576	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 424	12 / 436	73.1	0.77 [0.32,1.84]	
FIGARO-DKD	3 / 267	5 / 271	26.9	0.60 [0.14,2.56]	
Total	12 / 691	17 / 707		0.72 [0.34,1.52]	Z=-0.87, p=0.3849
Heterogeneity:	Q=0.08 (df=1)	p=0.7829	I^2=0.0%		
Asia					
FIDELIO-DKD	11 / 751	11 / 745	61.1	0.99 [0.43,2.30]	
FIGARO-DKD	5 / 289	12 / 290	38.9	0.41 [0.14,1.17]	
Total	16 / 1040	23 / 1035		0.69 [0.36,1.31]	Z=-1.14, p=0.2559
Heterogeneity:	Q=1.67 (df=1)	p=0.1967	I^2=40.0%		
Latin America					
FIDELIO-DKD	1 / 273	0 / 270	0.0	154E9 [154E9,154E9]	
FIGARO-DKD	2 / 102	2 / 101	100.0	0.99 [0.14,7.17]	
Total	3 / 375	2 / 371		1.49 [0.25,9.07]	Z=0.44, p=0.6623
Heterogeneity:	Q=0.17 (df=1)	p=0.6835	I^2=0.0%		
Others					
FIDELIO-DKD	1 / 94	3 / 97	50.3	0.34 [0.03,3.30]	
FIGARO-DKD	3 / 61	1 / 57	49.7	2.90 [0.29,28.68]	
Total	4 / 155	4 / 154		0.98 [0.24,4.00]	Z=-0.03, p=0.9792
Heterogeneity:	Q=1.70 (df=1)	p=0.1923	I^2=41.2%		
Subgroup Heterogeneity:	Q=1.62 (df=4)	p=0.8060	I^2=0.0%		

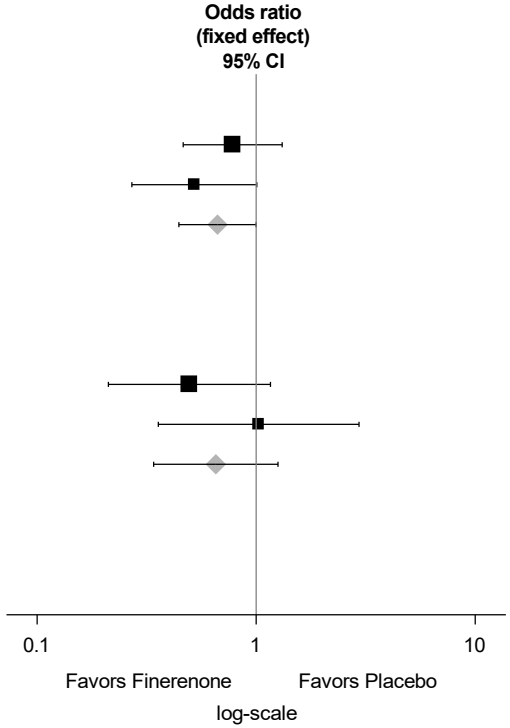


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.152.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

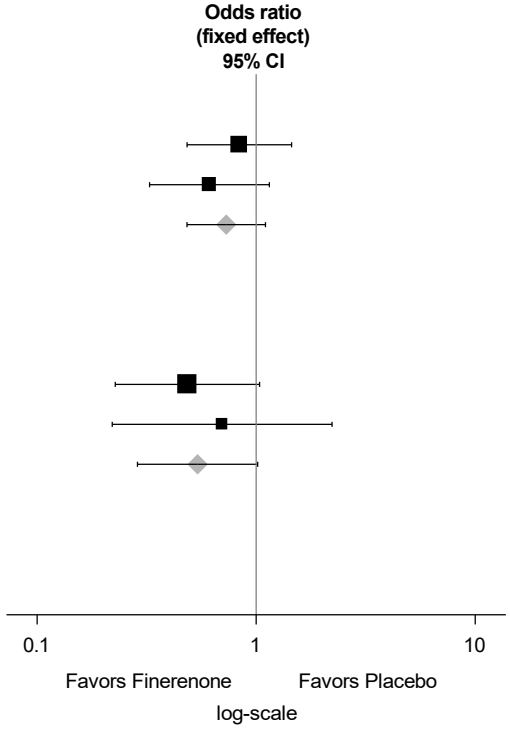
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	26 / 1213	33 / 1210	61.4	0.78 [0.46,1.31]	
FIGARO-DKD	14 / 862	26 / 848	38.6	0.52 [0.27,1.01]	
Total	40 / 2075	59 / 2058		0.67 [0.44,1.00]	Z=-1.96, p=0.0499
Heterogeneity:	Q=0.89 (df=1)	p=0.3454	I^2=0.0%		
Absent					
FIDELIO-DKD	8 / 1404	16 / 1400	60.5	0.50 [0.21,1.16]	
FIGARO-DKD	7 / 495	7 / 508	39.5	1.03 [0.36,2.95]	
Total	15 / 1899	23 / 1908		0.65 [0.34,1.26]	Z=-1.27, p=0.2036
Heterogeneity:	Q=1.11 (df=1)	p=0.2925	I^2=9.8%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9640	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.152.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

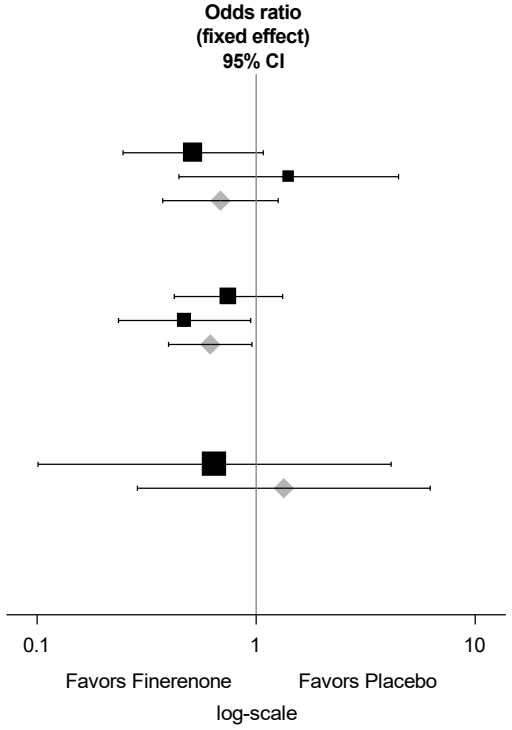
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	24 / 1735	28 / 1700	56.8	0.84 [0.48,1.45]	
FIGARO-DKD	16 / 924	26 / 929	43.2	0.61 [0.33,1.15]	
Total	40 / 2659	54 / 2629		0.73 [0.48,1.10]	Z=-1.50, p=0.1349
Heterogeneity:	Q=0.54 (df=1)	p=0.4616	I^2=0.0%		
> 4.5					
FIDELIO-DKD	10 / 882	21 / 910	69.9	0.49 [0.23,1.04]	
FIGARO-DKD	5 / 433	7 / 426	30.1	0.70 [0.22,2.22]	
Total	15 / 1315	28 / 1336		0.54 [0.29,1.02]	Z=-1.91, p=0.0560
Heterogeneity:	Q=0.27 (df=1)	p=0.6048	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4340	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.152.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

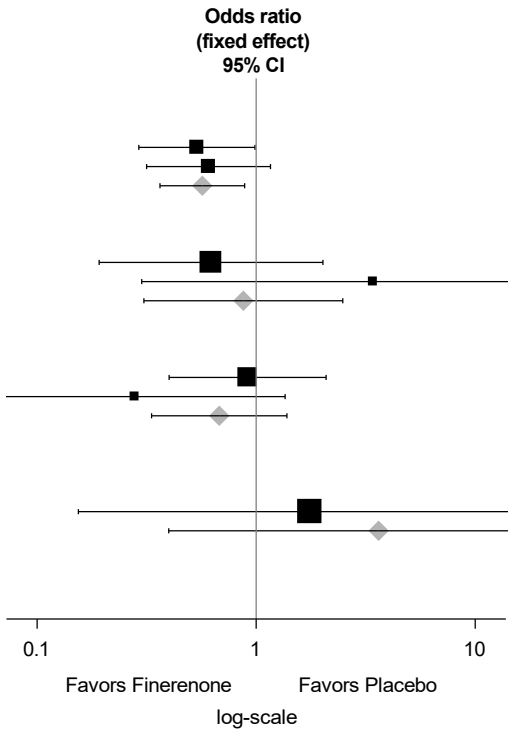
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	11 / 724	21 / 723	71.1	0.52 [0.25,1.08]	
FIGARO-DKD	7 / 494	5 / 495	28.9	1.41 [0.44,4.47]	
Total	18 / 1218	26 / 1218		0.69 [0.37,1.26]	Z=-1.21, p=0.2252
Heterogeneity:	Q=2.07 (df=1)	p=0.1504	I^2=51.6%		
130 - < 160					
FIDELIO-DKD	21 / 1759	28 / 1760	59.8	0.75 [0.42,1.32]	
FIGARO-DKD	12 / 829	25 / 827	40.2	0.47 [0.24,0.94]	
Total	33 / 2588	53 / 2587		0.62 [0.40,0.96]	Z=-2.16, p=0.0308
Heterogeneity:	Q=1.01 (df=1)	p=0.3142	I^2=1.3%		
>= 160					
FIDELIO-DKD	2 / 133	0 / 127	0.0	865E8 [865E8,865E8]	
FIGARO-DKD	2 / 34	3 / 34	100.0	0.65 [0.10,4.13]	
Total	4 / 167	3 / 161		1.34 [0.29,6.23]	Z=0.37, p=0.7116
Heterogeneity:	Q=0.59 (df=1)	p=0.4423	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.91 (df=2)	p=0.6332	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.152.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

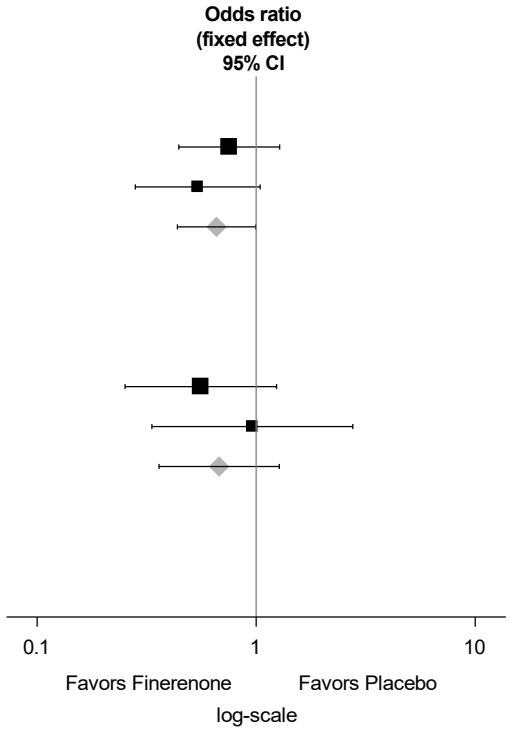
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	16 / 1634	30 / 1657	53.2	0.54 [0.29,0.99]	
FIGARO-DKD	15 / 1010	24 / 989	46.8	0.61 [0.32,1.16]	
Total	31 / 2644	54 / 2646		0.57 [0.36,0.89]	Z=-2.49, p=0.0127
Heterogeneity:	Q=0.07 (df=1)	p=0.7880	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	7 / 115	81.0	0.62 [0.19,2.02]	
FIGARO-DKD	2 / 43	1 / 71	19.0	3.41 [0.30,38.83]	
Total	7 / 172	8 / 186		0.87 [0.31,2.49]	Z=-0.25, p=0.8002
Heterogeneity:	Q=1.53 (df=1)	p=0.2165	I^2=34.5%		
Asian					
FIDELIO-DKD	11 / 678	12 / 677	78.6	0.91 [0.40,2.09]	
FIGARO-DKD	2 / 252	7 / 251	21.4	0.28 [0.06,1.36]	
Total	13 / 930	19 / 928		0.68 [0.33,1.38]	Z=-1.07, p=0.2847
Heterogeneity:	Q=1.72 (df=1)	p=0.1903	I^2=41.7%		
Others					
FIDELIO-DKD	2 / 176	0 / 161	0.0	177E9 [177E9,177E9]	
FIGARO-DKD	2 / 52	1 / 45	100.0	1.76 [0.15,20.08]	
Total	4 / 228	1 / 206		3.62 [0.40,32.89]	Z=1.14, p=0.2529
Heterogeneity:	Q=0.34 (df=1)	p=0.5612	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.01 (df=3)	p=0.3908	I^2=0.2%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.152.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

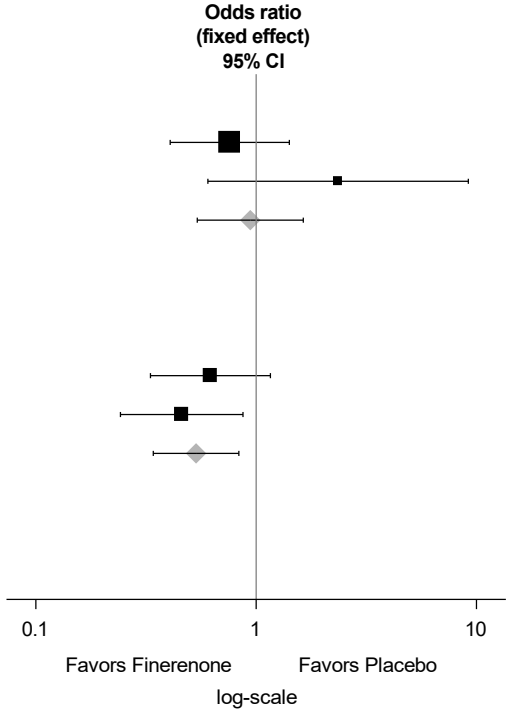
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	24 / 1797	33 / 1870	60.5	0.75 [0.44,1.28]	
FIGARO-DKD	14 / 917	26 / 933	39.5	0.54 [0.28,1.04]	
Total	38 / 2714	59 / 2803		0.66 [0.44,0.99]	Z=-1.99, p=0.0470
Heterogeneity:	Q=0.59 (df=1)	p=0.4408	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	16 / 740	63.8	0.56 [0.25,1.24]	
FIGARO-DKD	7 / 440	7 / 423	36.2	0.96 [0.33,2.76]	
Total	17 / 1260	23 / 1163		0.68 [0.36,1.27]	Z=-1.21, p=0.2274
Heterogeneity:	Q=0.65 (df=1)	p=0.4217	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9429	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.152.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

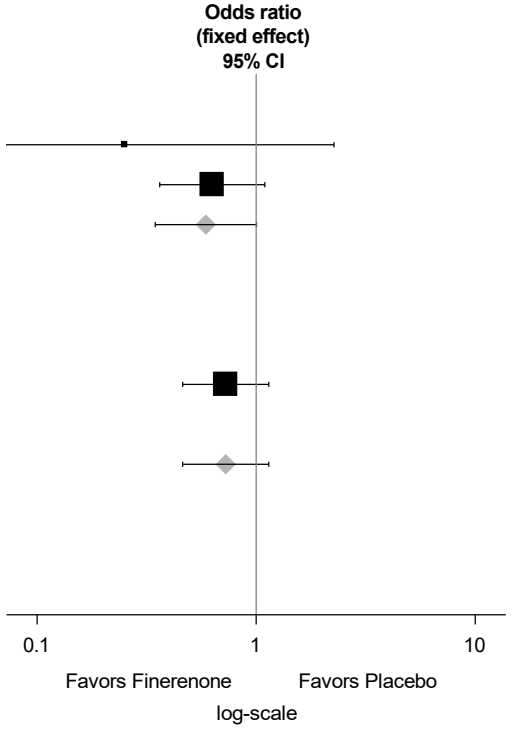
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	18 / 1103	23 / 1075	82.7	0.76 [0.41,1.41]	
FIGARO-DKD	7 / 336	3 / 335	17.3	2.35 [0.60,9.18]	
Total	25 / 1439	26 / 1410		0.94 [0.54,1.64]	Z=-0.22, p=0.8275
Heterogeneity:	Q=2.20 (df=1)	p=0.1377	I^2=54.6%		
>= 65					
FIDELIO-DKD	16 / 1514	26 / 1535	51.1	0.62 [0.33,1.16]	
FIGARO-DKD	14 / 1021	30 / 1021	48.9	0.46 [0.24,0.87]	
Total	30 / 2535	56 / 2556		0.53 [0.34,0.83]	Z=-2.75, p=0.0059
Heterogeneity:	Q=0.43 (df=1)	p=0.5117	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1187	I^2=58.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.152.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

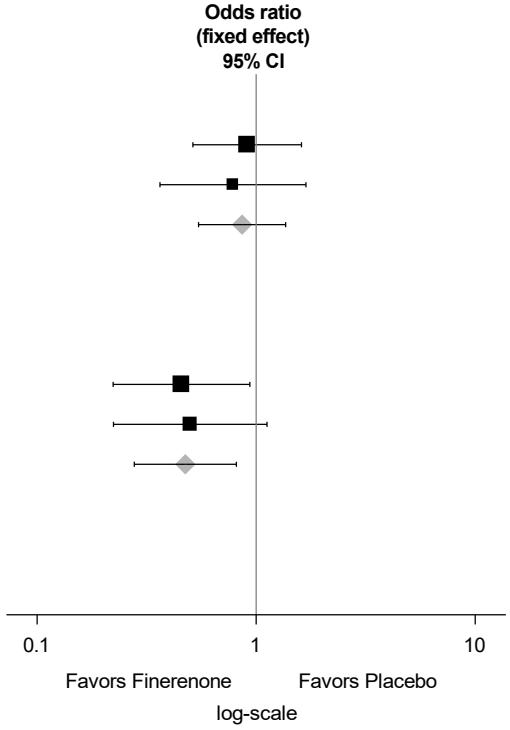
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	1 / 209	4 / 213	5.9	0.25 [0.03,2.27]	
FIGARO-DKD	21 / 1357	33 / 1356	94.1	0.63 [0.36,1.09]	
Total	22 / 1566	37 / 1569		0.59 [0.35,1.00]	Z=-1.95, p=0.0516
Heterogeneity:	Q=0.63 (df=1)	p=0.4259	I^2=0.0%		
Very High					
FIDELIO-DKD	33 / 2408	45 / 2397	100.0	0.73 [0.46,1.14]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	33 / 2408	45 / 2397		0.73 [0.46,1.14]	Z=-1.38, p=0.1662
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.34 (df=1)	p=0.5578	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.152.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

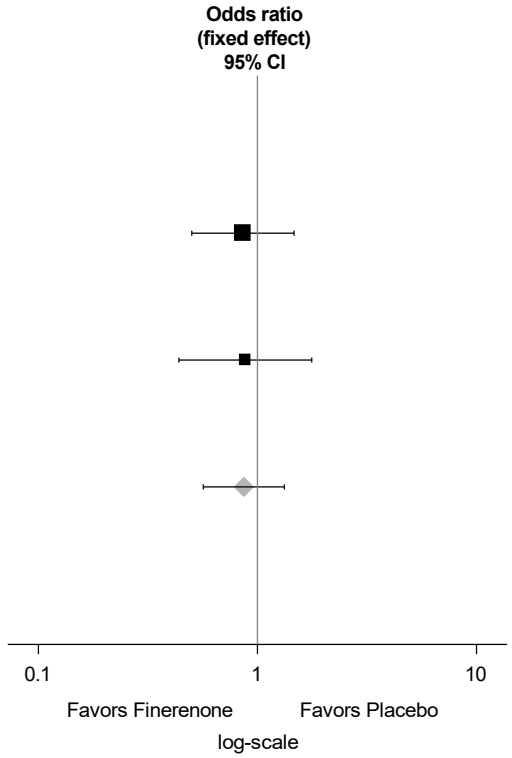
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	23 / 1556	25 / 1541	64.4	0.91 [0.51,1.61]	
FIGARO-DKD	12 / 637	15 / 627	35.6	0.78 [0.36,1.69]	
Total	35 / 2193	40 / 2168		0.86 [0.55,1.36]	Z=-0.63, p=0.5261
Heterogeneity:	Q=0.09 (df=1)	p=0.7591	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	24 / 1069	55.8	0.46 [0.22,0.94]	
FIGARO-DKD	9 / 720	18 / 729	44.2	0.50 [0.22,1.12]	
Total	20 / 1781	42 / 1798		0.47 [0.28,0.81]	Z=-2.72, p=0.0065
Heterogeneity:	Q=0.03 (df=1)	p=0.8678	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.75 (df=1)	p=0.0973	I^2=63.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.153: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hepatobiliary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

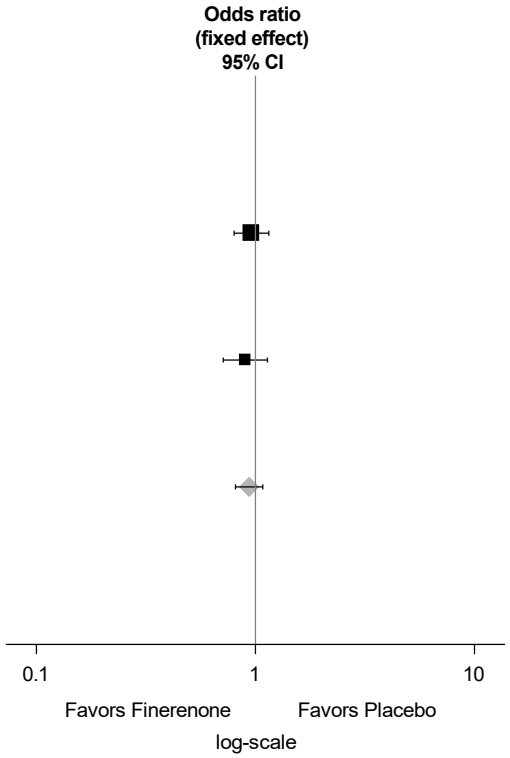
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	25 / 2617	29 / 2610	62.8	0.86 [0.50,1.47]	
FIGARO-DKD	15 / 1357	17 / 1356	37.2	0.88 [0.44,1.77]	
Total	40 / 3974	46 / 3966		0.87 [0.57,1.33]	Z=-0.66, p=0.5098
Heterogeneity:	Q=0.00 (df=1)	p=0.9552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.154: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

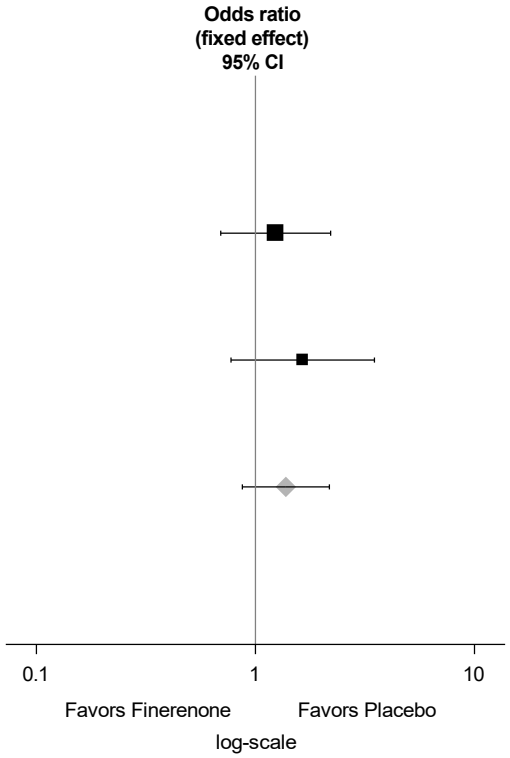
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	251 / 2617	260 / 2610	61.9	0.96 [0.80,1.15]	
FIGARO-DKD	154 / 1357	169 / 1356	38.1	0.90 [0.71,1.13]	
Total	405 / 3974	429 / 3966		0.94 [0.81,1.08]	Z=-0.91, p=0.3638
Heterogeneity:	Q=0.18 (df=1)	p=0.6699	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.155: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Cellulitis (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

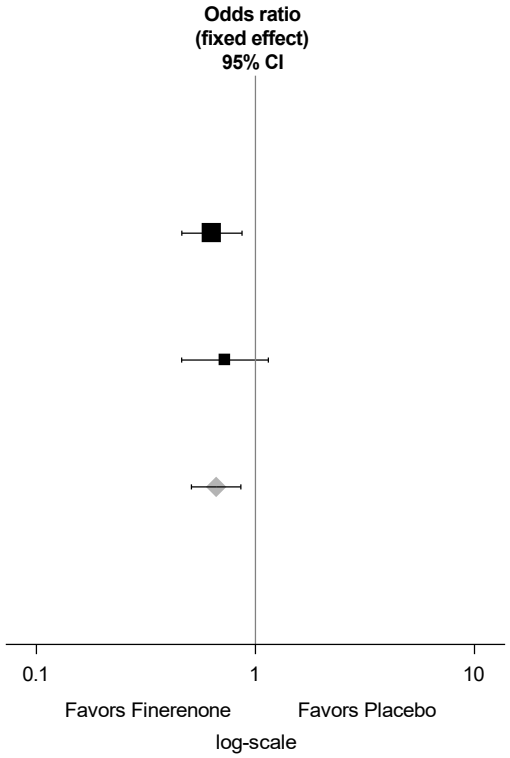
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	26 / 2617	21 / 2610	63.0	1.24 [0.69,2.20]	
FIGARO-DKD	18 / 1357	11 / 1356	37.0	1.64 [0.77,3.49]	
Total	44 / 3974	32 / 3966		1.38 [0.87,2.18]	Z=1.37, p=0.1710
Heterogeneity:	Q=0.34 (df=1)	p=0.5576	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.156: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

