

SUPPLEMENTARY TABLE. Baseline demographic and disease characteristics of Evaluation of Protease Inhibition for Covid-19 in High-Risk Patients (EPIC-HR) and Evaluation of Protease Inhibition for Covid-19 in Standard-Risk Patients (EPIC-SR) study participants — United States and International Sites, 2021–2022

Characteristic	No. (%)								
	EPIC-HR			EPIC-SR 2021/Preomicron			EPIC-SR 2022/omicron		
	Nirmatrelvir/ Ritonavir (N = 1,038)	Placebo (N = 1,053)	Overall (N = 2,091)	Nirmatrelvir/ Ritonavir (N = 540)	Placebo (N = 528)	Overall (N = 1068)	Nirmatrelvir/ Ritonavir (N = 114)	Placebo (N = 106)	Overall (N = 220)
Sex									
Female	522 (50.3)	515 (48.9)	1,037 (49.6)	275 (50.9)	284 (53.8)	559 (52.3)	69 (60.5)	68 (64.2)	137 (62.3)
Male	516 (49.7)	538 (51.1)	1,054 (50.4)	265 (49.1)	244 (46.2)	509 (47.7)	45 (39.5)	38 (35.8)	83 (37.7)
Age									
Mean (SD)	44.9 (15.4)	46.0 (15.6)	45.4 (15.5)	41.7 (13.8)	42.4 (13.2)	42.0 (13.5)	42.2 (12.0)	43.8 (12.9)	43.0 (12.4)
Median (range)	44.0 (18.0–86.0)	46.0 (18.0–88.0)	45.0 (18.0–88.0)	40.0 (18.0–87.0)	42.0 (18.0–82.0)	41.0 (18.0–87.0)	42.0 (19.0–64.0)	45.0 (20.0–74.0)	43.0 (19.0–74.0)
Age group									
18–44	534 (51.4)	499 (47.4)	1,033 (49.4)	328 (60.7)	310 (58.7)	638 (59.7)	66 (57.9)	52 (49.1)	118 (53.6)
45–59	306 (29.5)	316 (30.0)	622 (29.7)	157 (29.1)	169 (32.0)	326 (30.5)	36 (31.6)	38 (35.8)	74 (33.6)
60–64	69 (6.6)	104 (9.9)	173 (8.3)	19 (3.5)	24 (4.5)	43 (4.0)	12 (10.5)	12 (11.3)	24 (10.9)
65–74	96 (9.2)	103 (9.8)	199 (9.5)	30 (5.6)	15 (2.8)	45 (4.2)	0 (0)	4 (3.8)	4 (1.8)
≥75	33 (3.2)	31 (2.9)	64 (3.1)	6 (1.1)	10 (1.9)	16 (1.5)	0 (0)	0 (0)	0 (0)
Race									
White	728 (70.1)	756 (71.8)	1484 (71.0)	425 (78.7)	413 (78.2)	838 (78.5)	87 (76.3)	84 (79.2)	171 (77.7)
Asian	153 (14.7)	156 (14.8)	309 (14.8)	67 (12.4)	70 (13.3)	137 (12.8)	2 (1.8)	3 (2.8)	5 (2.3)
AI/AN	95 (9.2)	94 (8.9)	189 (9.0)	23 (4.3)	18 (3.4)	41 (3.8)	16 (14.0)	14 (13.2)	30 (13.6)
Black or African American	52 (5.0)	35 (3.3)	87 (4.2)	19 (3.5)	18 (3.4)	37 (3.5)	9 (7.9)	5 (4.7)	14 (6.4)
Unknown or missing	9 (0.9)	10 (0.9)	19 (0.9)	6 (1.1)	9 (1.7)	15 (1.4)	0 (0)	0 (0)	0 (0)
Multiple	1 (0.1)	2 (0.2)	3 (0.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ethnicity									
Hispanic or Latino	425 (40.9)	439 (41.7)	864 (41.3)	233 (43.1)	224 (42.4)	457 (42.8)	39 (34.2)	37 (34.9)	76 (34.5)
Not Hispanic or Latino	608 (58.6)	607 (57.6)	1215 (58.1)	304 (56.3)	299 (56.6)	603 (56.5)	74 (64.9)	68 (64.2)	142 (64.5)
Not reported	5 (0.5)	7 (0.7)	12 (0.6)	3 (0.6)	5 (0.9)	8 (0.7)	1 (0.9)	1 (0.9)	2 (0.9)
Region									
United States	387 (37.3)	399 (37.9)	786 (37.6)	214 (39.6)	205 (38.8)	419 (39.2)	0 (0)	0 (0)	0 (0)
Europe	330 (31.8)	333 (31.6)	663 (31.7)	160 (29.6)	156 (29.5)	316 (29.6)	61 (53.5)	57 (53.8)	118 (53.6)
India	94 (9.1)	97 (9.2)	191 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Rest of world	227 (21.9)	224 (21.3)	451 (21.6)	166 (30.7)	167 (31.6)	333 (31.2)	53 (46.5)	49 (46.2)	102 (46.4)
BMI (kg/m²)									
Mean (SD)	29.0 (5.43)	29.1 (5.65)	29.1 (5.54)	26.4 (5.22)	26.6 (5.66)	26.5 (5.44)	24.9 (2.94)	25.1 (3.27)	25.0 (3.10)

Median (range)	28.1 (16.6–58.1)	28