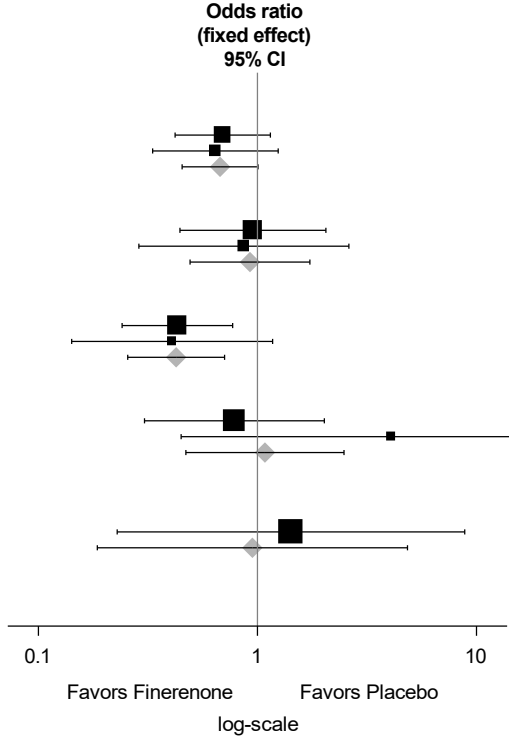
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	65 / 2617	101 / 2610	67.5	0.63 [0.46,0.87]	
FIGARO-DKD	33 / 1357	45 / 1356	32.5	0.73 [0.46,1.15]	
Total	98 / 3974	146 / 3966		0.66 [0.51,0.86]	Z=-3.12, p=0.0018
Heterogeneity:	Q=0.24 (df=1)	p=0.6266	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.156.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

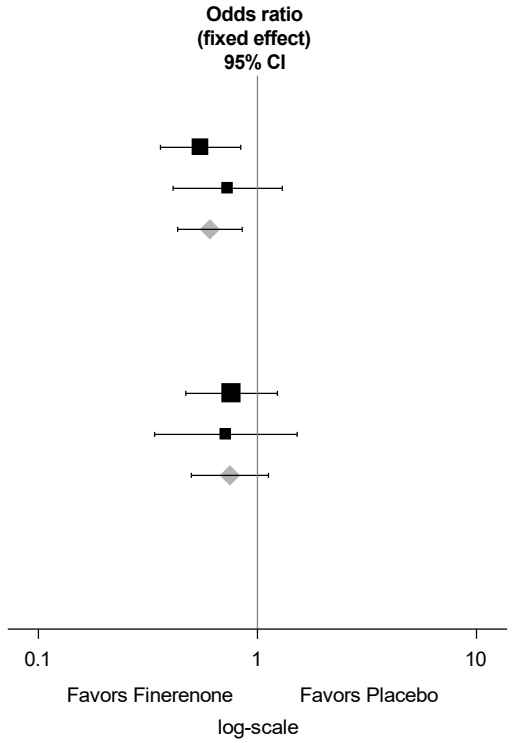
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	27 / 1075	38 / 1062	63.5	0.69 [0.42,1.15]	
FIGARO-DKD	15 / 638	23 / 637	36.5	0.64 [0.33,1.24]	
Total	42 / 1713	61 / 1699		0.67 [0.45,1.01]	Z=-1.93, p=0.0533
Heterogeneity:	Q=0.03 (df=1)	p=0.8553	I^2=0.0%		
North America					
FIDELIO-DKD	13 / 424	14 / 436	67.4	0.95 [0.44,2.05]	
FIGARO-DKD	6 / 267	7 / 271	32.6	0.87 [0.29,2.61]	
Total	19 / 691	21 / 707		0.92 [0.49,1.74]	Z=-0.24, p=0.8065
Heterogeneity:	Q=0.02 (df=1)	p=0.8898	I^2=0.0%		
Asia					
FIDELIO-DKD	17 / 751	38 / 745	76.8	0.43 [0.24,0.77]	
FIGARO-DKD	5 / 289	12 / 290	23.2	0.41 [0.14,1.17]	
Total	22 / 1040	50 / 1035		0.43 [0.26,0.71]	Z=-3.29, p=0.0010
Heterogeneity:	Q=0.01 (df=1)	p=0.9288	I^2=0.0%		
Latin America					
FIDELIO-DKD	8 / 273	10 / 270	84.5	0.78 [0.30,2.02]	
FIGARO-DKD	4 / 102	1 / 101	15.5	4.08 [0.45,37.17]	
Total	12 / 375	11 / 371		1.08 [0.47,2.48]	Z=0.19, p=0.8528
Heterogeneity:	Q=1.83 (df=1)	p=0.1761	I^2=45.4%		
Others					
FIDELIO-DKD	0 / 94	1 / 97	0.0	0.00 [0.00,1E296]	
FIGARO-DKD	3 / 61	2 / 57	100.0	1.42 [0.23,8.84]	
Total	3 / 155	3 / 154		0.95 [0.19,4.84]	Z=-0.06, p=0.9490
Heterogeneity:	Q=0.19 (df=1)	p=0.6635	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.51 (df=4)	p=0.2387	I^2=27.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.156.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

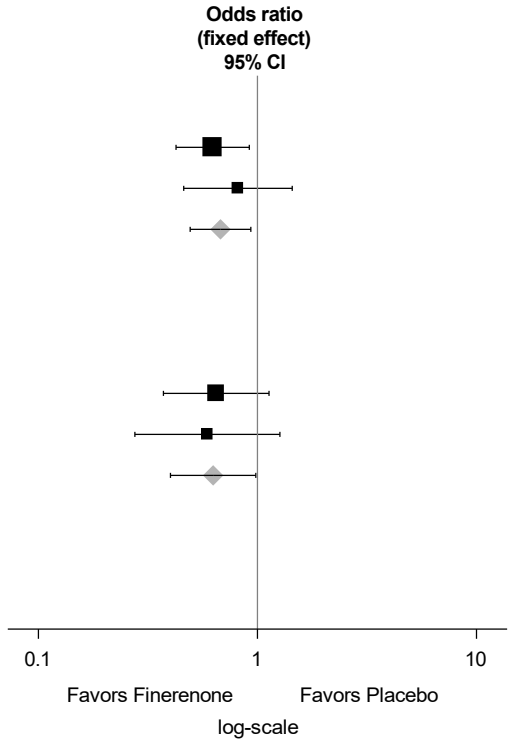
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	35 / 1213	62 / 1210	64.9	0.55 [0.36,0.84]	
FIGARO-DKD	21 / 862	28 / 848	35.1	0.73 [0.41,1.30]	
Total	56 / 2075	90 / 2058		0.61 [0.43,0.85]	Z=-2.88, p=0.0039
Heterogeneity:	Q=0.61 (df=1)	p=0.4337	I^2=0.0%		
Absent					
FIDELIO-DKD	30 / 1404	39 / 1400	70.8	0.76 [0.47,1.23]	
FIGARO-DKD	12 / 495	17 / 508	29.2	0.72 [0.34,1.52]	
Total	42 / 1899	56 / 1908		0.75 [0.50,1.12]	Z=-1.40, p=0.1615
Heterogeneity:	Q=0.02 (df=1)	p=0.8950	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.61 (df=1)	p=0.4365	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.156.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

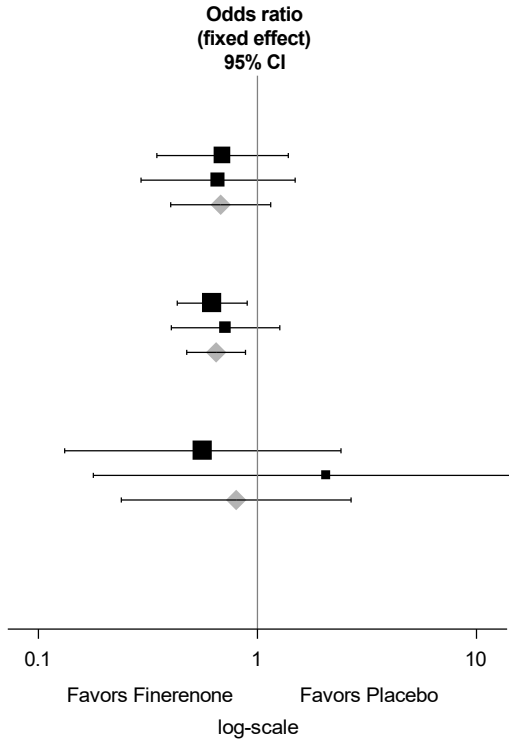
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	44 / 1735	68 / 1700	68.7	0.62 [0.42,0.92]	
FIGARO-DKD	22 / 924	27 / 929	31.3	0.81 [0.46,1.44]	
Total	66 / 2659	95 / 2629		0.68 [0.49,0.93]	Z=-2.39, p=0.0169
Heterogeneity:	Q=0.57 (df=1)	p=0.4487	I^2=0.0%		
> 4.5					
FIDELIO-DKD	21 / 882	33 / 910	65.3	0.65 [0.37,1.13]	
FIGARO-DKD	11 / 433	18 / 426	34.7	0.59 [0.28,1.27]	
Total	32 / 1315	51 / 1336		0.63 [0.40,0.98]	Z=-2.03, p=0.0419
Heterogeneity:	Q=0.04 (df=1)	p=0.8473	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.08 (df=1)	p=0.7832	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.156.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

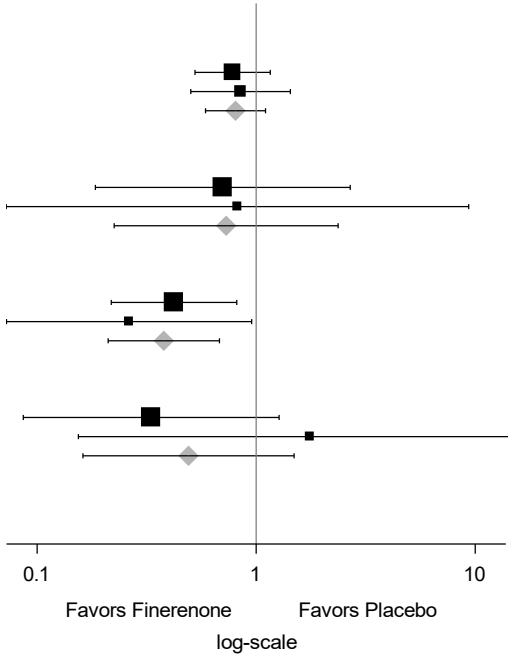
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	14 / 724	20 / 723	57.9	0.69 [0.35,1.38]	
FIGARO-DKD	10 / 494	15 / 495	42.1	0.66 [0.29,1.49]	
Total	24 / 1218	35 / 1218		0.68 [0.40,1.15]	Z=-1.44, p=0.1495
Heterogeneity:	Q=0.01 (df=1)	p=0.9308	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	48 / 1759	76 / 1760	70.6	0.62 [0.43,0.90]	
FIGARO-DKD	21 / 829	29 / 827	29.4	0.72 [0.40,1.26]	
Total	69 / 2588	105 / 2587		0.65 [0.48,0.88]	Z=-2.76, p=0.0058
Heterogeneity:	Q=0.16 (df=1)	p=0.6854	I^2=0.0%		
>= 160					
FIDELIO-DKD	3 / 133	5 / 127	74.0	0.56 [0.13,2.41]	
FIGARO-DKD	2 / 34	1 / 34	26.0	2.06 [0.18,23.88]	
Total	5 / 167	6 / 161		0.80 [0.24,2.68]	Z=-0.36, p=0.7167
Heterogeneity:	Q=0.80 (df=1)	p=0.3714	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.12 (df=2)	p=0.9403	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.156.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

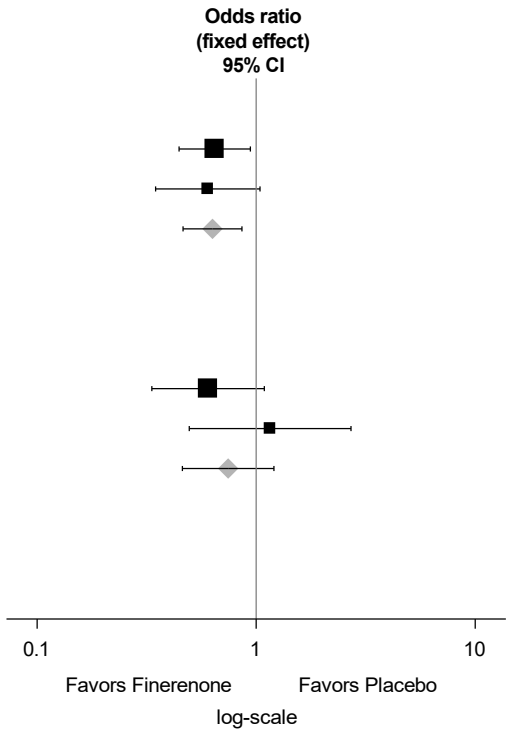
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	45 / 1634	58 / 1657	63.7	0.78 [0.53,1.16]	
FIGARO-DKD	27 / 1010	31 / 989	36.3	0.85 [0.50,1.43]	
Total	72 / 2644	89 / 2646		0.80 [0.59,1.10]	Z=-1.35, p=0.1772
Heterogeneity:	Q=0.06 (df=1)	p=0.8028	I^2=0.0%		
Black					
FIDELIO-DKD	4 / 129	5 / 115	76.7	0.70 [0.18,2.69]	
FIGARO-DKD	1 / 43	2 / 71	23.3	0.82 [0.07,9.34]	
Total	5 / 172	7 / 186		0.73 [0.22,2.37]	Z=-0.53, p=0.5992
Heterogeneity:	Q=0.01 (df=1)	p=0.9132	I^2=0.0%		
Asian					
FIDELIO-DKD	13 / 678	30 / 677	79.2	0.42 [0.22,0.82]	
FIGARO-DKD	3 / 252	11 / 251	20.8	0.26 [0.07,0.95]	
Total	16 / 930	41 / 928		0.38 [0.21,0.68]	Z=-3.25, p=0.0011
Heterogeneity:	Q=0.41 (df=1)	p=0.5220	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 176	8 / 161	76.6	0.33 [0.09,1.27]	
FIGARO-DKD	2 / 52	1 / 45	23.4	1.76 [0.15,20.08]	
Total	5 / 228	9 / 206		0.49 [0.16,1.49]	Z=-1.26, p=0.2091
Heterogeneity:	Q=1.38 (df=1)	p=0.2395	I^2=27.7%		
Subgroup Heterogeneity:	Q=5.27 (df=3)	p=0.1531	I^2=43.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.156.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

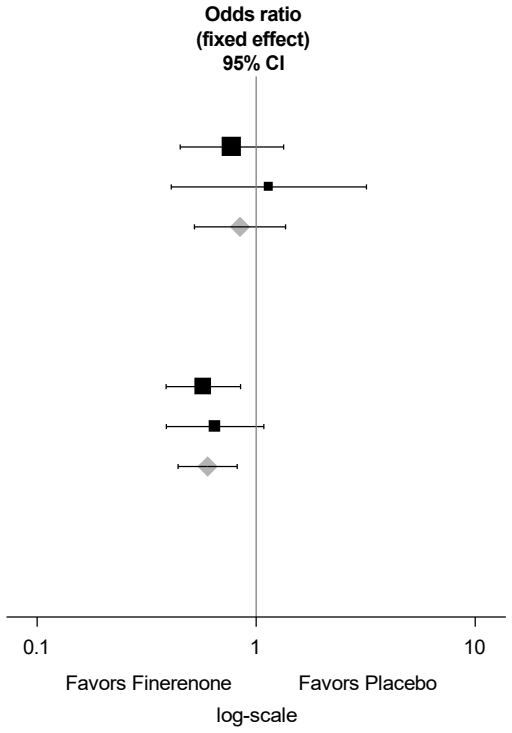
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	46 / 1797	73 / 1870	68.2	0.65 [0.44,0.94]	
FIGARO-DKD	21 / 917	35 / 933	31.8	0.60 [0.35,1.04]	
Total	67 / 2714	108 / 2803		0.63 [0.46,0.86]	Z=-2.91, p=0.0036
Heterogeneity:	Q=0.05 (df=1)	p=0.8302	I^2=0.0%		
Female					
FIDELIO-DKD	19 / 820	28 / 740	67.4	0.60 [0.33,1.09]	
FIGARO-DKD	12 / 440	10 / 423	32.6	1.16 [0.49,2.71]	
Total	31 / 1260	38 / 1163		0.74 [0.46,1.21]	Z=-1.20, p=0.2303
Heterogeneity:	Q=1.52 (df=1)	p=0.2170	I^2=34.4%		
Subgroup Heterogeneity:	Q=0.32 (df=1)	p=0.5730	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.156.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

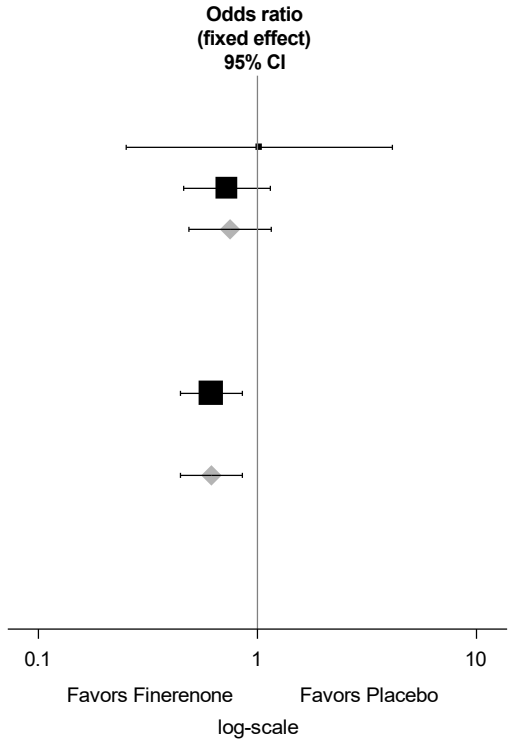
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	24 / 1103	30 / 1075	78.1	0.77 [0.45,1.33]	
FIGARO-DKD	8 / 336	7 / 335	21.9	1.14 [0.41,3.19]	
Total	32 / 1439	37 / 1410		0.84 [0.52,1.36]	Z=-0.70, p=0.4865
Heterogeneity:	Q=0.43 (df=1)	p=0.5117	I^2=0.0%		
>= 65					
FIDELIO-DKD	41 / 1514	71 / 1535	63.2	0.57 [0.39,0.85]	
FIGARO-DKD	25 / 1021	38 / 1021	36.8	0.65 [0.39,1.08]	
Total	66 / 2535	109 / 2556		0.60 [0.44,0.82]	Z=-3.22, p=0.0013
Heterogeneity:	Q=0.14 (df=1)	p=0.7075	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.36 (df=1)	p=0.2430	I^2=26.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.156.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

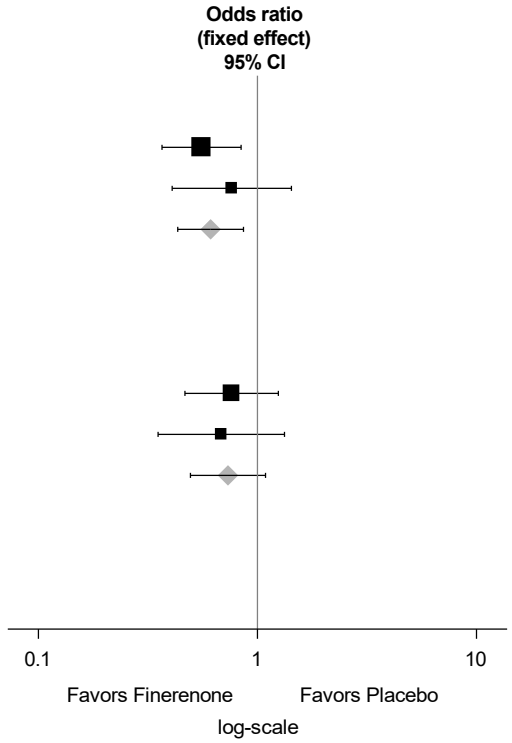
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	4 / 213	9.6	1.02 [0.25,4.13]	
FIGARO-DKD	33 / 1357	45 / 1356	90.4	0.73 [0.46,1.15]	
Total	37 / 1566	49 / 1569		0.75 [0.49,1.16]	Z=-1.30, p=0.1925
Heterogeneity:	Q=0.20 (df=1)	p=0.6513	I^2=0.0%		
Very High					
FIDELIO-DKD	61 / 2408	97 / 2397	100.0	0.62 [0.45,0.85]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	61 / 2408	97 / 2397		0.62 [0.45,0.85]	Z=-2.92, p=0.0035
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.50 (df=1)	p=0.4774	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.156.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

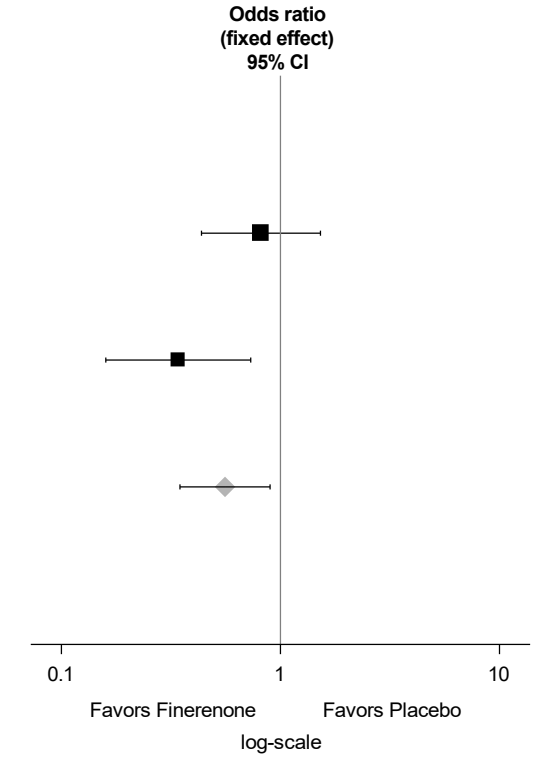
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	36 / 1556	63 / 1541	69.5	0.56 [0.37,0.84]	
FIGARO-DKD	18 / 637	23 / 627	30.5	0.76 [0.41,1.43]	
Total	54 / 2193	86 / 2168		0.61 [0.43,0.86]	Z=-2.79, p=0.0052
Heterogeneity:	Q=0.69 (df=1)	p=0.4073	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	29 / 1061	38 / 1069	64.7	0.76 [0.47,1.25]	
FIGARO-DKD	15 / 720	22 / 729	35.3	0.68 [0.35,1.33]	
Total	44 / 1781	60 / 1798		0.73 [0.49,1.09]	Z=-1.54, p=0.1238
Heterogeneity:	Q=0.07 (df=1)	p=0.7961	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.46 (df=1)	p=0.4954	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

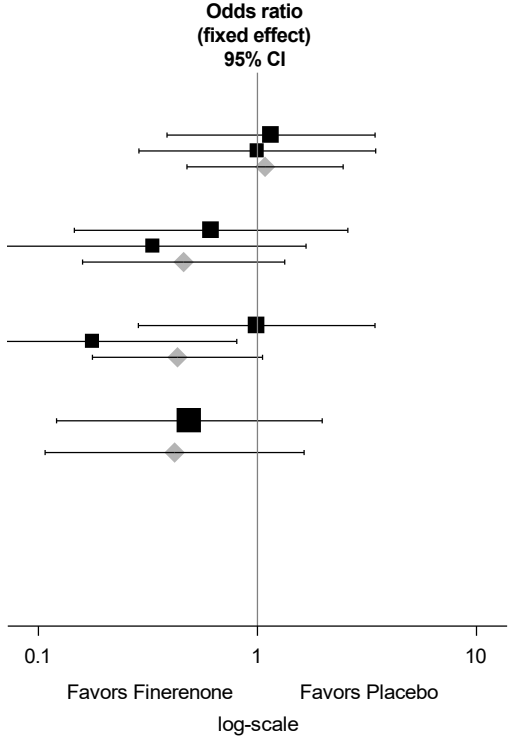
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	22 / 2610	59.7	0.81 [0.44,1.52]	
FIGARO-DKD	9 / 1357	26 / 1356	40.3	0.34 [0.16,0.73]	
Total	27 / 3974	48 / 3966		0.56 [0.35,0.90]	Z=-2.41, p=0.0159
Heterogeneity:	Q=3.00 (df=1)	p=0.0831	I^2=66.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.157.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

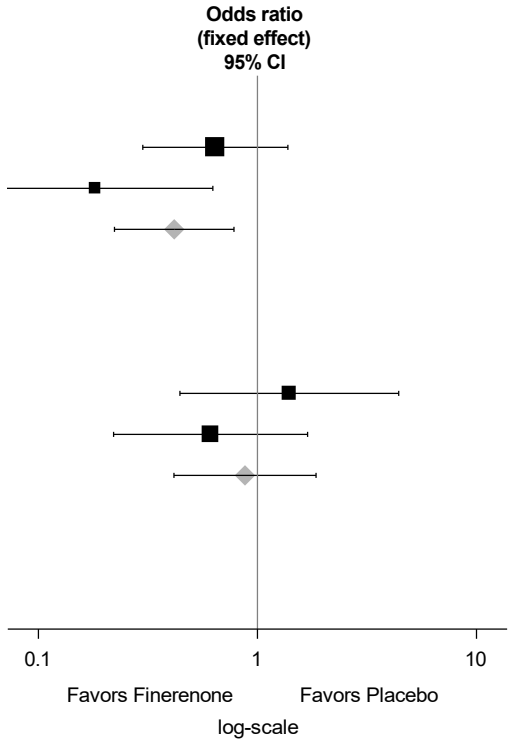
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	7 / 1075	6 / 1062	56.4	1.15 [0.39,3.44]	
FIGARO-DKD	5 / 638	5 / 637	43.6	1.00 [0.29,3.47]	
Total	12 / 1713	11 / 1699		1.08 [0.48,2.46]	Z=0.19, p=0.8485
Heterogeneity:	Q=0.03 (df=1)	p=0.8643	I^2=0.0%		
North America					
FIDELIO-DKD	3 / 424	5 / 436	55.6	0.61 [0.15,2.59]	
FIGARO-DKD	2 / 267	6 / 271	44.4	0.33 [0.07,1.67]	
Total	5 / 691	11 / 707		0.46 [0.16,1.33]	Z=-1.43, p=0.1524
Heterogeneity:	Q=0.31 (df=1)	p=0.5782	I^2=0.0%		
Asia					
FIDELIO-DKD	5 / 751	5 / 745	59.8	0.99 [0.29,3.44]	
FIGARO-DKD	2 / 289	11 / 290	40.2	0.18 [0.04,0.80]	
Total	7 / 1040	16 / 1035		0.43 [0.18,1.05]	Z=-1.84, p=0.0654
Heterogeneity:	Q=3.05 (df=1)	p=0.0806	I^2=67.2%		
Latin America					
FIDELIO-DKD	3 / 273	6 / 270	100.0	0.49 [0.12,1.98]	
FIGARO-DKD	0 / 102	1 / 101	0.0	0.00 [0.00,11E296]	
Total	3 / 375	7 / 371		0.42 [0.11,1.63]	Z=-1.25, p=0.2099
Heterogeneity:	Q=0.05 (df=1)	p=0.8274	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	0 / 97	0.0	-	
FIGARO-DKD	0 / 61	3 / 57	0.0	0.00 [0.00,57E295]	
Total	0 / 155	3 / 154		0.00 [0.00,25E295]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.02 (df=4)	p=0.5546	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	11 / 1213	17 / 1210	72.5	0.64 [0.30,1.38]	
FIGARO-DKD	3 / 862	16 / 848	27.5	0.18 [0.05,0.63]	
Total	14 / 2075	33 / 2058		0.42 [0.22,0.78]	Z=-2.73, p=0.0063
Heterogeneity:	Q=2.97 (df=1)	p=0.0850	I^2=66.3%		
Absent					
FIDELIO-DKD	7 / 1404	5 / 1400	44.0	1.40 [0.44,4.42]	
FIGARO-DKD	6 / 495	10 / 508	56.0	0.61 [0.22,1.69]	
Total	13 / 1899	15 / 1908		0.88 [0.42,1.85]	Z=-0.34, p=0.7311
Heterogeneity:	Q=1.11 (df=1)	p=0.2913	I^2=10.2%		
Subgroup Heterogeneity:	Q=2.23 (df=1)	p=0.1351	I^2=55.2%		

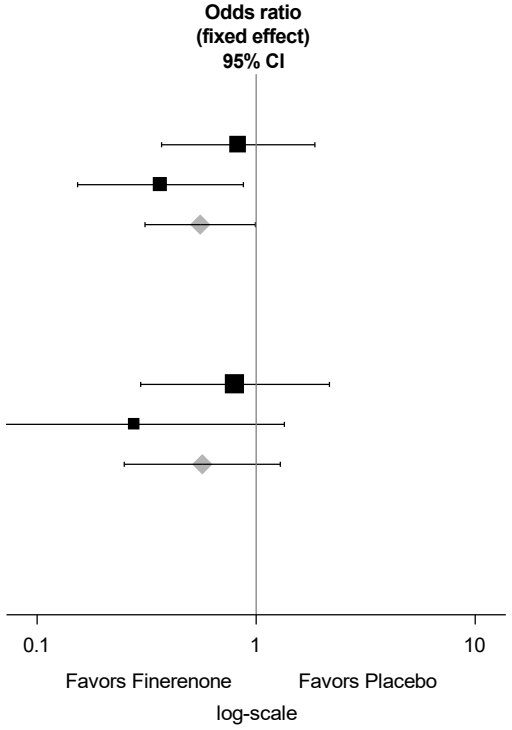


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Urinary tract infection (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

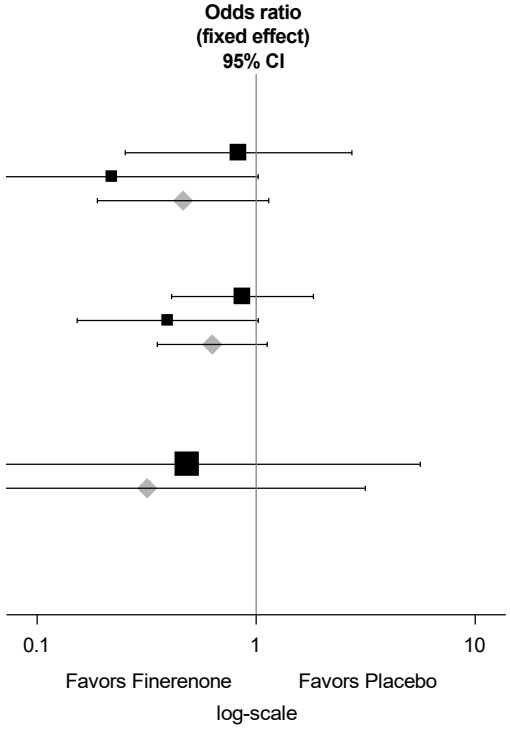
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	11 / 1735	13 / 1700	53.9	0.83 [0.37,1.85]	
FIGARO-DKD	7 / 924	19 / 929	46.1	0.37 [0.15,0.87]	
Total	18 / 2659	32 / 2629		0.56 [0.31,0.99]	Z=-1.99, p=0.0469
Heterogeneity:	Q=1.83 (df=1)	p=0.1764	I^2=45.3%		
> 4.5					
FIDELIO-DKD	7 / 882	9 / 910	71.7	0.80 [0.30,2.16]	
FIGARO-DKD	2 / 433	7 / 426	28.3	0.28 [0.06,1.34]	
Total	9 / 1315	16 / 1336		0.57 [0.25,1.29]	Z=-1.35, p=0.1759
Heterogeneity:	Q=1.25 (df=1)	p=0.2633	I^2=20.1%		
Subgroup Heterogeneity:	Q=0.00 (df=1)	p=0.9659	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

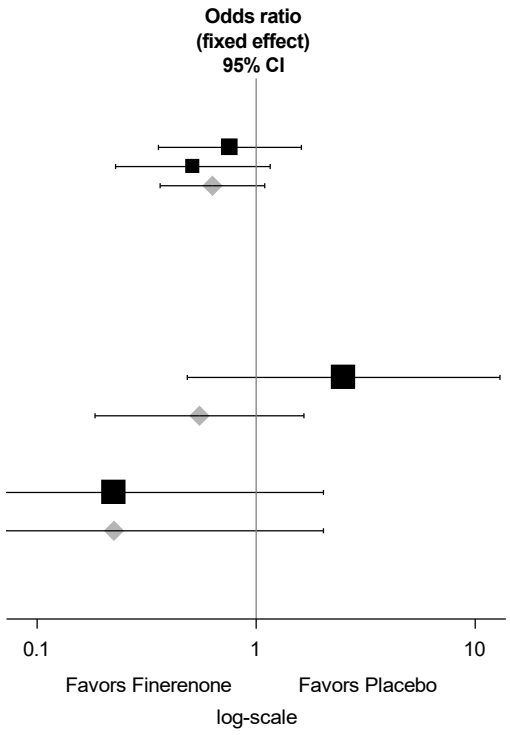
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	5 / 724	6 / 723	62.5	0.83 [0.25,2.74]	
FIGARO-DKD	2 / 494	9 / 495	37.5	0.22 [0.05,1.02]	
Total	7 / 1218	15 / 1218		0.46 [0.19,1.14]	Z=-1.67, p=0.0944
Heterogeneity:	Q=1.83 (df=1)	p=0.1761	I^2=45.4%		
130 - < 160					
FIDELIO-DKD	13 / 1759	15 / 1760	62.0	0.87 [0.41,1.83]	
FIGARO-DKD	6 / 829	15 / 827	38.0	0.39 [0.15,1.02]	
Total	19 / 2588	30 / 2587		0.63 [0.35,1.12]	Z=-1.57, p=0.1168
Heterogeneity:	Q=1.63 (df=1)	p=0.2020	I^2=38.6%		
>= 160					
FIDELIO-DKD	0 / 133	1 / 127	0.0	0.00 [0.00,15E296]	
FIGARO-DKD	1 / 34	2 / 34	100.0	0.48 [0.04,5.61]	
Total	1 / 167	3 / 161		0.32 [0.03,3.15]	Z=-0.98, p=0.3274
Heterogeneity:	Q=0.11 (df=1)	p=0.7357	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.56 (df=2)	p=0.7548	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

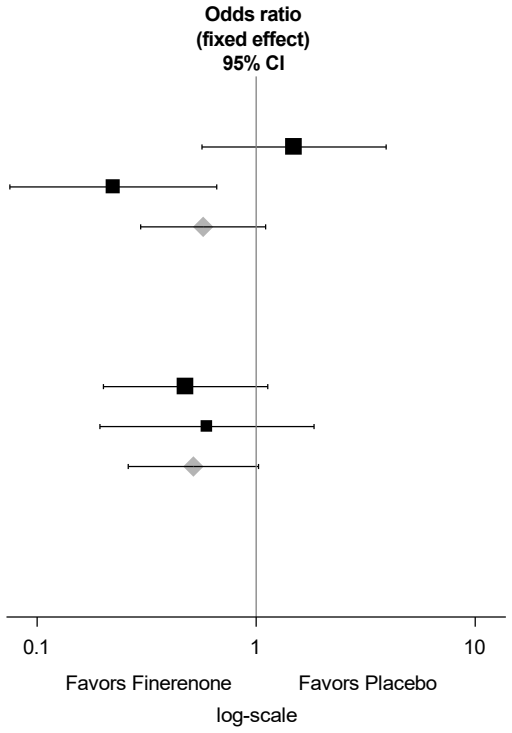
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	12 / 1634	16 / 1657	53.9	0.76 [0.36,1.61]	
FIGARO-DKD	9 / 1010	17 / 989	46.1	0.51 [0.23,1.16]	
Total	21 / 2644	33 / 2646		0.63 [0.36,1.09]	Z=-1.64, p=0.1013
Heterogeneity:	Q=0.48 (df=1)	p=0.4905	I^2=0.0%		
Black					
FIDELIO-DKD	0 / 129	0 / 115	0.0	-	
FIGARO-DKD	0 / 43	2 / 71	0.0	0.00 [0.00,1E297]	
Total	0 / 172	2 / 186		0.00 [0.00,8E296]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	5 / 678	2 / 677	100.0	2.51 [0.48,12.97]	
FIGARO-DKD	0 / 252	7 / 251	0.0	0.00 [0.00,11E296]	
Total	5 / 930	9 / 928		0.55 [0.18,1.65]	Z=-1.06, p=0.2874
Heterogeneity:	Q=3.27 (df=1)	p=0.0707	I^2=69.4%		
Others					
FIDELIO-DKD	1 / 176	4 / 161	100.0	0.22 [0.02,2.03]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	1 / 228	4 / 206		0.22 [0.02,2.03]	Z=-1.33, p=0.1833
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.81 (df=3)	p=0.8462	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.157.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

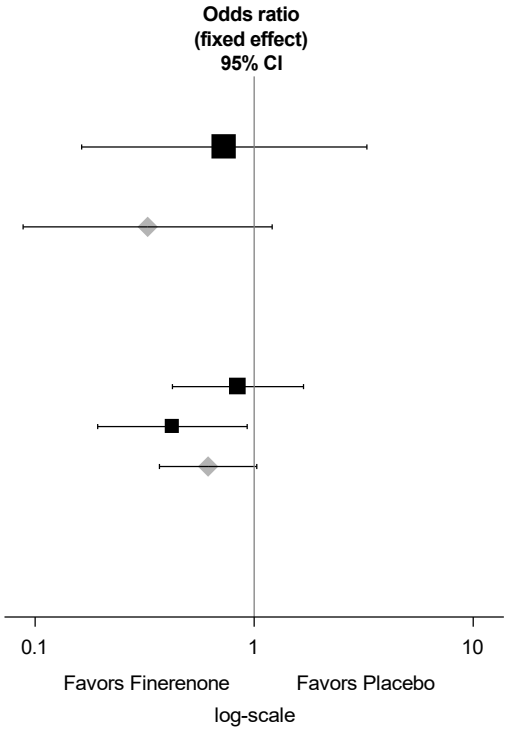
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	10 / 1797	7 / 1870	55.8	1.49 [0.57,3.92]	
FIGARO-DKD	4 / 917	18 / 933	44.2	0.22 [0.08,0.66]	
Total	14 / 2714	25 / 2803		0.57 [0.30,1.10]	Z=-1.66, p=0.0963
Heterogeneity:	Q=6.64 (df=1)	p=0.0100	I^2=84.9%		
Female					
FIDELIO-DKD	8 / 820	15 / 740	62.9	0.48 [0.20,1.13]	
FIGARO-DKD	5 / 440	8 / 423	37.1	0.60 [0.19,1.84]	
Total	13 / 1260	23 / 1163		0.52 [0.26,1.03]	Z=-1.89, p=0.0589
Heterogeneity:	Q=0.10 (df=1)	p=0.7560	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.04 (df=1)	p=0.8321	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.157.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

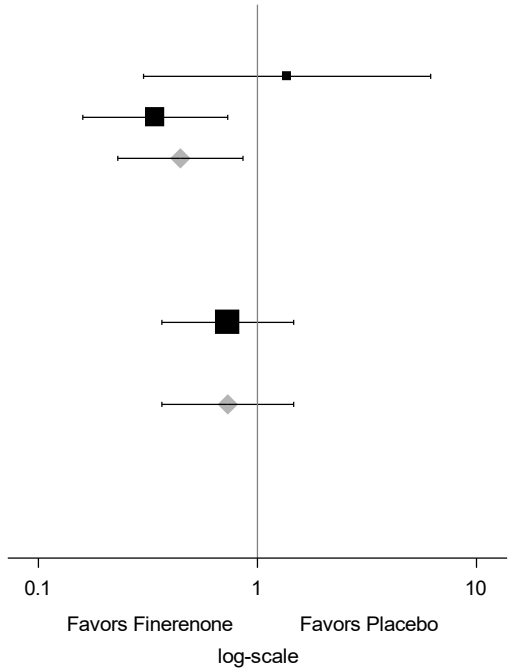
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	3 / 1103	4 / 1075	100.0	0.73 [0.16,3.27]	
FIGARO-DKD	0 / 336	5 / 335	0.0	0.00 [0.00,77E295]	
Total	3 / 1439	9 / 1410		0.33 [0.09,1.21]	Z=-1.68, p=0.0936
Heterogeneity:	Q=1.11 (df=1)	p=0.2923	I^2=9.8%		
>= 65					
FIDELIO-DKD	15 / 1514	18 / 1535	56.5	0.84 [0.42,1.68]	
FIGARO-DKD	9 / 1021	21 / 1021	43.5	0.42 [0.19,0.93]	
Total	24 / 2535	39 / 2556		0.62 [0.37,1.03]	Z=-1.86, p=0.0635
Heterogeneity:	Q=1.67 (df=1)	p=0.1960	I^2=40.2%		
Subgroup Heterogeneity:	Q=0.79 (df=1)	p=0.3754	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.157.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Urinary tract infection (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	3 / 213	20.3	1.37 [0.30,6.18]	
FIGARO-DKD	9 / 1357	26 / 1356	79.7	0.34 [0.16,0.73]	
Total	13 / 1566	29 / 1569		0.44 [0.23,0.86]	Z=-2.41, p=0.0158
Heterogeneity:	Q=2.58 (df=1)	p=0.1079	I^2=61.3%		
Very High					
FIDELIO-DKD	14 / 2408	19 / 2397	100.0	0.73 [0.37,1.46]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	14 / 2408	19 / 2397		0.73 [0.37,1.46]	Z=-0.88, p=0.3772
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.04 (df=1)	p=0.3068	I^2=4.2%		

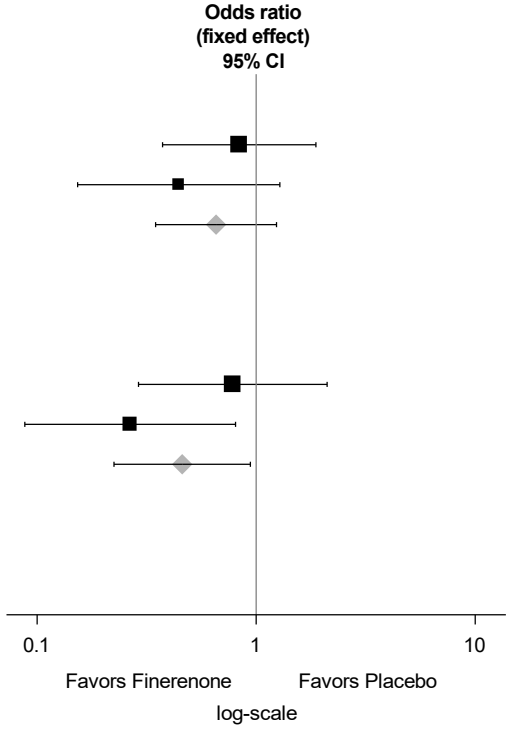


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.157.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Urinary tract infection (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

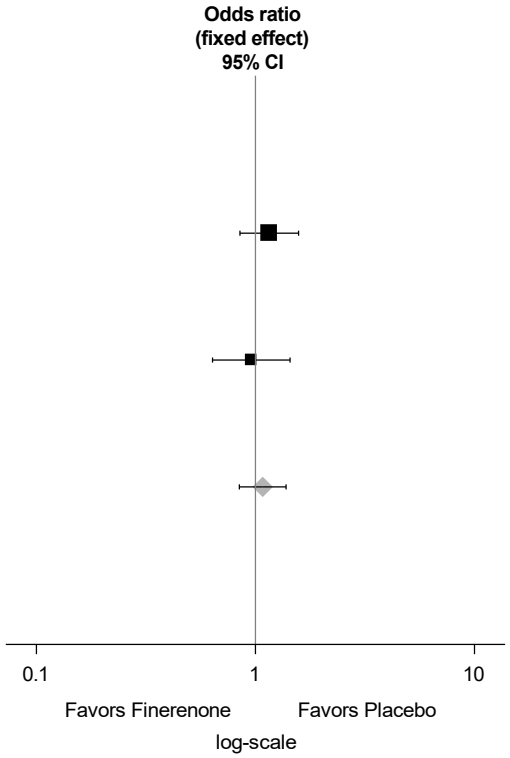
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	11 / 1556	13 / 1541	63.5	0.84 [0.37,1.87]	
FIGARO-DKD	5 / 637	11 / 627	36.5	0.44 [0.15,1.28]	
Total	16 / 2193	24 / 2168		0.66 [0.35,1.24]	Z=-1.30, p=0.1935
Heterogeneity:	Q=0.87 (df=1)	p=0.3498	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	7 / 1061	9 / 1069	55.5	0.78 [0.29,2.11]	
FIGARO-DKD	4 / 720	15 / 729	44.5	0.27 [0.09,0.81]	
Total	11 / 1781	24 / 1798		0.46 [0.22,0.94]	Z=-2.13, p=0.0335
Heterogeneity:	Q=2.04 (df=1)	p=0.1530	I^2=51.0%		
Subgroup Heterogeneity:	Q=0.53 (df=1)	p=0.4663	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.158: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

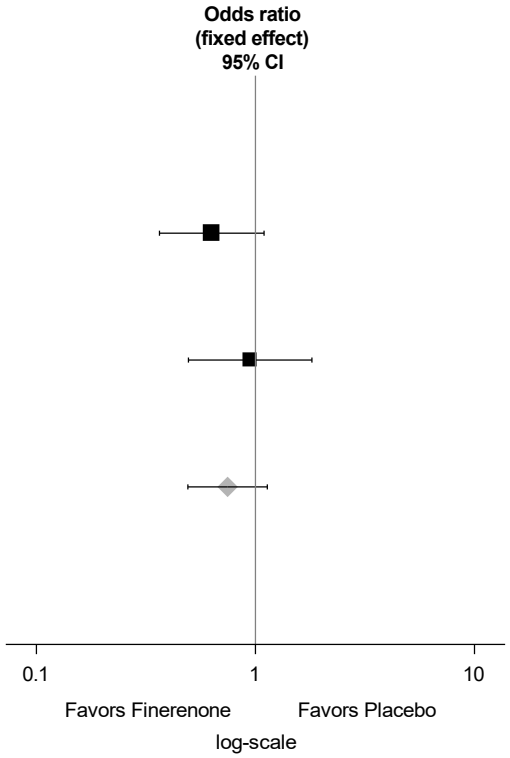
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	90 / 2617	78 / 2610	63.6	1.16 [0.85,1.57]	
FIGARO-DKD	47 / 1357	49 / 1356	36.4	0.96 [0.64,1.44]	
Total	137 / 3974	127 / 3966		1.08 [0.84,1.38]	Z=0.61, p=0.5422
Heterogeneity:	Q=0.53 (df=1)	p=0.4683	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.159: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Investigations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

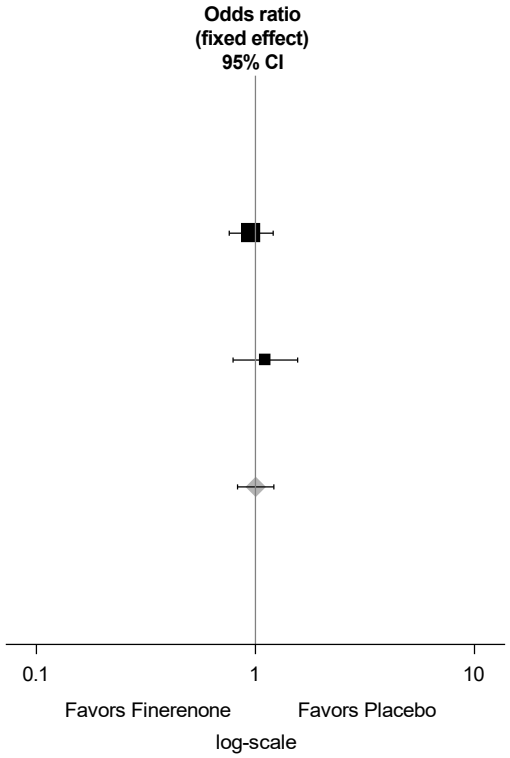
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	21 / 2617	33 / 2610	58.2	0.63 [0.36,1.09]	
FIGARO-DKD	18 / 1357	19 / 1356	41.8	0.95 [0.49,1.81]	
Total	39 / 3974	52 / 3966		0.75 [0.49,1.13]	Z=-1.38, p=0.1691
Heterogeneity:	Q=0.87 (df=1)	p=0.3522	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.160: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

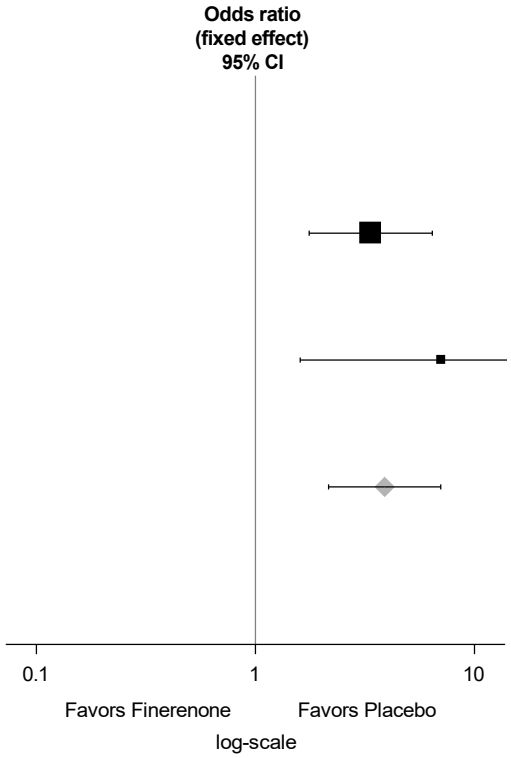
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	150 / 2617	156 / 2610	68.3	0.96 [0.76,1.21]	
FIGARO-DKD	74 / 1357	67 / 1356	31.7	1.11 [0.79,1.56]	
Total	224 / 3974	223 / 3966		1.00 [0.83,1.21]	Z=0.03, p=0.9791
Heterogeneity:	Q=0.50 (df=1)	p=0.4783	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.161: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

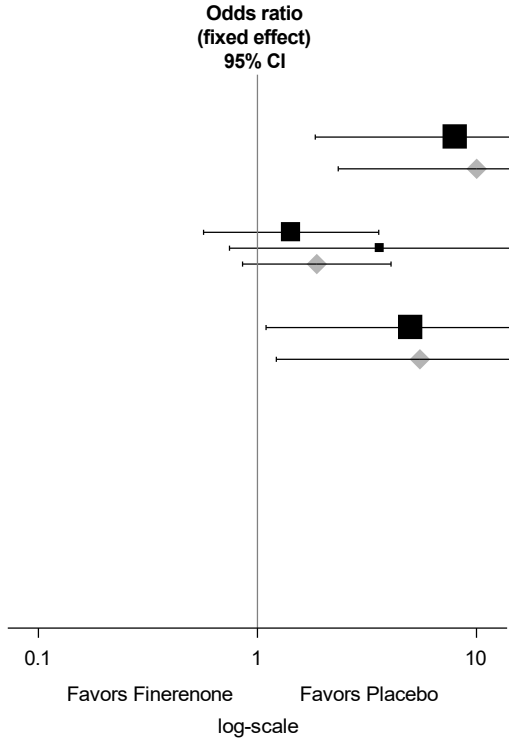
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	40 / 2617	12 / 2610	84.0	3.36 [1.76,6.42]	
FIGARO-DKD	14 / 1357	2 / 1356	16.0	7.06 [1.60,31.11]	
Total	54 / 3974	14 / 3966		3.89 [2.16,7.01]	Z=4.52, p=<.0001
Heterogeneity:	Q=0.82 (df=1)	p=0.3665	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.161.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

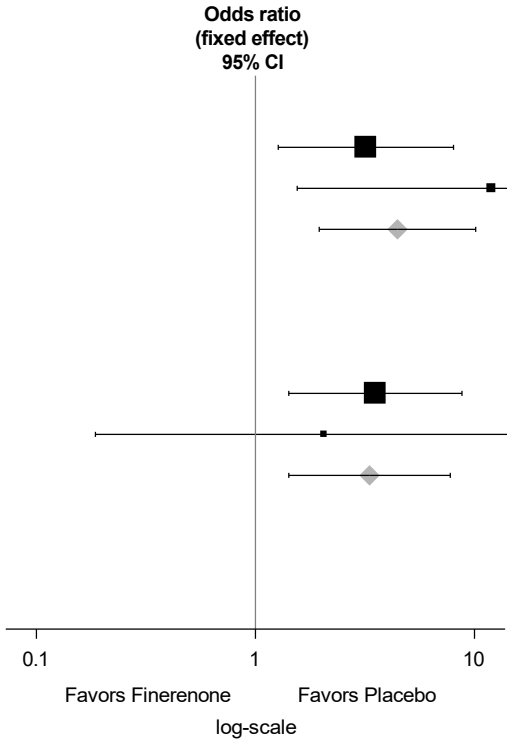
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	16 / 1075	2 / 1062	100.0	8.01 [1.84,34.91]	
FIGARO-DKD	4 / 638	0 / 637	0.0	973E8 [973E8,973E8]	
Total	20 / 1713	2 / 1699		10.02 [2.34,42.95]	Z=3.10, p=0.0019
Heterogeneity:	Q=0.09 (df=1)	p=0.7654	I^2=0.0%		
North America					
FIDELIO-DKD	11 / 424	8 / 436	74.7	1.42 [0.57,3.58]	
FIGARO-DKD	7 / 267	2 / 271	25.3	3.62 [0.75,17.59]	
Total	18 / 691	10 / 707		1.87 [0.86,4.07]	Z=1.57, p=0.1171
Heterogeneity:	Q=1.01 (df=1)	p=0.3160	I^2=0.5%		
Asia					
FIDELIO-DKD	10 / 751	2 / 745	100.0	5.01 [1.09,22.96]	
FIGARO-DKD	1 / 289	0 / 290	0.0	145E9 [145E9,145E9]	
Total	11 / 1040	2 / 1035		5.52 [1.22,24.97]	Z=2.22, p=0.0266
Heterogeneity:	Q=0.02 (df=1)	p=0.9017	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	0 / 270	0.0	114E9 [114E9,114E9]	
FIGARO-DKD	0 / 102	0 / 101	0.0	-	
Total	2 / 375	0 / 371		205E9 [205E9,205E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Others					
FIDELIO-DKD	1 / 94	0 / 97	0.0	166E9 [166E9,166E9]	
FIGARO-DKD	2 / 61	0 / 57	0.0	192E9 [192E9,192E9]	
Total	3 / 155	0 / 154		106E9 [106E9,106E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=4.68 (df=4)	p=0.3217	I^2=14.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.161.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

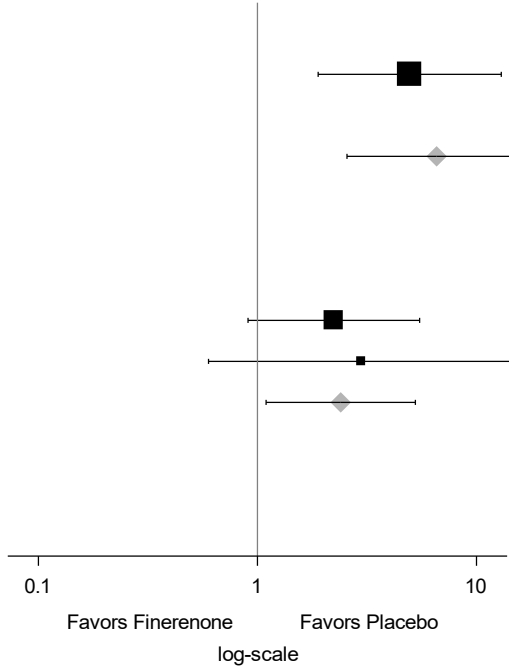
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	19 / 1213	6 / 1210	83.1	3.19 [1.27,8.02]	
FIGARO-DKD	12 / 862	1 / 848	16.9	11.96 [1.55,92.17]	
Total	31 / 2075	7 / 2058		4.45 [1.95,10.13]	Z=3.56, p=0.0004
Heterogeneity:	Q=1.40 (df=1)	p=0.2370	I^2=28.5%		
Absent					
FIDELIO-DKD	21 / 1404	6 / 1400	87.5	3.53 [1.42,8.77]	
FIGARO-DKD	2 / 495	1 / 508	12.5	2.06 [0.19,22.76]	
Total	23 / 1899	7 / 1908		3.32 [1.42,7.75]	Z=2.77, p=0.0056
Heterogeneity:	Q=0.17 (df=1)	p=0.6806	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.24 (df=1)	p=0.6265	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.161.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	25 / 1735	5 / 1700	100.0	4.96 [1.89,12.98]	
FIGARO-DKD	8 / 924	0 / 929	0.0	134E9 [134E9,134E9]	
Total	33 / 2659	5 / 2629		6.58 [2.56,16.88]	Z=3.92, p=<.0001
Heterogeneity:	Q=0.33 (df=1)	p=0.5645	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 882	7 / 910	76.0	2.23 [0.91,5.50]	
FIGARO-DKD	6 / 433	2 / 426	24.0	2.98 [0.60,14.84]	
Total	21 / 1315	9 / 1336		2.40 [1.10,5.26]	Z=2.19, p=0.0288
Heterogeneity:	Q=0.09 (df=1)	p=0.7586	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.60 (df=1)	p=0.1071	I^2=61.5%		

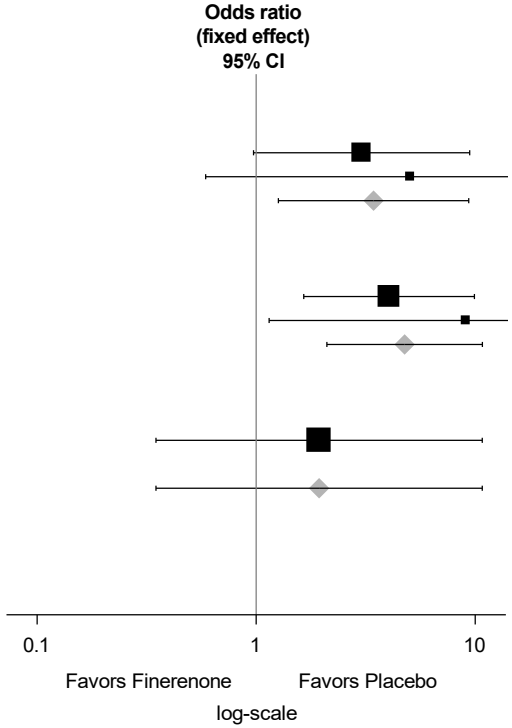


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.161.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

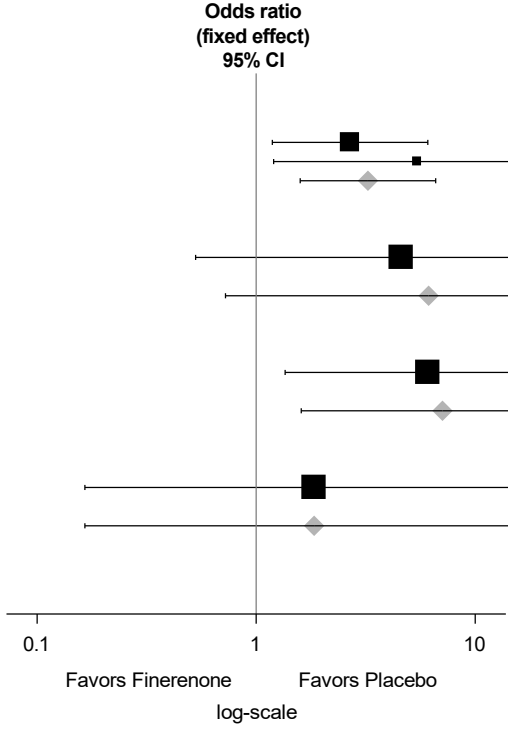
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	4 / 723	78.2	3.03 [0.97,9.44]	
FIGARO-DKD	5 / 494	1 / 495	21.8	5.05 [0.59,43.39]	
Total	17 / 1218	5 / 1218		3.43 [1.26,9.34]	Z=2.42, p=0.0156
Heterogeneity:	Q=0.17 (df=1)	p=0.6797	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	24 / 1759	6 / 1760	84.2	4.04 [1.65,9.92]	
FIGARO-DKD	9 / 829	1 / 827	15.8	9.07 [1.15,71.72]	
Total	33 / 2588	7 / 2587		4.76 [2.10,10.79]	Z=3.74, p=0.0002
Heterogeneity:	Q=0.50 (df=1)	p=0.4795	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	2 / 127	100.0	1.94 [0.35,10.77]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	4 / 167	2 / 161		1.94 [0.35,10.77]	Z=0.76, p=0.4496
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.92 (df=2)	p=0.6300	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.161.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

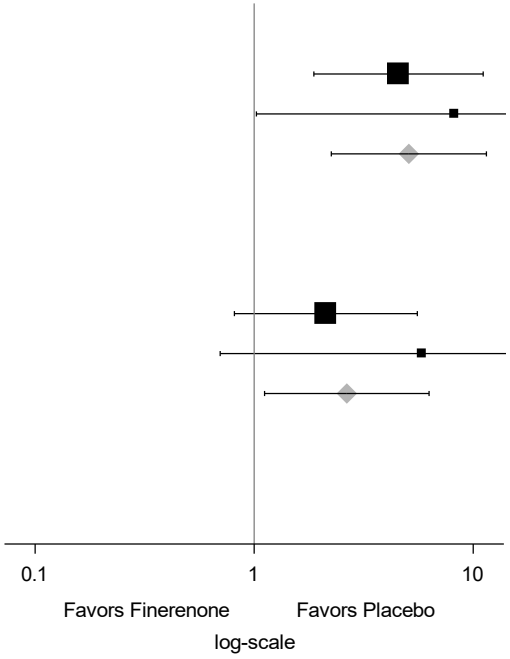
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1634	8 / 1657	77.3	2.68 [1.19,6.08]	
FIGARO-DKD	11 / 1010	2 / 989	22.7	5.43 [1.20,24.58]	
Total	32 / 2644	10 / 2646		3.24 [1.59,6.60]	Z=3.23, p=0.0012
Heterogeneity:	Q=0.65 (df=1)	p=0.4184	I^2=0.0%		
Black					
FIDELIO-DKD	5 / 129	1 / 115	100.0	4.60 [0.53,39.94]	
FIGARO-DKD	1 / 43	0 / 71	0.0	367E9 [367E9,367E9]	
Total	6 / 172	1 / 186		6.13 [0.72,51.86]	Z=1.66, p=0.0962
Heterogeneity:	Q=0.07 (df=1)	p=0.7943	I^2=0.0%		
Asian					
FIDELIO-DKD	12 / 678	2 / 677	100.0	6.08 [1.36,27.27]	
FIGARO-DKD	2 / 252	0 / 251	0.0	123E9 [123E9,123E9]	
Total	14 / 930	2 / 928		7.09 [1.61,31.29]	Z=2.59, p=0.0097
Heterogeneity:	Q=0.04 (df=1)	p=0.8412	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	1 / 161	100.0	1.84 [0.17,20.48]	
FIGARO-DKD	0 / 52	0 / 45	0.0	-	
Total	2 / 228	1 / 206		1.84 [0.17,20.48]	Z=0.50, p=0.6203
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.41 (df=3)	p=0.7036	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.161.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

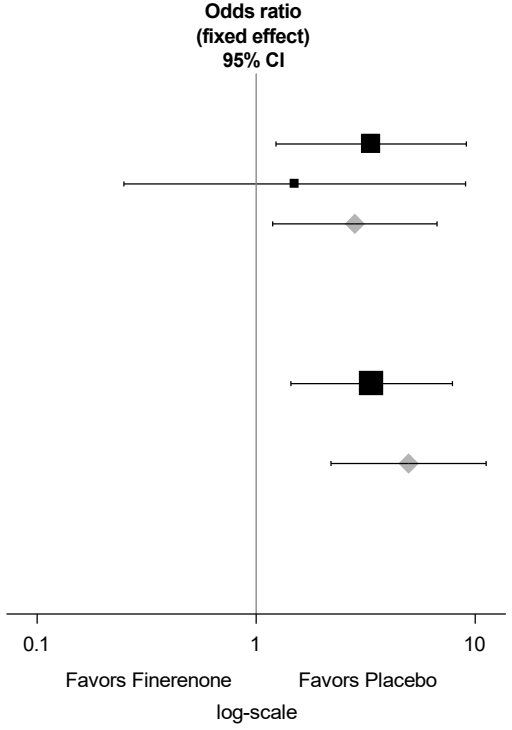
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	26 / 1797	6 / 1870	84.5	4.56 [1.87,11.11]	
FIGARO-DKD	8 / 917	1 / 933	15.5	8.20 [1.02,65.71]	
Total	34 / 2714	7 / 2803		5.08 [2.25,11.49]	Z=3.91, p=<.0001
Heterogeneity:	Q=0.26 (df=1)	p=0.6100	I^2=0.0%		
Female					
FIDELIO-DKD	14 / 820	6 / 740	83.0	2.12 [0.81,5.56]	
FIGARO-DKD	6 / 440	1 / 423	17.0	5.83 [0.70,48.66]	
Total	20 / 1260	7 / 1163		2.65 [1.12,6.29]	Z=2.21, p=0.0273
Heterogeneity:	Q=0.73 (df=1)	p=0.3916	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.16 (df=1)	p=0.2822	I^2=13.5%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.161.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

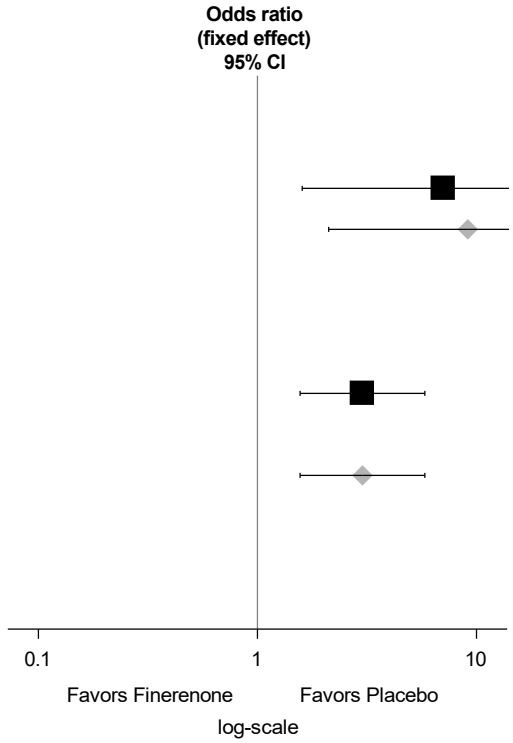
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	17 / 1103	5 / 1075	76.3	3.35 [1.23,9.11]	
FIGARO-DKD	3 / 336	2 / 335	23.7	1.50 [0.25,9.03]	
Total	20 / 1439	7 / 1410		2.82 [1.19,6.70]	Z=2.35, p=0.0186
Heterogeneity:	Q=0.59 (df=1)	p=0.4429	I^2=0.0%		
>= 65					
FIDELIO-DKD	23 / 1514	7 / 1535	100.0	3.37 [1.44,7.87]	
FIGARO-DKD	11 / 1021	0 / 1021	0.0	168E9 [168E9,168E9]	
Total	34 / 2535	7 / 2556		4.96 [2.20,11.22]	Z=3.85, p=0.0001
Heterogeneity:	Q=0.80 (df=1)	p=0.3704	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.87 (df=1)	p=0.3516	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.161.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

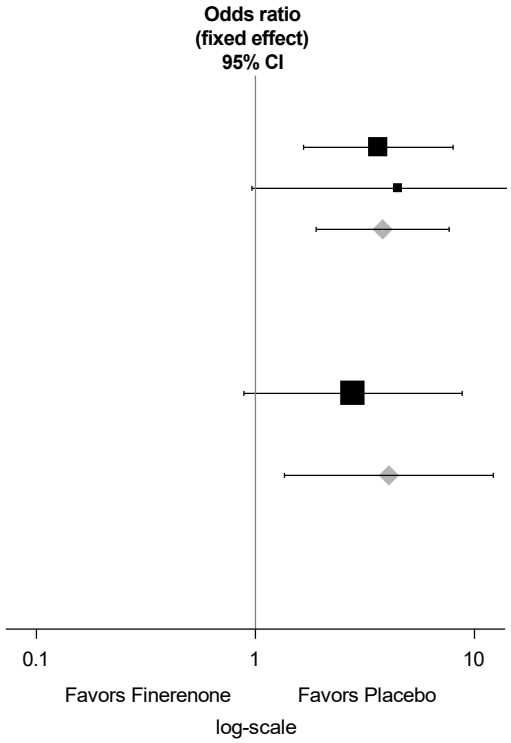
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	0 / 213	0.0	111E9 [111E9,111E9]	
FIGARO-DKD	14 / 1357	2 / 1356	100.0	7.06 [1.60,31.11]	
Total	18 / 1566	2 / 1569		9.13 [2.11,39.40]	Z=2.96, p=0.0030
Heterogeneity:	Q=0.12 (df=1)	p=0.7341	I^2=0.0%		
Very High					
FIDELIO-DKD	36 / 2408	12 / 2397	100.0	3.02 [1.57,5.81]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	36 / 2408	12 / 2397		3.02 [1.57,5.81]	Z=3.30, p=0.0010
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.83 (df=1)	p=0.1758	I^2=45.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.161.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

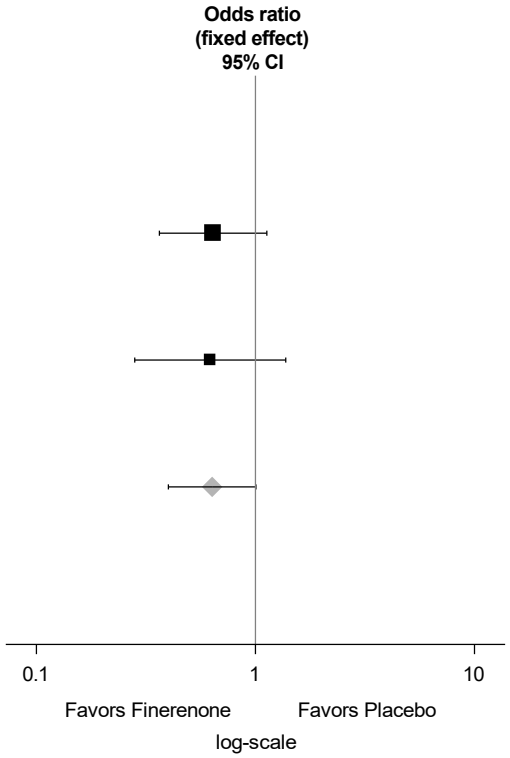
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	29 / 1556	8 / 1541	79.3	3.64 [1.66,7.99]	
FIGARO-DKD	9 / 637	2 / 627	20.7	4.48 [0.96,20.81]	
Total	38 / 2193	10 / 2168		3.81 [1.89,7.66]	Z=3.75, p=0.0002
Heterogeneity:	Q=0.06 (df=1)	p=0.8136	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	11 / 1061	4 / 1069	100.0	2.79 [0.89,8.79]	
FIGARO-DKD	5 / 720	0 / 729	0.0	108E9 [108E9,108E9]	
Total	16 / 1781	4 / 1798		4.07 [1.36,12.19]	Z=2.50, p=0.0123
Heterogeneity:	Q=0.41 (df=1)	p=0.5199	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.01 (df=1)	p=0.9214	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.162: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

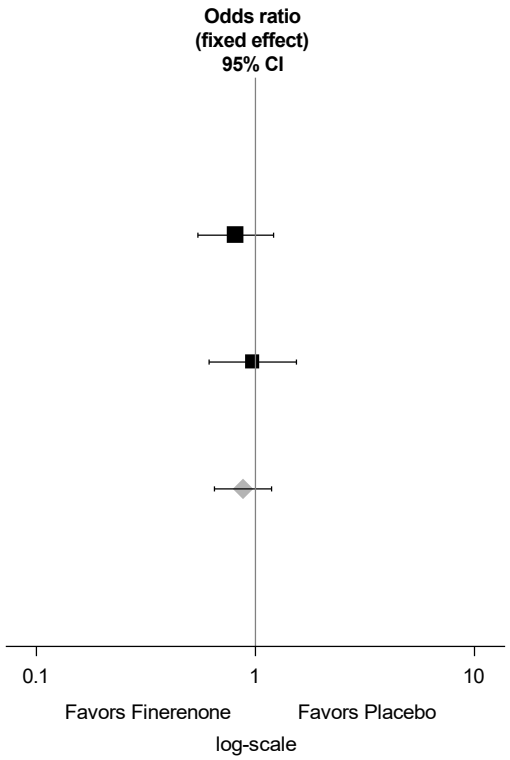
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	20 / 2617	31 / 2610	66.4	0.64 [0.36,1.13]	
FIGARO-DKD	10 / 1357	16 / 1356	33.6	0.62 [0.28,1.38]	
Total	30 / 3974	47 / 3966		0.63 [0.40,1.00]	Z=-1.94, p=0.0525
Heterogeneity:	Q=0.00 (df=1)	p=0.9519	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.163: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

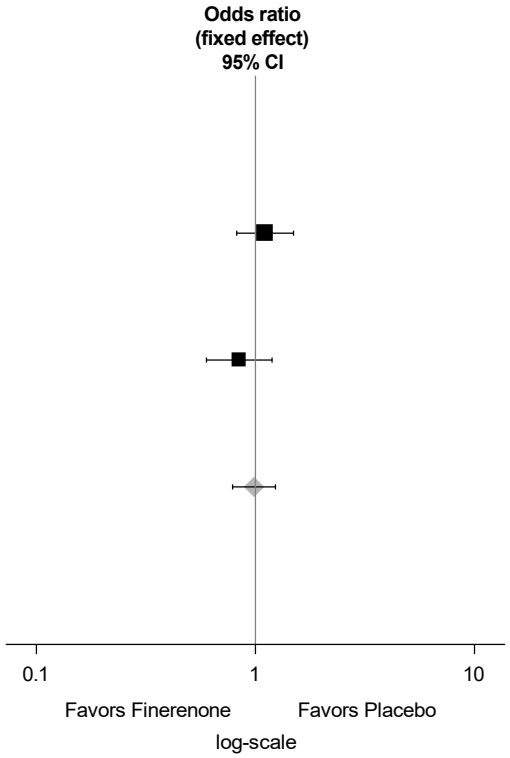
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	55 / 2610	57.1	0.81 [0.55,1.21]	
FIGARO-DKD	37 / 1357	38 / 1356	42.9	0.97 [0.61,1.54]	
Total	82 / 3974	93 / 3966		0.88 [0.65,1.18]	Z=-0.85, p=0.3937
Heterogeneity:	Q=0.33 (df=1)	p=0.5633	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.164: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

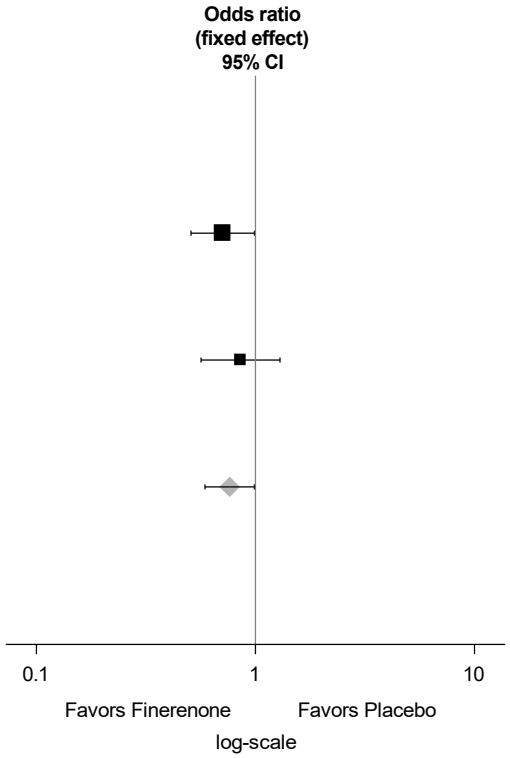
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	94 / 2617	85 / 2610	57.2	1.11 [0.82,1.49]	
FIGARO-DKD	63 / 1357	74 / 1356	42.8	0.84 [0.60,1.19]	
Total	157 / 3974	159 / 3966		0.98 [0.79,1.23]	Z=-0.13, p=0.8953
Heterogeneity:	Q=1.36 (df=1)	p=0.2429	I^2=26.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.165: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

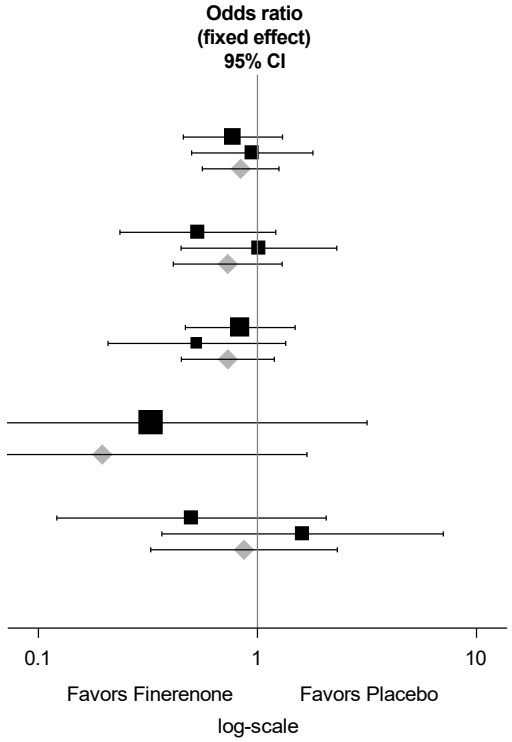
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	85 / 2610	60.7	0.71 [0.51,0.99]	
FIGARO-DKD	43 / 1357	50 / 1356	39.3	0.85 [0.56,1.29]	
Total	104 / 3974	135 / 3966		0.76 [0.59,0.99]	Z=-2.05, p=0.0408
Heterogeneity:	Q=0.47 (df=1)	p=0.4909	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.165.1: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Region - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

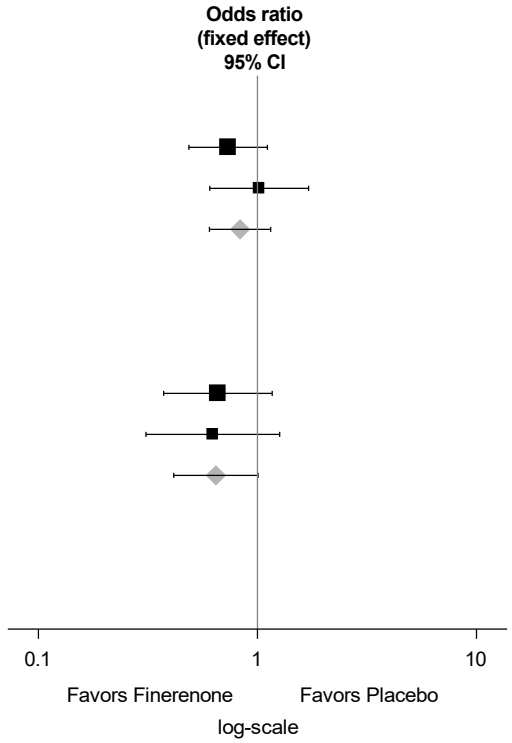
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	26 / 1075	33 / 1062	60.0	0.77 [0.46,1.30]	
FIGARO-DKD	19 / 638	20 / 637	40.0	0.95 [0.50,1.79]	
Total	45 / 1713	53 / 1699		0.84 [0.56,1.25]	Z=-0.86, p=0.3904
Heterogeneity:	Q=0.23 (df=1)	p=0.6288	I^2=0.0%		
North America					
FIDELIO-DKD	9 / 424	17 / 436	50.0	0.53 [0.24,1.21]	
FIGARO-DKD	12 / 267	12 / 271	50.0	1.02 [0.45,2.30]	
Total	21 / 691	29 / 707		0.73 [0.41,1.30]	Z=-1.07, p=0.2841
Heterogeneity:	Q=1.18 (df=1)	p=0.2772	I^2=15.3%		
Asia					
FIDELIO-DKD	22 / 751	26 / 745	72.4	0.83 [0.47,1.49]	
FIGARO-DKD	7 / 289	13 / 290	27.6	0.53 [0.21,1.35]	
Total	29 / 1040	39 / 1035		0.73 [0.45,1.19]	Z=-1.25, p=0.2120
Heterogeneity:	Q=0.66 (df=1)	p=0.4153	I^2=0.0%		
Latin America					
FIDELIO-DKD	1 / 273	3 / 270	100.0	0.33 [0.03,3.17]	
FIGARO-DKD	0 / 102	2 / 101	0.0	0.00 [0.00,16E296]	
Total	1 / 375	5 / 371		0.20 [0.02,1.68]	Z=-1.49, p=0.1374
Heterogeneity:	Q=0.20 (df=1)	p=0.6571	I^2=0.0%		
Others					
FIDELIO-DKD	3 / 94	6 / 97	52.2	0.50 [0.12,2.06]	
FIGARO-DKD	5 / 61	3 / 57	47.8	1.61 [0.37,7.06]	
Total	8 / 155	9 / 154		0.87 [0.33,2.32]	Z=-0.28, p=0.7779
Heterogeneity:	Q=1.25 (df=1)	p=0.2638	I^2=19.9%		
Subgroup Heterogeneity:	Q=1.85 (df=4)	p=0.7625	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.165.2: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by History of CVD - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

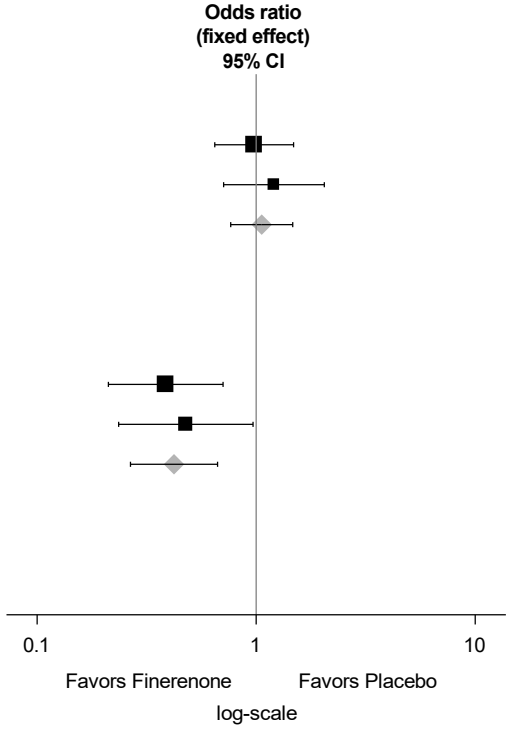
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	41 / 1213	55 / 1210	61.3	0.73 [0.49,1.11]	
FIGARO-DKD	30 / 862	29 / 848	38.7	1.02 [0.61,1.71]	
Total	71 / 2075	84 / 2058		0.83 [0.60,1.15]	Z=-1.11, p=0.2660
Heterogeneity:	Q=0.93 (df=1)	p=0.3346	I^2=0.0%		
Absent					
FIDELIO-DKD	20 / 1404	30 / 1400	60.3	0.66 [0.37,1.17]	
FIGARO-DKD	13 / 495	21 / 508	39.7	0.63 [0.31,1.26]	
Total	33 / 1899	51 / 1908		0.65 [0.41,1.01]	Z=-1.93, p=0.0532
Heterogeneity:	Q=0.01 (df=1)	p=0.9076	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.83 (df=1)	p=0.3630	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.165.3: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Serum Potassium (mmol/L) Category at Baseline - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

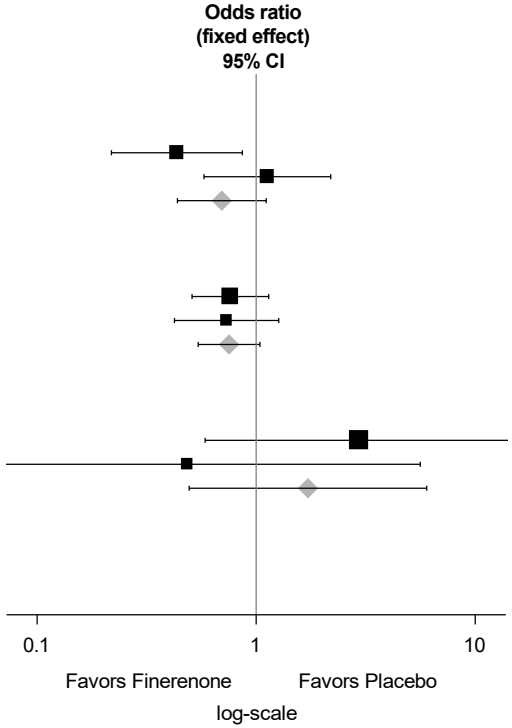
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	46 / 1735	46 / 1700	62.0	0.98 [0.65,1.48]	
FIGARO-DKD	31 / 924	26 / 929	38.0	1.21 [0.71,2.05]	
Total	77 / 2659	72 / 2629		1.06 [0.77,1.47]	Z=0.35, p=0.7261
Heterogeneity:	Q=0.37 (df=1)	p=0.5443	I^2=0.0%		
> 4.5					
FIDELIO-DKD	15 / 882	39 / 910	57.9	0.39 [0.21,0.71]	
FIGARO-DKD	12 / 433	24 / 426	42.1	0.48 [0.24,0.97]	
Total	27 / 1315	63 / 1336		0.42 [0.27,0.67]	Z=-3.70, p=0.0002
Heterogeneity:	Q=0.20 (df=1)	p=0.6551	I^2=0.0%		
Subgroup Heterogeneity:	Q=10.34 (df=1)	p=0.0013	I^2=90.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.165.4: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

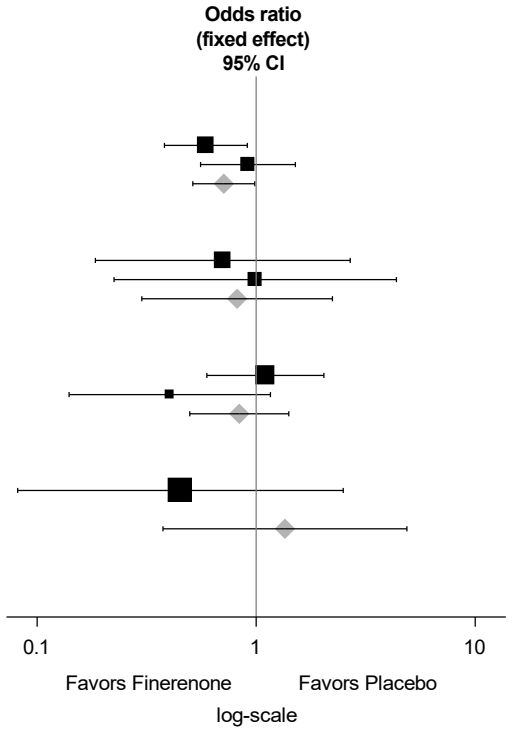
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	12 / 724	27 / 723	48.4	0.43 [0.22,0.86]	
FIGARO-DKD	19 / 494	17 / 495	51.6	1.12 [0.58,2.19]	
Total	31 / 1218	44 / 1218		0.70 [0.44,1.11]	Z=-1.52, p=0.1293
Heterogeneity:	Q=3.79 (df=1)	p=0.0515	I^2=73.6%		
130 - < 160					
FIDELIO-DKD	43 / 1759	56 / 1760	64.9	0.76 [0.51,1.14]	
FIGARO-DKD	23 / 829	31 / 827	35.1	0.73 [0.42,1.27]	
Total	66 / 2588	87 / 2587		0.75 [0.54,1.04]	Z=-1.72, p=0.0852
Heterogeneity:	Q=0.01 (df=1)	p=0.9087	I^2=0.0%		
>= 160					
FIDELIO-DKD	6 / 133	2 / 127	69.6	2.95 [0.58,14.91]	
FIGARO-DKD	1 / 34	2 / 34	30.4	0.48 [0.04,5.61]	
Total	7 / 167	4 / 161		1.72 [0.49,6.01]	Z=0.85, p=0.3929
Heterogeneity:	Q=1.45 (df=1)	p=0.2278	I^2=31.3%		
Subgroup Heterogeneity:	Q=1.79 (df=2)	p=0.4089	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.165.5: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Race - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

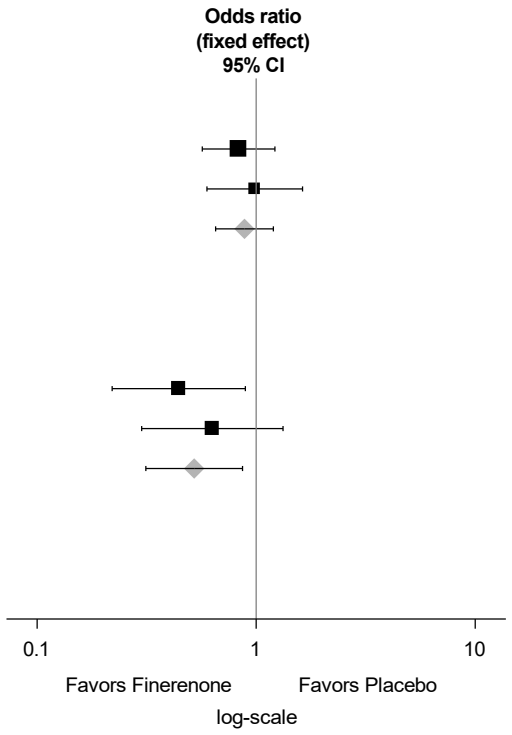
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	33 / 1634	56 / 1657	56.7	0.59 [0.38,0.91]	
FIGARO-DKD	31 / 1010	33 / 989	43.3	0.92 [0.56,1.51]	
Total	64 / 2644	89 / 2646		0.71 [0.51,0.99]	Z=-2.05, p=0.0407
Heterogeneity:	Q=1.72 (df=1)	p=0.1900	I^2=41.8%		
Black					
FIDELIO-DKD	4 / 129	5 / 115	55.1	0.70 [0.18,2.69]	
FIGARO-DKD	3 / 43	5 / 71	44.9	0.99 [0.22,4.37]	
Total	7 / 172	10 / 186		0.82 [0.30,2.23]	Z=-0.39, p=0.6951
Heterogeneity:	Q=0.11 (df=1)	p=0.7382	I^2=0.0%		
Asian					
FIDELIO-DKD	22 / 678	20 / 677	74.7	1.10 [0.60,2.04]	
FIGARO-DKD	5 / 252	12 / 251	25.3	0.40 [0.14,1.16]	
Total	27 / 930	32 / 928		0.84 [0.50,1.41]	Z=-0.67, p=0.5033
Heterogeneity:	Q=2.60 (df=1)	p=0.1071	I^2=61.5%		
Others					
FIDELIO-DKD	2 / 176	4 / 161	100.0	0.45 [0.08,2.50]	
FIGARO-DKD	4 / 52	0 / 45	0.0	174E9 [174E9,174E9]	
Total	6 / 228	4 / 206		1.35 [0.38,4.88]	Z=0.46, p=0.6440
Heterogeneity:	Q=1.58 (df=1)	p=0.2084	I^2=36.8%		
Subgroup Heterogeneity:	Q=1.08 (df=3)	p=0.7817	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.165.6: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Sex - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

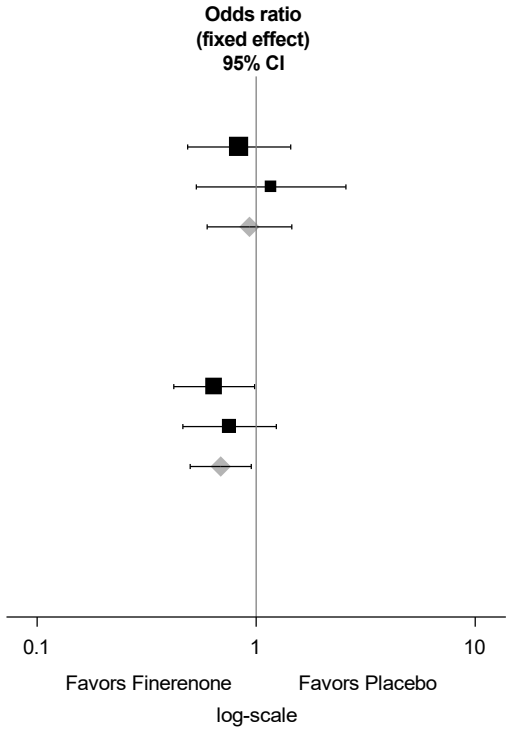
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	49 / 1797	61 / 1870	63.4	0.83 [0.57,1.22]	
FIGARO-DKD	31 / 917	32 / 933	36.6	0.99 [0.60,1.63]	
Total	80 / 2714	93 / 2803		0.88 [0.65,1.20]	Z=-0.79, p=0.4280
Heterogeneity:	Q=0.28 (df=1)	p=0.5980	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 820	24 / 740	53.0	0.44 [0.22,0.89]	
FIGARO-DKD	12 / 440	18 / 423	47.0	0.63 [0.30,1.33]	
Total	24 / 1260	42 / 1163		0.52 [0.31,0.87]	Z=-2.51, p=0.0120
Heterogeneity:	Q=0.46 (df=1)	p=0.4975	I^2=0.0%		
Subgroup Heterogeneity:	Q=3.07 (df=1)	p=0.0800	I^2=67.4%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.165.7: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Age Group (years) - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

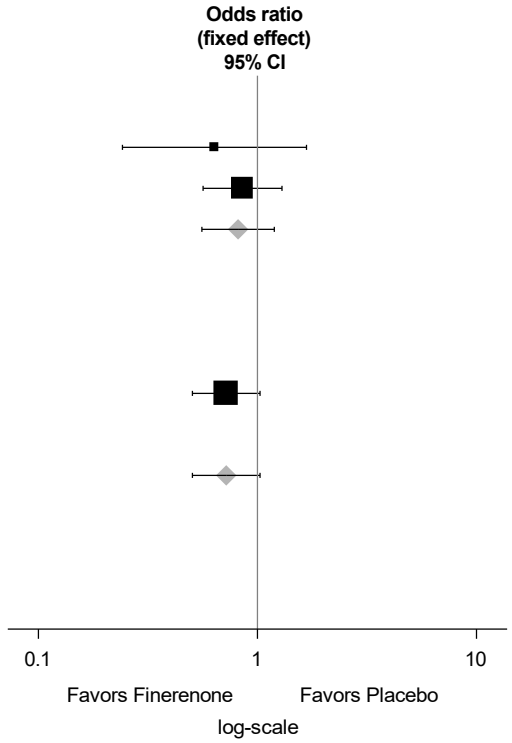
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	25 / 1103	29 / 1075	67.8	0.84 [0.49,1.44]	
FIGARO-DKD	14 / 336	12 / 335	32.2	1.17 [0.53,2.57]	
Total	39 / 1439	41 / 1410		0.93 [0.60,1.45]	Z=-0.31, p=0.7565
Heterogeneity:	Q=0.48 (df=1)	p=0.4906	I^2=0.0%		
>= 65					
FIDELIO-DKD	36 / 1514	56 / 1535	57.2	0.64 [0.42,0.98]	
FIGARO-DKD	29 / 1021	38 / 1021	42.8	0.76 [0.46,1.24]	
Total	65 / 2535	94 / 2556		0.69 [0.50,0.95]	Z=-2.27, p=0.0230
Heterogeneity:	Q=0.24 (df=1)	p=0.6255	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.16 (df=1)	p=0.2806	I^2=14.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.165.8: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by Type of Albuminuria at Screening - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	7 / 209	11 / 213	15.5	0.64 [0.24,1.67]	
FIGARO-DKD	43 / 1357	50 / 1356	84.5	0.85 [0.56,1.29]	
Total	50 / 1566	61 / 1569		0.82 [0.56,1.19]	Z=-1.05, p=0.2945
Heterogeneity:	Q=0.30 (df=1)	p=0.5827	I^2=0.0%		
Very High					
FIDELIO-DKD	54 / 2408	74 / 2397	100.0	0.72 [0.50,1.03]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	54 / 2408	74 / 2397		0.72 [0.50,1.03]	Z=-1.81, p=0.0702
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.22 (df=1)	p=0.6389	I^2=0.0%		

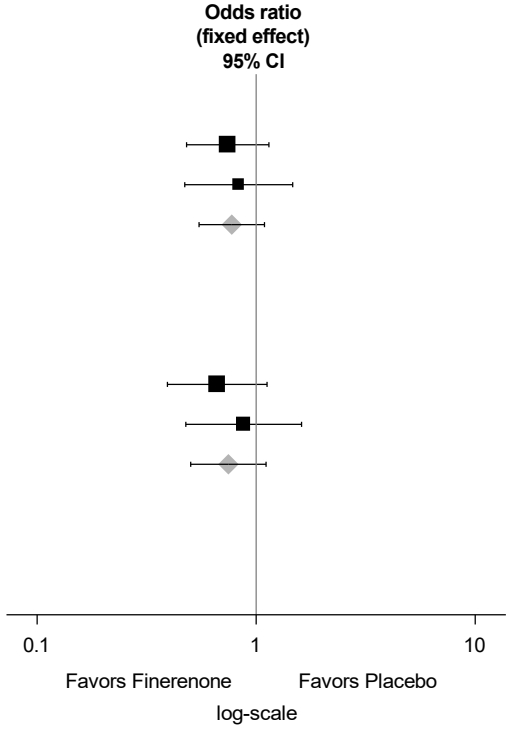


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.165.9: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs by eGFR (mL/min/1.73m2) Category at Screening - Nervous System Disorders (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

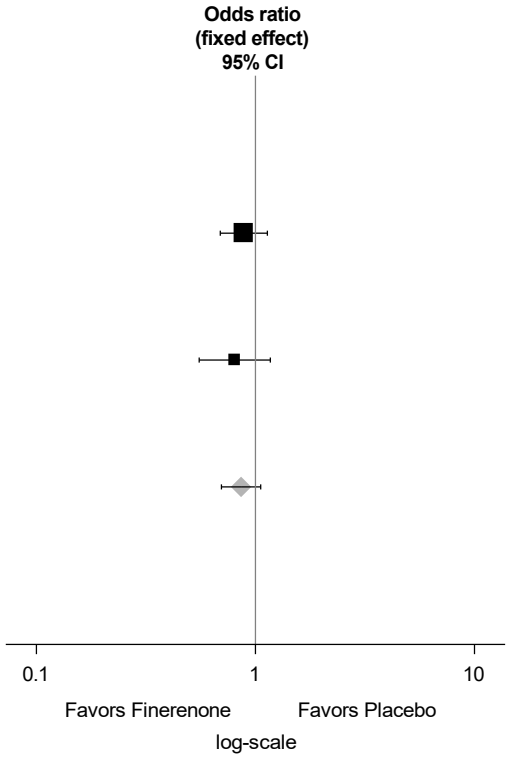
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	37 / 1556	49 / 1541	63.2	0.74 [0.48,1.14]	
FIGARO-DKD	23 / 637	27 / 627	36.8	0.83 [0.47,1.47]	
Total	60 / 2193	76 / 2168		0.77 [0.55,1.09]	Z=-1.46, p=0.1438
Heterogeneity:	Q=0.10 (df=1)	p=0.7512	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	24 / 1061	36 / 1069	57.4	0.66 [0.39,1.12]	
FIGARO-DKD	20 / 720	23 / 729	42.6	0.88 [0.48,1.61]	
Total	44 / 1781	59 / 1798		0.75 [0.50,1.11]	Z=-1.45, p=0.1482
Heterogeneity:	Q=0.46 (df=1)	p=0.4971	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.02 (df=1)	p=0.8942	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.166: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

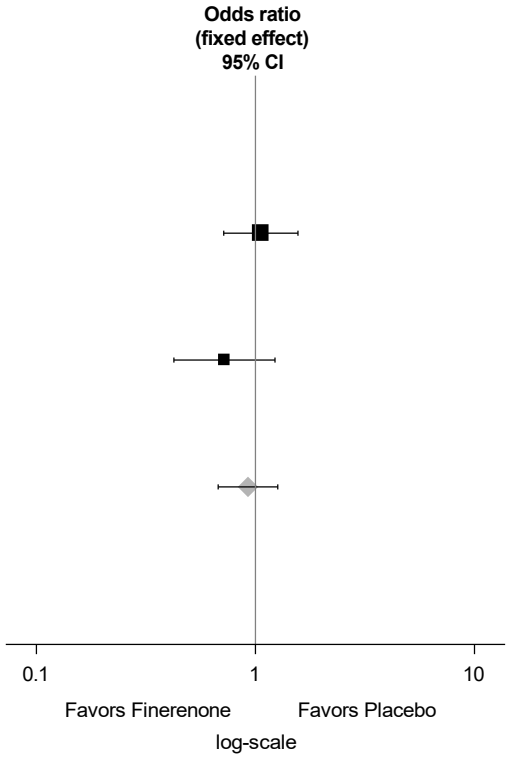
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	125 / 2617	140 / 2610	69.5	0.88 [0.69,1.13]	
FIGARO-DKD	52 / 1357	64 / 1356	30.5	0.80 [0.55,1.17]	
Total	177 / 3974	204 / 3966		0.86 [0.70,1.06]	Z=-1.44, p=0.1505
Heterogeneity:	Q=0.17 (df=1)	p=0.6765	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.167: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

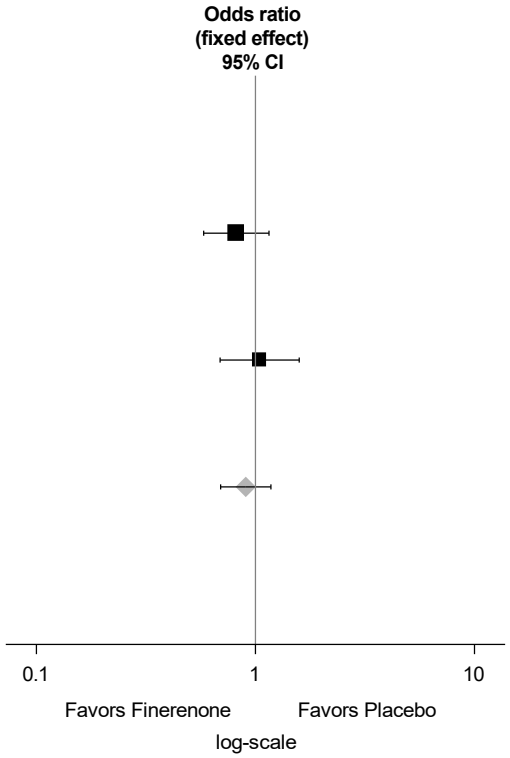
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	53 / 2617	50 / 2610	65.0	1.06 [0.72,1.56]	
FIGARO-DKD	24 / 1357	33 / 1356	35.0	0.72 [0.42,1.23]	
Total	77 / 3974	83 / 3966		0.92 [0.68,1.26]	Z=-0.49, p=0.6229
Heterogeneity:	Q=1.29 (df=1)	p=0.2552	I^2=22.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.168: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

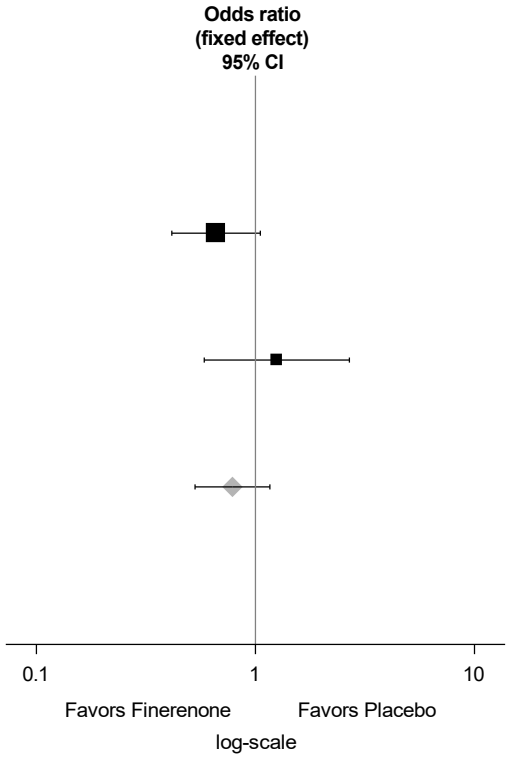
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	61 / 2617	74 / 2610	59.5	0.82 [0.58,1.15]	
FIGARO-DKD	47 / 1357	45 / 1356	40.5	1.05 [0.69,1.58]	
Total	108 / 3974	119 / 3966		0.90 [0.69,1.18]	Z=-0.76, p=0.4502
Heterogeneity:	Q=0.79 (df=1)	p=0.3727	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.169: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Skin And Subcutaneous Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

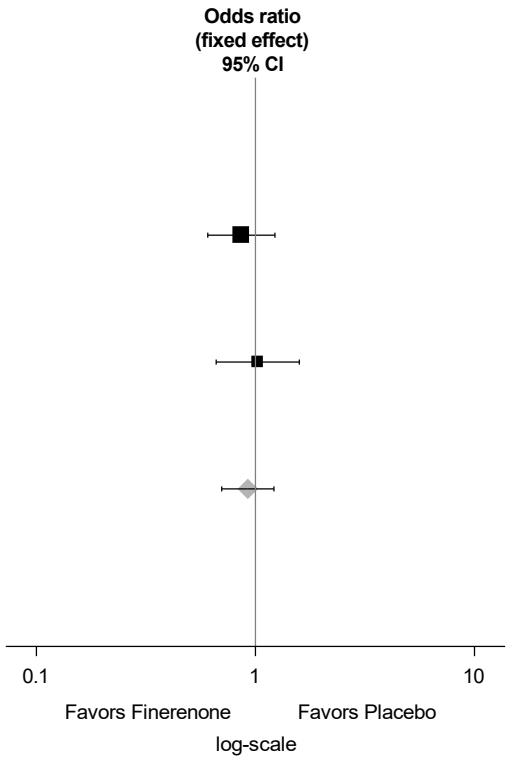
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	45 / 2610	72.9	0.66 [0.42,1.05]	
FIGARO-DKD	15 / 1357	12 / 1356	27.1	1.25 [0.58,2.68]	
Total	45 / 3974	57 / 3966		0.79 [0.53,1.16]	Z=-1.20, p=0.2285
Heterogeneity:	Q=1.96 (df=1)	p=0.1612	I^2=49.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.170: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Surgical And Medical Procedures (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

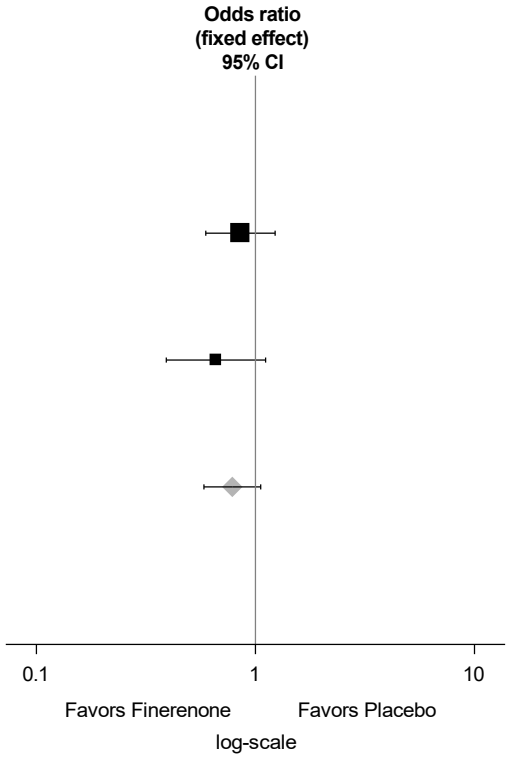
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	59 / 2617	68 / 2610	60.5	0.86 [0.61,1.23]	
FIGARO-DKD	42 / 1357	41 / 1356	39.5	1.02 [0.66,1.59]	
Total	101 / 3974	109 / 3966		0.92 [0.70,1.21]	Z=-0.57, p=0.5663
Heterogeneity:	Q=0.36 (df=1)	p=0.5477	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.171: Forest Plot for Odds Ratio of Proportion of Subjects with TESAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

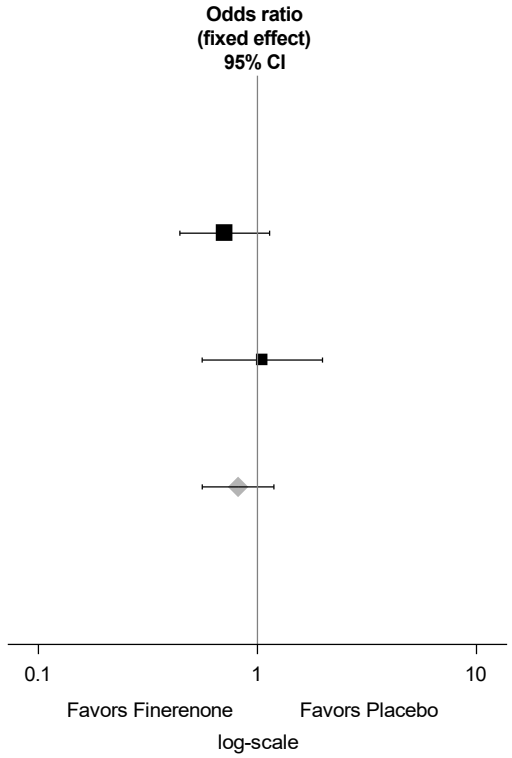
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	55 / 2617	64 / 2610	67.2	0.85 [0.59,1.23]	
FIGARO-DKD	24 / 1357	36 / 1356	32.8	0.66 [0.39,1.11]	
Total	79 / 3974	100 / 3966		0.78 [0.58,1.06]	Z=-1.60, p=0.1101
Heterogeneity:	Q=0.63 (df=1)	p=0.4281	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.172: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Cardiac Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

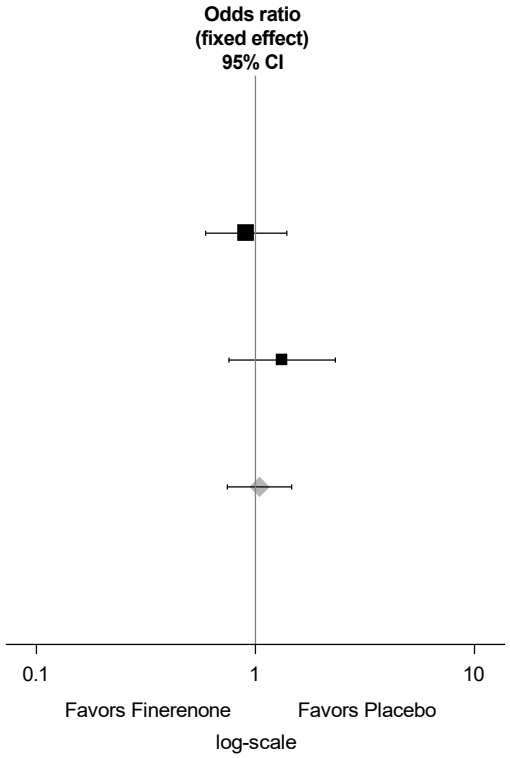
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	42 / 2610	64.3	0.71 [0.44,1.14]	
FIGARO-DKD	20 / 1357	19 / 1356	35.7	1.05 [0.56,1.98]	
Total	50 / 3974	61 / 3966		0.82 [0.56,1.19]	Z=-1.06, p=0.2890
Heterogeneity:	Q=0.96 (df=1)	p=0.3263	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.173: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Gastrointestinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

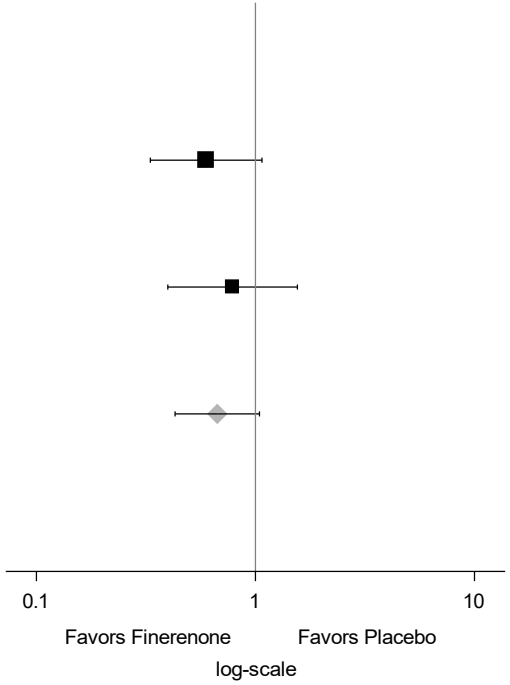
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	41 / 2617	45 / 2610	63.2	0.91 [0.59,1.39]	
FIGARO-DKD	29 / 1357	22 / 1356	36.8	1.32 [0.76,2.32]	
Total	70 / 3974	67 / 3966		1.04 [0.74,1.46]	Z=0.25, p=0.8049
Heterogeneity:	Q=1.11 (df=1)	p=0.2921	I^2=9.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.174: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - General Disorders And Administration Site Conditions (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

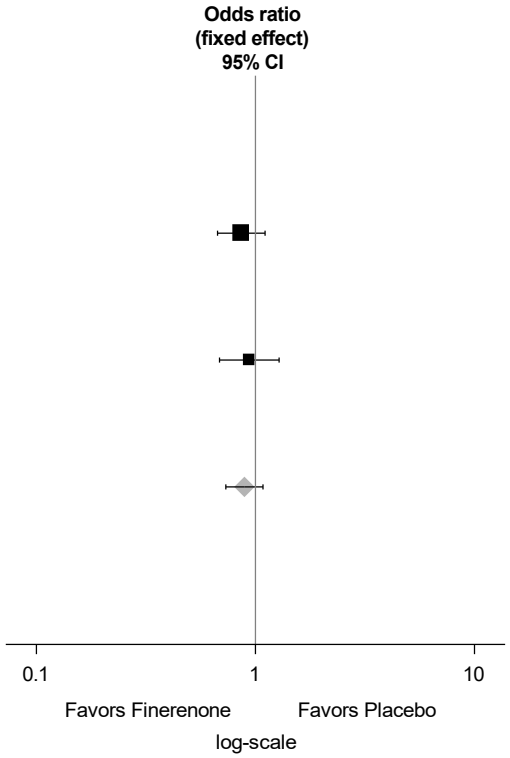
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	18 / 2617	30 / 2610	57.4	0.60 [0.33,1.07]	
FIGARO-DKD	15 / 1357	19 / 1356	42.6	0.79 [0.40,1.55]	
Total	33 / 3974	49 / 3966		0.67 [0.43,1.04]	Z=-1.77, p=0.0762
Heterogeneity:	Q=0.37 (df=1)	p=0.5444	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.175: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Infections And Infestations (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

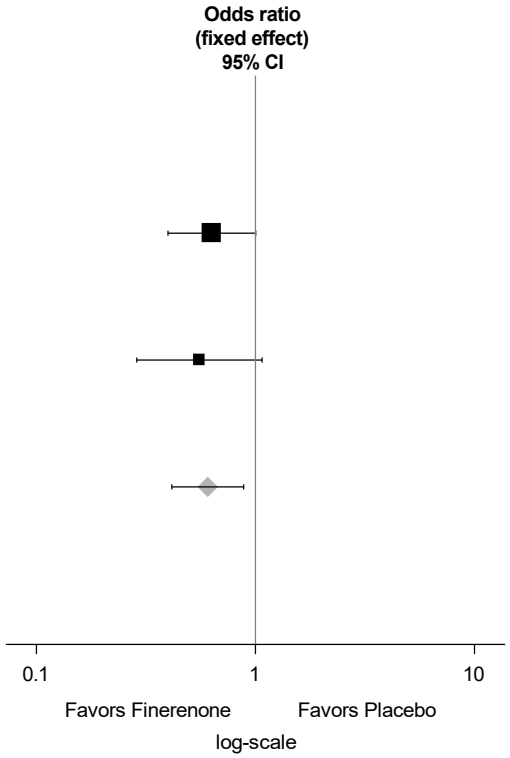
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	121 / 2617	139 / 2610	61.1	0.86 [0.67,1.11]	
FIGARO-DKD	81 / 1357	86 / 1356	38.9	0.94 [0.69,1.28]	
Total	202 / 3974	225 / 3966		0.89 [0.73,1.08]	Z=-1.16, p=0.2442
Heterogeneity:	Q=0.17 (df=1)	p=0.6807	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.176: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

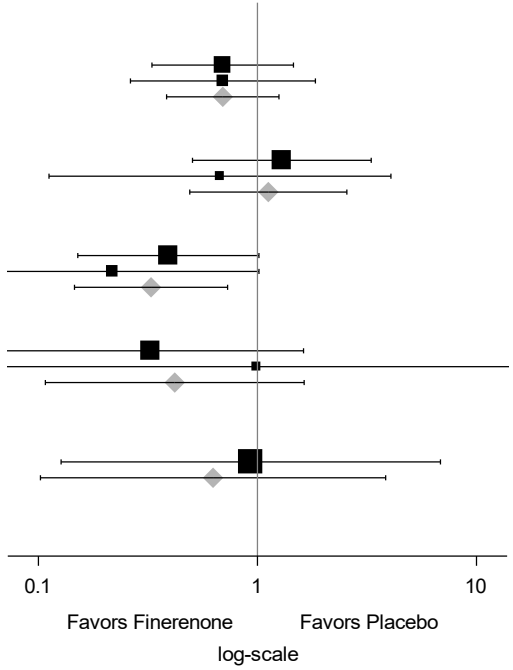
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	30 / 2617	47 / 2610	67.1	0.63 [0.40,1.00]	
FIGARO-DKD	14 / 1357	25 / 1356	32.9	0.55 [0.29,1.07]	
Total	44 / 3974	72 / 3966		0.61 [0.42,0.88]	Z=-2.60, p=0.0092
Heterogeneity:	Q=0.10 (df=1)	p=0.7504	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.176.1: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

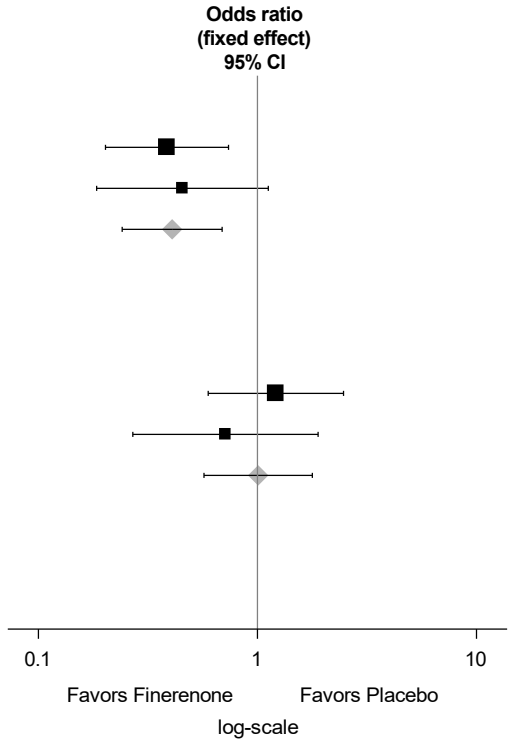
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	12 / 1075	17 / 1062	63.1	0.69 [0.33,1.46]	
FIGARO-DKD	7 / 638	10 / 637	36.9	0.70 [0.26,1.84]	
Total	19 / 1713	27 / 1699		0.69 [0.38,1.25]	Z=-1.21, p=0.2265
Heterogeneity:	Q=0.00 (df=1)	p=0.9970	I^2=0.0%		
North America					
FIDELIO-DKD	10 / 424	8 / 436	78.5	1.29 [0.51,3.31]	
FIGARO-DKD	2 / 267	3 / 271	21.5	0.67 [0.11,4.07]	
Total	12 / 691	11 / 707		1.12 [0.49,2.56]	Z=0.27, p=0.7864
Heterogeneity:	Q=0.40 (df=1)	p=0.5295	I^2=0.0%		
Asia					
FIDELIO-DKD	6 / 751	15 / 745	72.4	0.39 [0.15,1.02]	
FIGARO-DKD	2 / 289	9 / 290	27.6	0.22 [0.05,1.02]	
Total	8 / 1040	24 / 1035		0.33 [0.15,0.73]	Z=-2.72, p=0.0064
Heterogeneity:	Q=0.41 (df=1)	p=0.5231	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	6 / 270	75.0	0.32 [0.06,1.62]	
FIGARO-DKD	1 / 102	1 / 101	25.0	0.99 [0.06,16.05]	
Total	3 / 375	7 / 371		0.42 [0.11,1.63]	Z=-1.25, p=0.2104
Heterogeneity:	Q=0.46 (df=1)	p=0.4965	I^2=0.0%		
Others					
FIDELIO-DKD	0 / 94	1 / 97	0.0	0.00 [0.00,11E296]	
FIGARO-DKD	2 / 61	2 / 57	100.0	0.93 [0.13,6.85]	
Total	2 / 155	3 / 154		0.63 [0.10,3.85]	Z=-0.50, p=0.6142
Heterogeneity:	Q=0.15 (df=1)	p=0.6968	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.87 (df=4)	p=0.3009	I^2=17.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.176.2: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

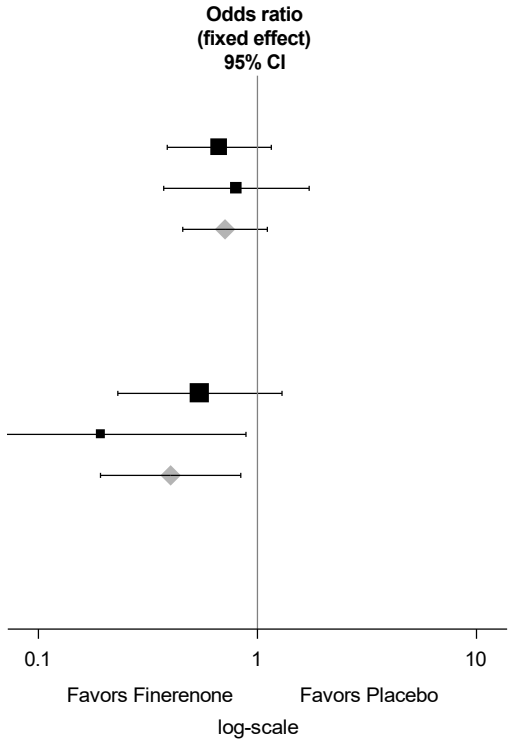
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	13 / 1213	33 / 1210	66.1	0.39 [0.20,0.74]	
FIGARO-DKD	7 / 862	15 / 848	33.9	0.45 [0.18,1.12]	
Total	20 / 2075	48 / 2058		0.41 [0.24,0.69]	Z=-3.35, p=0.0008
Heterogeneity:	Q=0.08 (df=1)	p=0.7739	I^2=0.0%		
Absent					
FIDELIO-DKD	17 / 1404	14 / 1400	65.2	1.21 [0.60,2.47]	
FIGARO-DKD	7 / 495	10 / 508	34.8	0.71 [0.27,1.89]	
Total	24 / 1899	24 / 1908		1.01 [0.57,1.78]	Z=0.03, p=0.9796
Heterogeneity:	Q=0.74 (df=1)	p=0.3892	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.23 (df=1)	p=0.0222	I^2=80.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.176.3: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	22 / 1735	32 / 1700	66.1	0.67 [0.39,1.16]	
FIGARO-DKD	12 / 924	15 / 929	33.9	0.80 [0.37,1.72]	
Total	34 / 2659	47 / 2629		0.71 [0.46,1.11]	Z=-1.50, p=0.1330
Heterogeneity:	Q=0.14 (df=1)	p=0.7069	I^2=0.0%		
> 4.5					
FIDELIO-DKD	8 / 882	15 / 910	75.7	0.55 [0.23,1.29]	
FIGARO-DKD	2 / 433	10 / 426	24.3	0.19 [0.04,0.89]	
Total	10 / 1315	25 / 1336		0.40 [0.19,0.84]	Z=-2.43, p=0.0153
Heterogeneity:	Q=1.38 (df=1)	p=0.2409	I^2=27.3%		
Subgroup Heterogeneity:	Q=1.70 (df=1)	p=0.1929	I^2=41.0%		

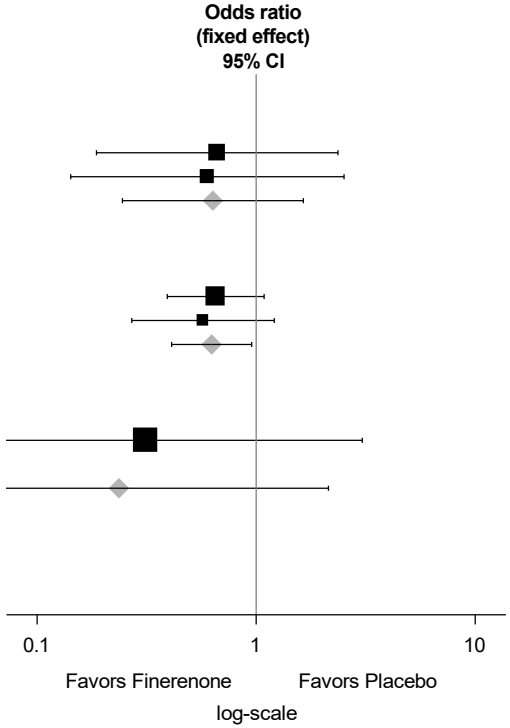


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.176.4: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Pneumonia (PT with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

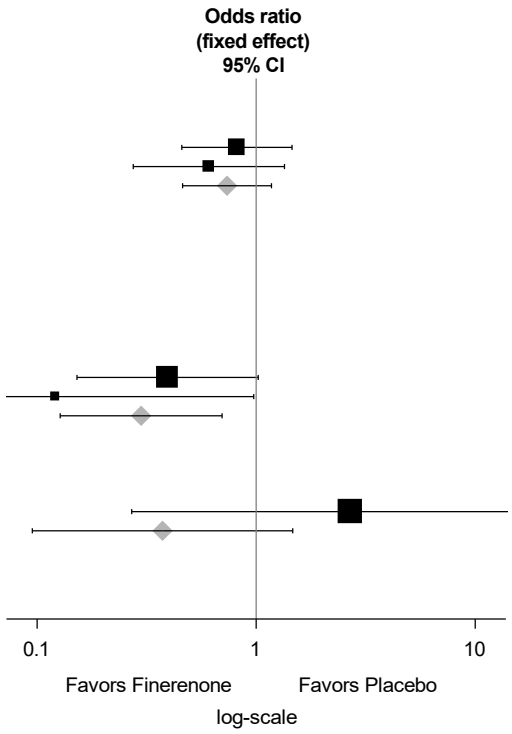
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	4 / 724	6 / 723	56.2	0.66 [0.19,2.36]	
FIGARO-DKD	3 / 494	5 / 495	43.8	0.60 [0.14,2.52]	
Total	7 / 1218	11 / 1218		0.63 [0.25,1.64]	Z=-0.94, p=0.3482
Heterogeneity:	Q=0.01 (df=1)	p=0.9160	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	25 / 1759	38 / 1760	68.4	0.65 [0.39,1.09]	
FIGARO-DKD	11 / 829	19 / 827	31.6	0.57 [0.27,1.21]	
Total	36 / 2588	57 / 2587		0.63 [0.41,0.95]	Z=-2.18, p=0.0292
Heterogeneity:	Q=0.08 (df=1)	p=0.7731	I^2=0.0%		
>= 160					
FIDELIO-DKD	1 / 133	3 / 127	100.0	0.31 [0.03,3.05]	
FIGARO-DKD	0 / 34	1 / 34	0.0	0.00 [0.00,1E297]	
Total	1 / 167	4 / 161		0.24 [0.03,2.14]	Z=-1.28, p=0.1992
Heterogeneity:	Q=0.06 (df=1)	p=0.8086	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.73 (df=2)	p=0.6930	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.176.5: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

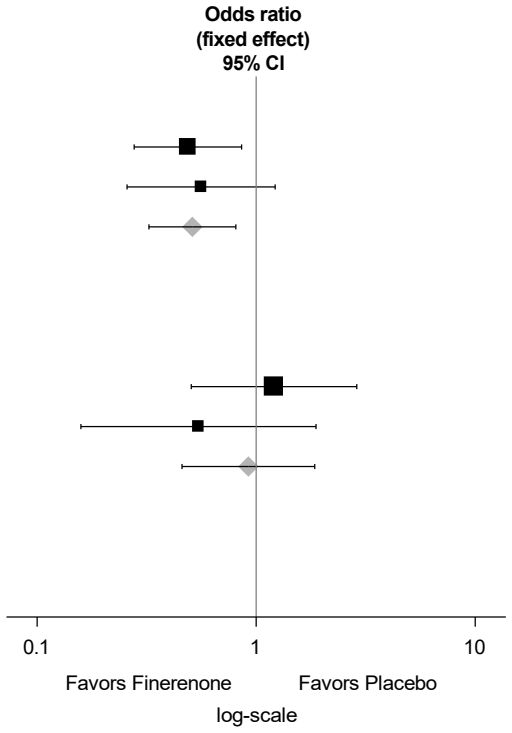
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	21 / 1634	26 / 1657	65.3	0.82 [0.46,1.46]	
FIGARO-DKD	10 / 1010	16 / 989	34.7	0.61 [0.27,1.35]	
Total	31 / 2644	42 / 2646		0.74 [0.46,1.17]	Z=-1.29, p=0.1987
Heterogeneity:	Q=0.35 (df=1)	p=0.5567	I^2=0.0%		
Black					
FIDELIO-DKD	3 / 129	0 / 115	0.0	135E9 [135E9,135E9]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	3 / 172	0 / 186		2E11 [2E11,2E11]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	6 / 678	15 / 677	82.7	0.39 [0.15,1.02]	
FIGARO-DKD	1 / 252	8 / 251	17.3	0.12 [0.02,0.97]	
Total	7 / 930	23 / 928		0.30 [0.13,0.70]	Z=-2.79, p=0.0053
Heterogeneity:	Q=1.05 (df=1)	p=0.3064	I^2=4.4%		
Others					
FIDELIO-DKD	0 / 176	6 / 161	0.0	0.00 [0.00,82E295]	
FIGARO-DKD	3 / 52	1 / 45	100.0	2.69 [0.27,26.86]	
Total	3 / 228	7 / 206		0.37 [0.10,1.47]	Z=-1.41, p=0.1586
Heterogeneity:	Q=2.84 (df=1)	p=0.0922	I^2=64.7%		
Subgroup Heterogeneity:	Q=3.74 (df=3)	p=0.2913	I^2=19.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.176.6: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

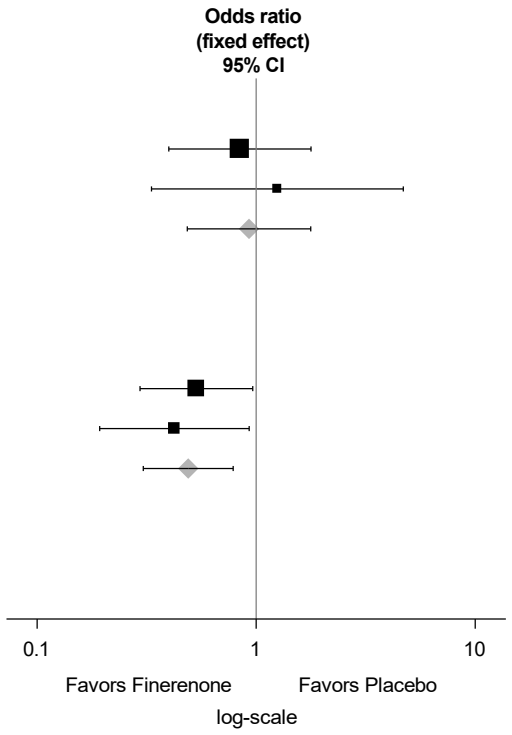
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	18 / 1797	38 / 1870	65.5	0.49 [0.28,0.86]	
FIGARO-DKD	10 / 917	18 / 933	34.5	0.56 [0.26,1.22]	
Total	28 / 2714	56 / 2803		0.51 [0.32,0.81]	Z=-2.88, p=0.0040
Heterogeneity:	Q=0.08 (df=1)	p=0.7772	I^2=0.0%		
Female					
FIDELIO-DKD	12 / 820	9 / 740	66.9	1.21 [0.51,2.88]	
FIGARO-DKD	4 / 440	7 / 423	33.1	0.55 [0.16,1.88]	
Total	16 / 1260	16 / 1163		0.92 [0.46,1.85]	Z=-0.23, p=0.8178
Heterogeneity:	Q=1.06 (df=1)	p=0.3030	I^2=5.7%		
Subgroup Heterogeneity:	Q=1.91 (df=1)	p=0.1665	I^2=47.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.176.7: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years) - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

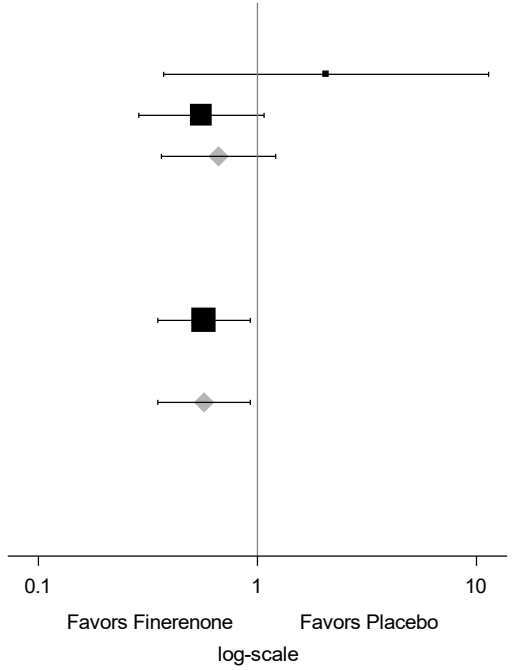
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	13 / 1103	15 / 1075	75.8	0.84 [0.40,1.78]	
FIGARO-DKD	5 / 336	4 / 335	24.2	1.25 [0.33,4.70]	
Total	18 / 1439	19 / 1410		0.93 [0.48,1.77]	Z=-0.23, p=0.8202
Heterogeneity:	Q=0.26 (df=1)	p=0.6113	I^2=0.0%		
>= 65					
FIDELIO-DKD	17 / 1514	32 / 1535	63.7	0.53 [0.29,0.96]	
FIGARO-DKD	9 / 1021	21 / 1021	36.3	0.42 [0.19,0.93]	
Total	26 / 2535	53 / 2556		0.49 [0.31,0.79]	Z=-2.96, p=0.0030
Heterogeneity:	Q=0.21 (df=1)	p=0.6458	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.43 (df=1)	p=0.1187	I^2=58.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.176.8: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

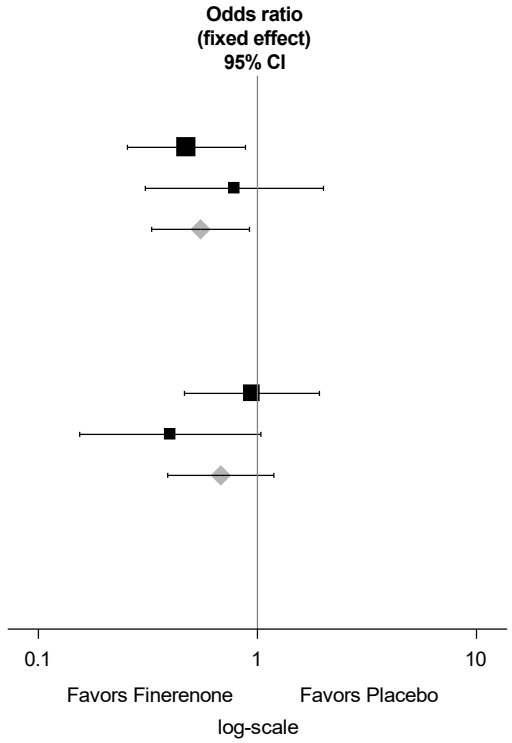
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	4 / 209	2 / 213	12.9	2.06 [0.37,11.36]	
FIGARO-DKD	14 / 1357	25 / 1356	87.1	0.55 [0.29,1.07]	
Total	18 / 1566	27 / 1569		0.66 [0.36,1.21]	Z=-1.34, p=0.1815
Heterogeneity:	Q=1.97 (df=1)	p=0.1604	I^2=49.2%		
Very High					
FIDELIO-DKD	26 / 2408	45 / 2397	100.0	0.57 [0.35,0.93]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	26 / 2408	45 / 2397		0.57 [0.35,0.93]	Z=-2.26, p=0.0237
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.15 (df=1)	p=0.7001	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.176.9: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Pneumonia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

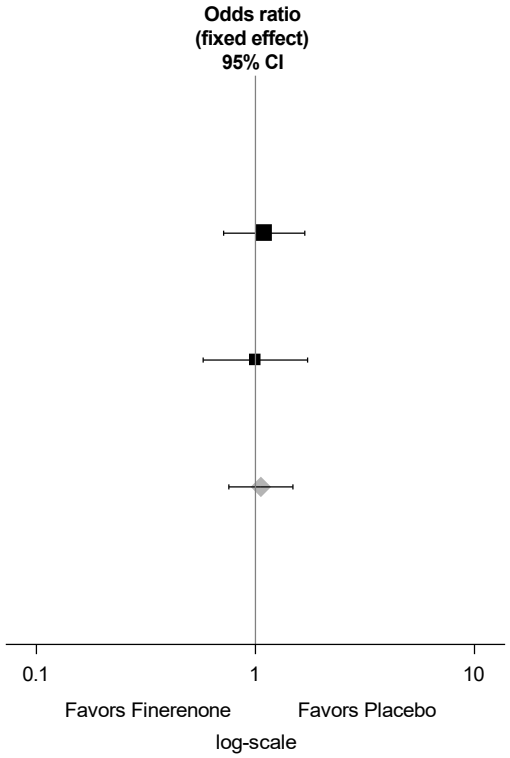
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	15 / 1556	31 / 1541	69.5	0.47 [0.25,0.88]	
FIGARO-DKD	8 / 637	10 / 627	30.5	0.78 [0.31,2.00]	
Total	23 / 2193	41 / 2168		0.55 [0.33,0.92]	Z=-2.28, p=0.0226
Heterogeneity:	Q=0.77 (df=1)	p=0.3792	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	15 / 1061	16 / 1069	64.3	0.94 [0.46,1.92]	
FIGARO-DKD	6 / 720	15 / 729	35.7	0.40 [0.15,1.04]	
Total	21 / 1781	31 / 1798		0.68 [0.39,1.19]	Z=-1.35, p=0.1756
Heterogeneity:	Q=2.01 (df=1)	p=0.1561	I^2=50.3%		
Subgroup Heterogeneity:	Q=0.30 (df=1)	p=0.5829	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.177: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

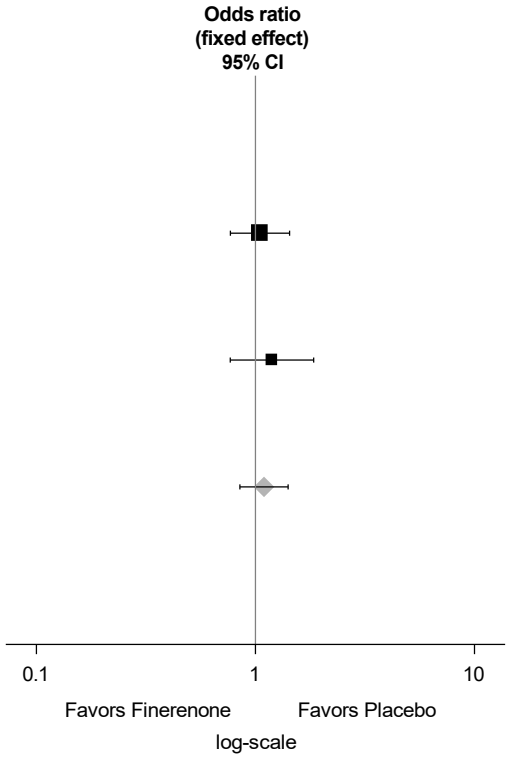
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	45 / 2617	41 / 2610	62.3	1.10 [0.72,1.68]	
FIGARO-DKD	26 / 1357	26 / 1356	37.7	1.00 [0.58,1.73]	
Total	71 / 3974	67 / 3966		1.06 [0.76,1.48]	Z=0.33, p=0.7399
Heterogeneity:	Q=0.07 (df=1)	p=0.7939	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.178: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Metabolism And Nutrition Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

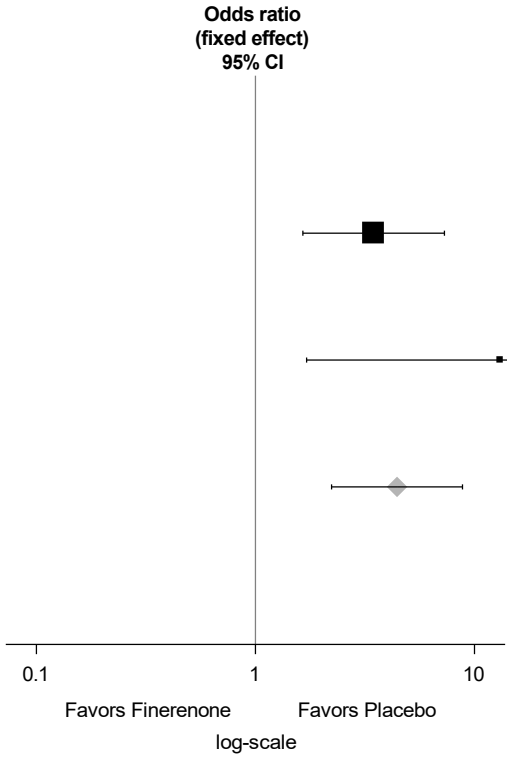
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	84 / 2617	80 / 2610	66.5	1.05 [0.77,1.43]	
FIGARO-DKD	45 / 1357	38 / 1356	33.5	1.19 [0.77,1.84]	
Total	129 / 3974	118 / 3966		1.09 [0.85,1.41]	Z=0.69, p=0.4873
Heterogeneity:	Q=0.21 (df=1)	p=0.6459	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.179: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

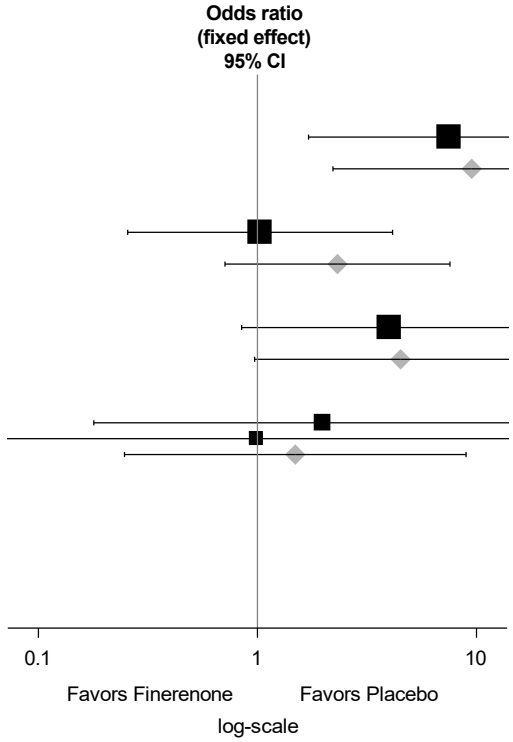
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	31 / 2617	9 / 2610	88.2	3.46 [1.65,7.29]	
FIGARO-DKD	13 / 1357	1 / 1356	11.8	13.11 [1.71,100.33]	
Total	44 / 3974	10 / 3966		4.43 [2.23,8.81]	Z=4.24, p=<.0001
Heterogeneity:	Q=1.51 (df=1)	p=0.2191	I^2=33.8%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.179.1: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Region - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

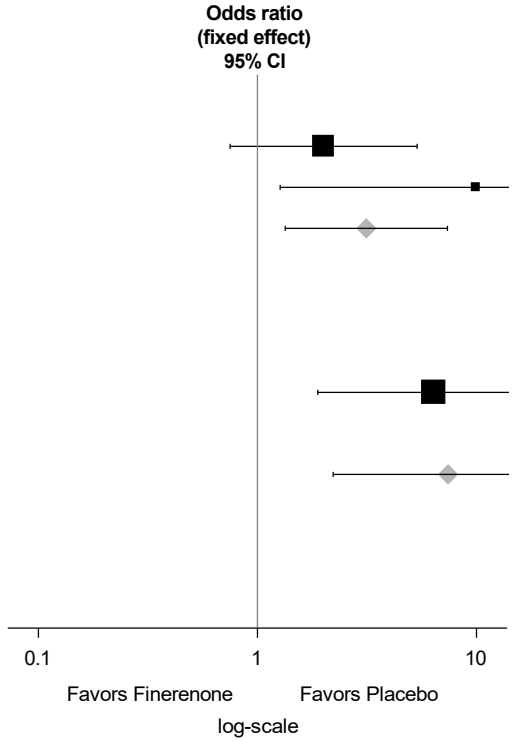
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Europe					
FIDELIO-DKD	15 / 1075	2 / 1062	100.0	7.50 [1.71,32.88]	
FIGARO-DKD	4 / 638	0 / 637	0.0	973E8 [973E8,973E8]	
Total	19 / 1713	2 / 1699		9.51 [2.21,40.91]	Z=3.03, p=0.0025
Heterogeneity:	Q=0.10 (df=1)	p=0.7526	I^2=0.0%		
North America					
FIDELIO-DKD	4 / 424	4 / 436	100.0	1.03 [0.26,4.14]	
FIGARO-DKD	5 / 267	0 / 271	0.0	108E9 [108E9,108E9]	
Total	9 / 691	4 / 707		2.32 [0.71,7.57]	Z=1.39, p=0.1632
Heterogeneity:	Q=1.31 (df=1)	p=0.2524	I^2=23.7%		
Asia					
FIDELIO-DKD	8 / 751	2 / 745	100.0	4.00 [0.85,18.90]	
FIGARO-DKD	1 / 289	0 / 290	0.0	145E9 [145E9,145E9]	
Total	9 / 1040	2 / 1035		4.50 [0.97,20.91]	Z=1.92, p=0.0546
Heterogeneity:	Q=0.02 (df=1)	p=0.8809	I^2=0.0%		
Latin America					
FIDELIO-DKD	2 / 273	1 / 270	57.3	1.99 [0.18,22.02]	
FIGARO-DKD	1 / 102	1 / 101	42.7	0.99 [0.06,16.05]	
Total	3 / 375	2 / 371		1.49 [0.25,8.96]	Z=0.43, p=0.6642
Heterogeneity:	Q=0.14 (df=1)	p=0.7110	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 94	0 / 97	0.0	123E9 [123E9,123E9]	
FIGARO-DKD	2 / 61	0 / 57	0.0	192E9 [192E9,192E9]	
Total	4 / 155	0 / 154		148E9 [148E9,148E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Subgroup Heterogeneity:	Q=3.24 (df=4)	p=0.5179	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.179.2: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by History of CVD - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

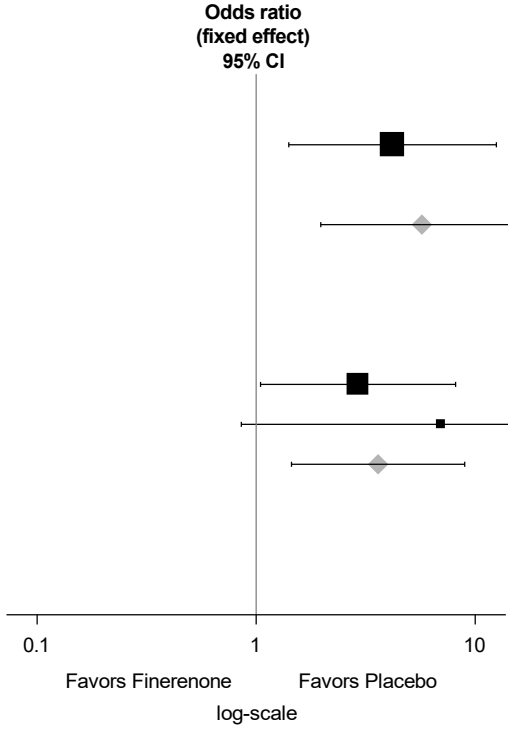
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Present					
FIDELIO-DKD	12 / 1213	6 / 1210	81.4	2.00 [0.75,5.36]	
FIGARO-DKD	10 / 862	1 / 848	18.6	9.94 [1.27,77.83]	
Total	22 / 2075	7 / 2058		3.14 [1.34,7.37]	Z=2.63, p=0.0085
Heterogeneity:	Q=2.01 (df=1)	p=0.1568	I^2=50.1%		
Absent					
FIDELIO-DKD	19 / 1404	3 / 1400	100.0	6.39 [1.89,21.64]	
FIGARO-DKD	3 / 495	0 / 508	0.0	94E9 [94E9,94E9]	
Total	22 / 1899	3 / 1908		7.42 [2.22,24.84]	Z=3.25, p=0.0011
Heterogeneity:	Q=0.06 (df=1)	p=0.8099	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.30 (df=1)	p=0.2546	I^2=22.9%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.179.3: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Serum Potassium (mmol/L) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

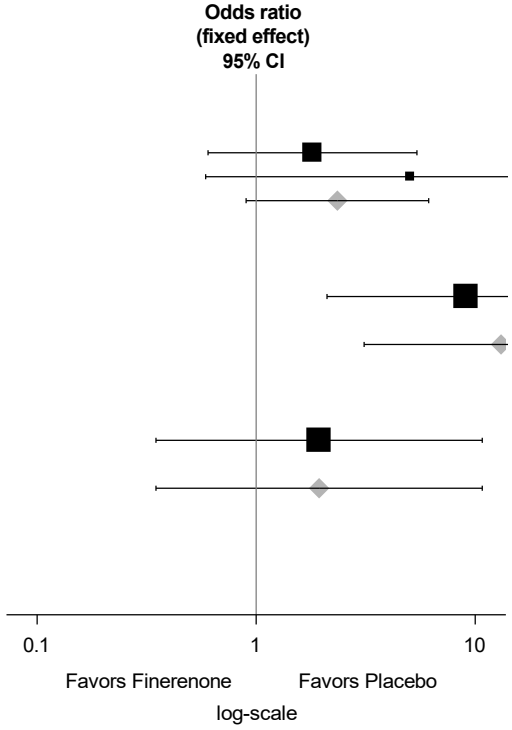
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
<= 4.5					
FIDELIO-DKD	17 / 1735	4 / 1700	100.0	4.20 [1.41,12.49]	
FIGARO-DKD	6 / 924	0 / 929	0.0	101E9 [101E9,101E9]	
Total	23 / 2659	4 / 2629		5.71 [1.97,16.54]	Z=3.21, p=0.0013
Heterogeneity:	Q=0.31 (df=1)	p=0.5799	I^2=0.0%		
> 4.5					
FIDELIO-DKD	14 / 882	5 / 910	80.7	2.92 [1.05,8.14]	
FIGARO-DKD	7 / 433	1 / 426	19.3	6.98 [0.86,57.01]	
Total	21 / 1315	6 / 1336		3.60 [1.45,8.96]	Z=2.76, p=0.0058
Heterogeneity:	Q=0.54 (df=1)	p=0.4610	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.42 (df=1)	p=0.5191	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.179.4: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Systolic Blood Pressure (mmHg) Category at Baseline - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

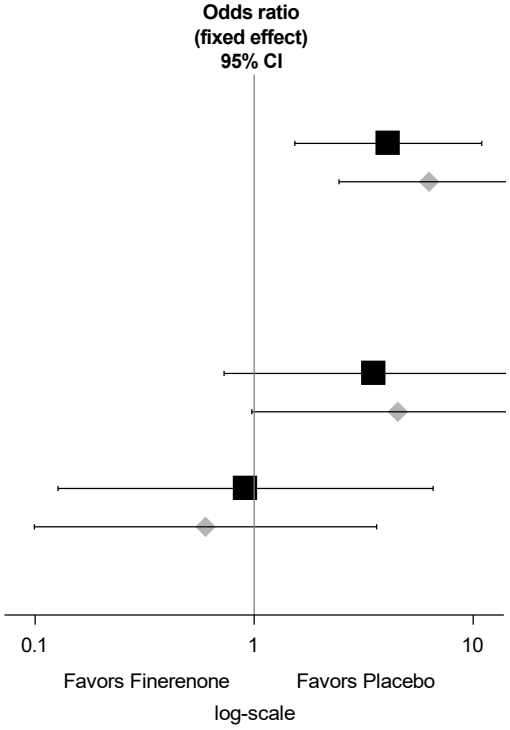
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 130					
FIDELIO-DKD	9 / 724	5 / 723	79.3	1.81 [0.60,5.42]	
FIGARO-DKD	5 / 494	1 / 495	20.7	5.05 [0.59,43.39]	
Total	14 / 1218	6 / 1218		2.35 [0.90,6.13]	Z=1.74, p=0.0812
Heterogeneity:	Q=0.71 (df=1)	p=0.4009	I^2=0.0%		
130 - < 160					
FIDELIO-DKD	18 / 1759	2 / 1760	100.0	9.09 [2.11,39.23]	
FIGARO-DKD	8 / 829	0 / 827	0.0	15E10 [15E10,15E10]	
Total	26 / 2588	2 / 2587		13.12 [3.11,55.33]	Z=3.51, p=0.0005
Heterogeneity:	Q=0.24 (df=1)	p=0.6227	I^2=0.0%		
>= 160					
FIDELIO-DKD	4 / 133	2 / 127	100.0	1.94 [0.35,10.77]	
FIGARO-DKD	0 / 34	0 / 34	0.0	-	
Total	4 / 167	2 / 161		1.94 [0.35,10.77]	Z=0.76, p=0.4496
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=4.36 (df=2)	p=0.1132	I^2=54.1%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.179.5: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Race - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

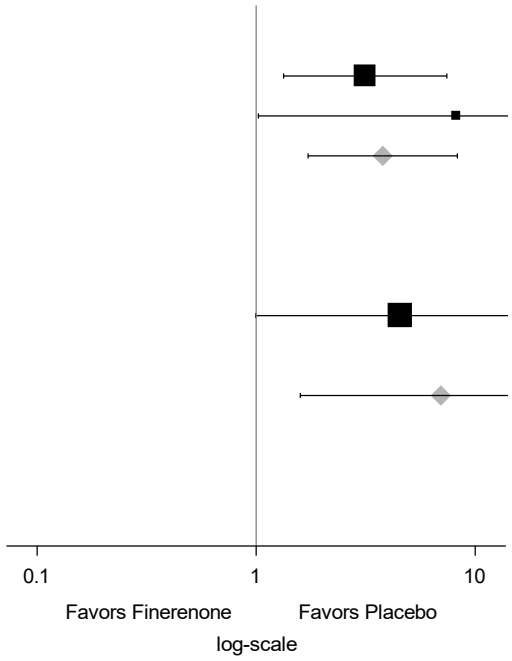
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
White					
FIDELIO-DKD	20 / 1634	5 / 1657	100.0	4.09 [1.53,10.93]	
FIGARO-DKD	11 / 1010	0 / 989	0.0	17E10 [17E10,17E10]	
Total	31 / 2644	5 / 2646		6.28 [2.44,16.19]	Z=3.81, p=0.0001
Heterogeneity:	Q=0.73 (df=1)	p=0.3926	I^2=0.0%		
Black					
FIDELIO-DKD	2 / 129	0 / 115	0.0	892E8 [892E8,892E8]	
FIGARO-DKD	0 / 43	0 / 71	0.0	-	
Total	2 / 172	0 / 186		359E9 [359E9,359E9]	Z=. , p=.
Heterogeneity:	Q=.	p=.	I^2=.		
Asian					
FIDELIO-DKD	7 / 678	2 / 677	100.0	3.52 [0.73,17.01]	
FIGARO-DKD	2 / 252	0 / 251	0.0	123E9 [123E9,123E9]	
Total	9 / 930	2 / 928		4.53 [0.98,21.01]	Z=1.93, p=0.0538
Heterogeneity:	Q=0.10 (df=1)	p=0.7545	I^2=0.0%		
Others					
FIDELIO-DKD	2 / 176	2 / 161	100.0	0.91 [0.13,6.56]	
FIGARO-DKD	0 / 52	1 / 45	0.0	0.00 [0.00,14E296]	
Total	2 / 228	3 / 206		0.60 [0.10,3.62]	Z=-0.56, p=0.5774
Heterogeneity:	Q=0.18 (df=1)	p=0.6753	I^2=0.0%		
Subgroup Heterogeneity:	Q=5.17 (df=3)	p=0.1596	I^2=42.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.179.6: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Sex - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

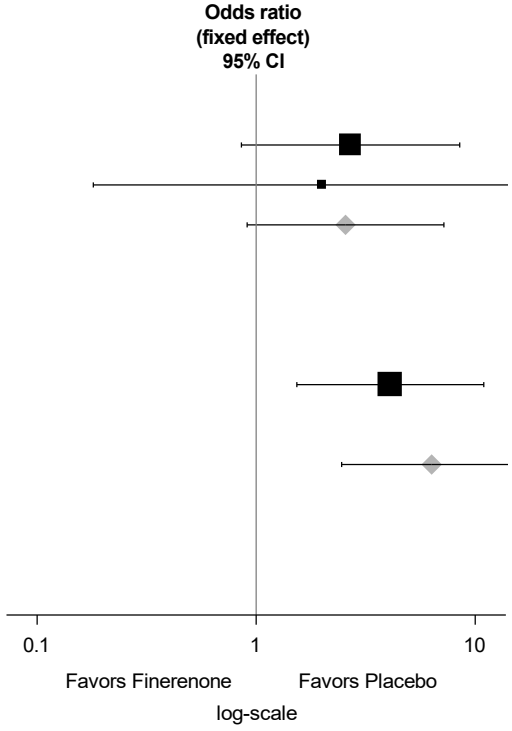
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Male					
FIDELIO-DKD	21 / 1797	7 / 1870	85.5	3.15 [1.33,7.42]	
FIGARO-DKD	8 / 917	1 / 933	14.5	8.20 [1.02,65.71]	
Total	29 / 2714	8 / 2803		3.78 [1.73,8.29]	Z=3.32, p=0.0009
Heterogeneity:	Q=0.71 (df=1)	p=0.4000	I^2=0.0%		
Female					
FIDELIO-DKD	10 / 820	2 / 740	100.0	4.56 [0.99,20.86]	
FIGARO-DKD	5 / 440	0 / 423	0.0	177E9 [177E9,177E9]	
Total	15 / 1260	2 / 1163		6.97 [1.59,30.54]	Z=2.58, p=0.0100
Heterogeneity:	Q=0.30 (df=1)	p=0.5839	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.51 (df=1)	p=0.4741	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.179.7: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Age Group (years) - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

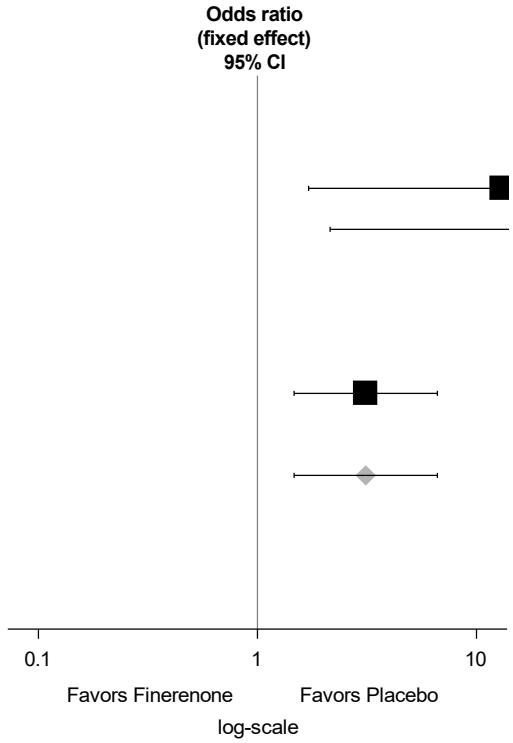
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
< 65					
FIDELIO-DKD	11 / 1103	4 / 1075	81.5	2.70 [0.86,8.50]	
FIGARO-DKD	2 / 336	1 / 335	18.5	2.00 [0.18,22.16]	
Total	13 / 1439	5 / 1410		2.56 [0.91,7.19]	Z=1.78, p=0.0750
Heterogeneity:	Q=0.05 (df=1)	p=0.8259	I^2=0.0%		
>= 65					
FIDELIO-DKD	20 / 1514	5 / 1535	100.0	4.10 [1.53,10.94]	
FIGARO-DKD	11 / 1021	0 / 1021	0.0	168E9 [168E9,168E9]	
Total	31 / 2535	5 / 2556		6.33 [2.46,16.30]	Z=3.82, p=0.0001
Heterogeneity:	Q=0.75 (df=1)	p=0.3858	I^2=0.0%		
Subgroup Heterogeneity:	Q=1.60 (df=1)	p=0.2054	I^2=37.6%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.
Category 'Missing' was excluded from meta-analysis.

Figure A2.2.179.8: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by Type of Albuminuria at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

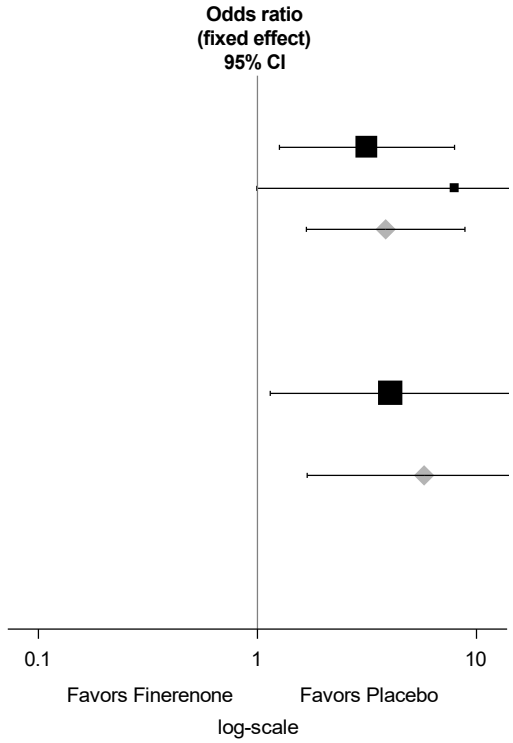
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
High					
FIDELIO-DKD	3 / 209	0 / 213	0.0	225E9 [225E9,225E9]	
FIGARO-DKD	13 / 1357	1 / 1356	100.0	13.11 [1.71,100.33]	
Total	16 / 1566	1 / 1569		16.20 [2.15,122.32]	Z=2.70, p=0.0069
Heterogeneity:	Q=0.04 (df=1)	p=0.8382	I^2=0.0%		
Very High					
FIDELIO-DKD	28 / 2408	9 / 2397	100.0	3.12 [1.47,6.63]	
FIGARO-DKD	0 / 0	0 / 0	0.0	-	
Total	28 / 2408	9 / 2397		3.12 [1.47,6.63]	Z=2.96, p=0.0031
Heterogeneity:	Q=0.00 (df=1)	p=1.0000	I^2=0.0%		
Subgroup Heterogeneity:	Q=2.24 (df=1)	p=0.1346	I^2=55.3%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.179.9: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs by eGFR (mL/min/1.73m2) Category at Screening - Hyperkalaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

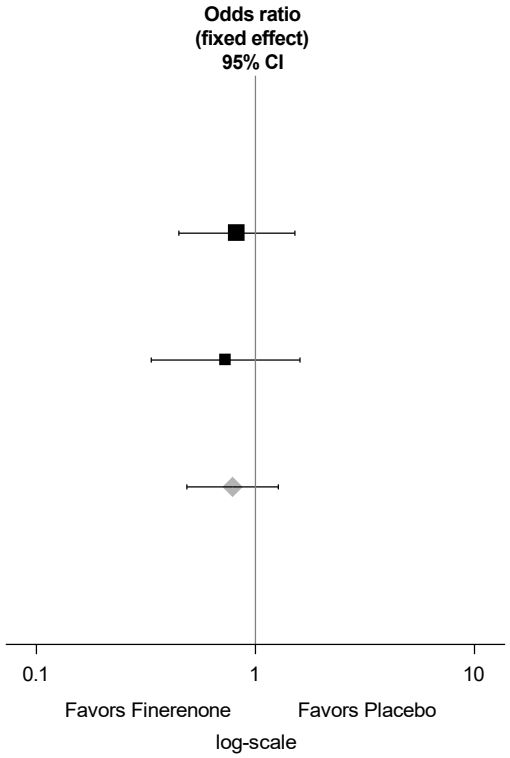
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
25 - < 45					
FIDELIO-DKD	19 / 1556	6 / 1541	83.6	3.16 [1.26,7.94]	
FIGARO-DKD	8 / 637	1 / 627	16.4	7.96 [0.99,63.85]	
Total	27 / 2193	7 / 2168		3.85 [1.67,8.86]	Z=3.17, p=0.0015
Heterogeneity:	Q=0.64 (df=1)	p=0.4226	I^2=0.0%		
45 - < 60					
FIDELIO-DKD	12 / 1061	3 / 1069	100.0	4.06 [1.14,14.45]	
FIGARO-DKD	5 / 720	0 / 729	0.0	108E9 [108E9,108E9]	
Total	17 / 1781	3 / 1798		5.77 [1.69,19.71]	Z=2.79, p=0.0052
Heterogeneity:	Q=0.29 (df=1)	p=0.5889	I^2=0.0%		
Subgroup Heterogeneity:	Q=0.28 (df=1)	p=0.5937	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights. The same method was applied to assess the heterogeneity between subgroups.

Figure A2.2.180: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Hypoglycaemia (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

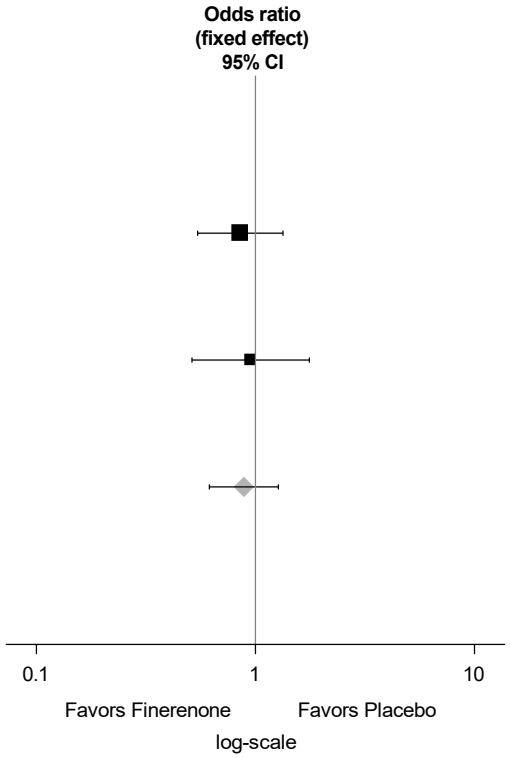
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	19 / 2617	23 / 2610	62.1	0.82 [0.45,1.51]	
FIGARO-DKD	11 / 1357	15 / 1356	37.9	0.73 [0.33,1.60]	
Total	30 / 3974	38 / 3966		0.79 [0.49,1.27]	Z=-0.98, p=0.3271
Heterogeneity:	Q=0.05 (df=1)	p=0.8147	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.181: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	36 / 2617	42 / 2610	65.4	0.85 [0.54,1.34]	
FIGARO-DKD	20 / 1357	21 / 1356	34.6	0.95 [0.51,1.76]	
Total	56 / 3974	63 / 3966		0.89 [0.62,1.27]	Z=-0.66, p=0.5110
Heterogeneity:	Q=0.08 (df=1)	p=0.7796	I^2=0.0%		

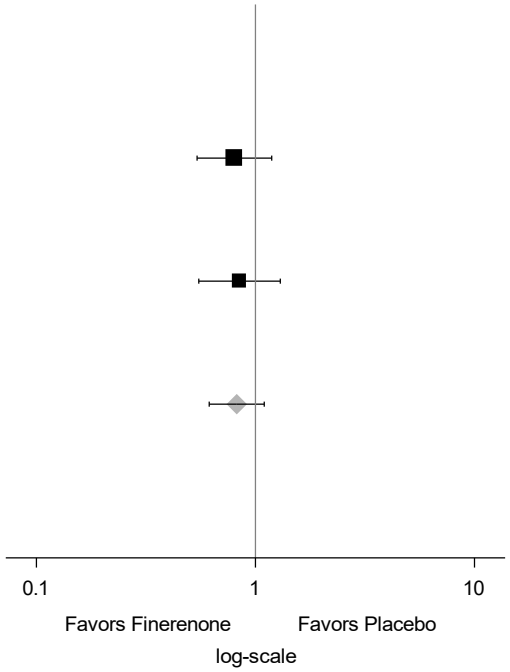


Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.182: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC with Incidence >=1%)

Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

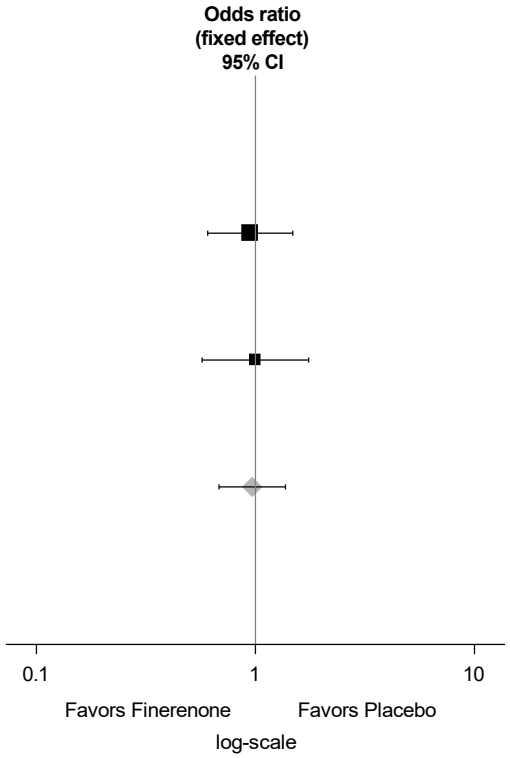
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	46 / 2617	57 / 2610	54.4	0.80 [0.54,1.19]	
FIGARO-DKD	40 / 1357	47 / 1356	45.6	0.85 [0.55,1.30]	
Total	86 / 3974	104 / 3966		0.82 [0.61,1.10]	Z=-1.33, p=0.1825
Heterogeneity:	Q=0.03 (df=1)	p=0.8552	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.183: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Nervous System Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

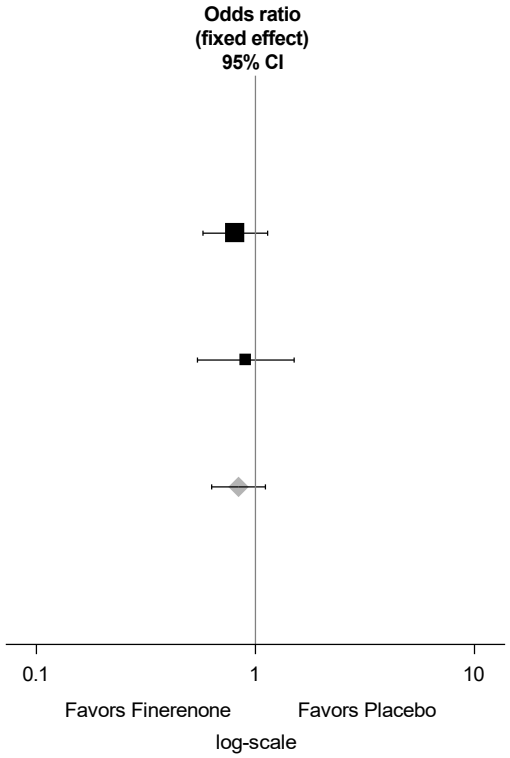
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	38 / 2617	40 / 2610	61.0	0.95 [0.61,1.48]	
FIGARO-DKD	25 / 1357	25 / 1356	39.0	1.00 [0.57,1.75]	
Total	63 / 3974	65 / 3966		0.97 [0.68,1.37]	Z=-0.19, p=0.8500
Heterogeneity:	Q=0.02 (df=1)	p=0.8825	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.184: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Renal And Urinary Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

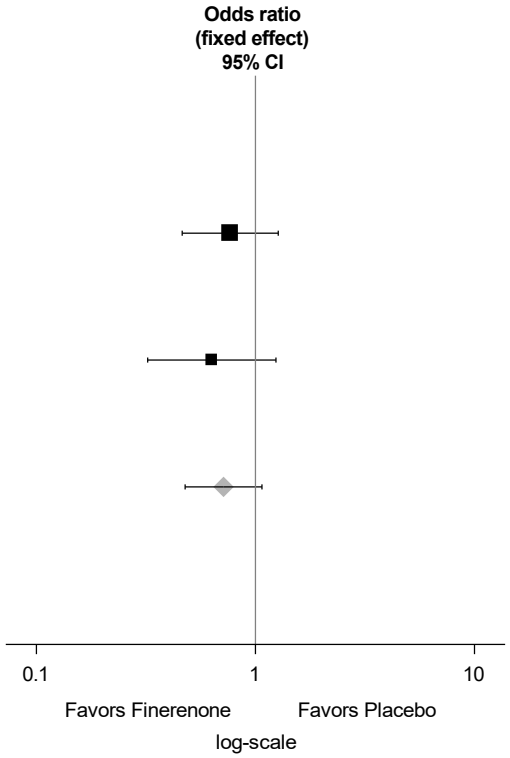
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	62 / 2617	76 / 2610	69.1	0.81 [0.58,1.14]	
FIGARO-DKD	29 / 1357	32 / 1356	30.9	0.90 [0.54,1.50]	
Total	91 / 3974	108 / 3966		0.84 [0.63,1.11]	Z=-1.23, p=0.2172
Heterogeneity:	Q=0.13 (df=1)	p=0.7234	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.185: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Acute kidney injury (PT with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

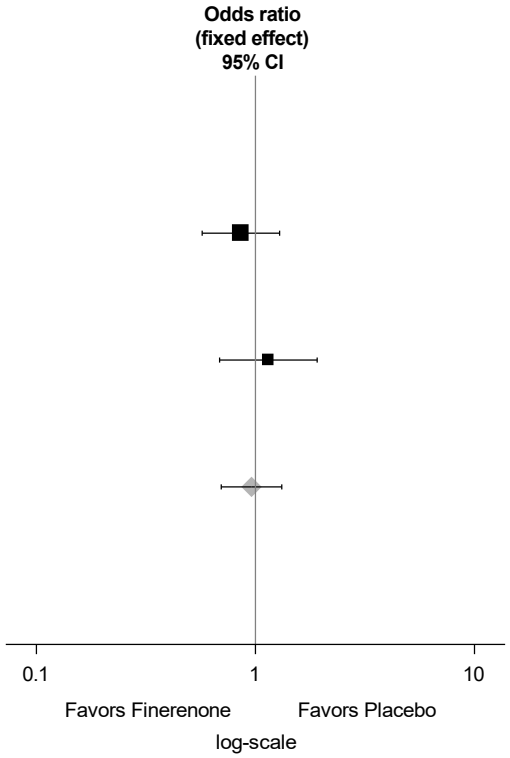
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	27 / 2617	35 / 2610	64.1	0.77 [0.46,1.27]	
FIGARO-DKD	14 / 1357	22 / 1356	35.9	0.63 [0.32,1.24]	
Total	41 / 3974	57 / 3966		0.71 [0.48,1.07]	Z=-1.63, p=0.1034
Heterogeneity:	Q=0.20 (df=1)	p=0.6528	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.186: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

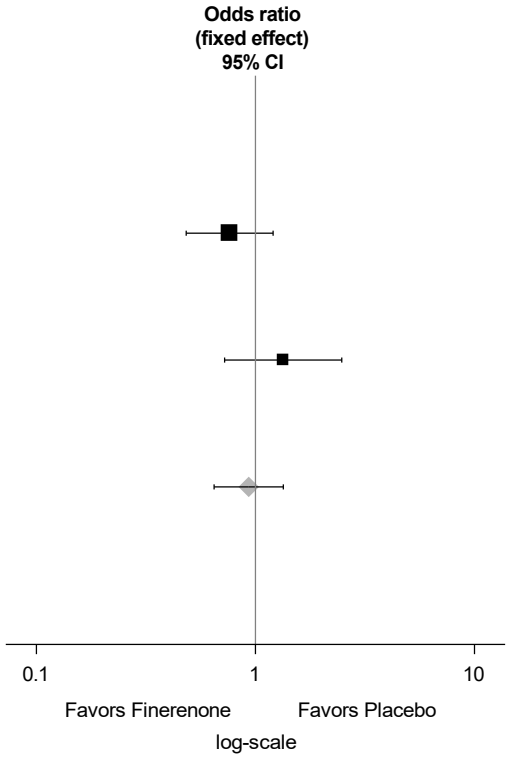
Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	44 / 2617	51 / 2610	61.4	0.86 [0.57,1.29]	
FIGARO-DKD	32 / 1357	28 / 1356	38.6	1.15 [0.69,1.91]	
Total	76 / 3974	79 / 3966		0.96 [0.70,1.32]	Z=-0.26, p=0.7984
Heterogeneity:	Q=0.75 (df=1)	p=0.3871	I^2=0.0%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.

Figure A2.2.187: Forest Plot for Odds Ratio of Proportion of Subjects with Severe TEAEs - Vascular Disorders (SOC with Incidence >=1%)
Safety Analysis Set - Screening eGFR < 60 ml/min/1.73m2

Subgroup Study	Finerenone + SoC Events / Total	Placebo + SoC Events / Total	Weight (%)	Odds ratio (fixed effect) 95% CI	Overall treatment effect
Overall					
FIDELIO-DKD	33 / 2617	43 / 2610	64.5	0.76 [0.48,1.20]	
FIGARO-DKD	24 / 1357	18 / 1356	35.5	1.34 [0.72,2.48]	
Total	57 / 3974	61 / 3966		0.93 [0.65,1.34]	Z=-0.38, p=0.7026
Heterogeneity:	Q=2.07 (df=1)	p=0.1503	I^2=51.7%		



Abbreviations: CI=confidence interval, CVD=cardiovascular disease, eGFR=estimated glomerular filtration rate, GLM=generalized linear model, N=number of subjects, PT=preferred term, OR=odds ratio, SOC=system organ class, SoC=standard of care, TE(S)AE=treatment-emergent (serious) adverse event.
Note: For single studies the OR is estimated by a GLM with classification term for treatment using a binomial distribution and logit as link function.
For 'Total' the same model as for single studies including study as additional factor was applied.
The heterogeneity between studies was analyzed using Cochrane's Q statistic with inverse variance weights.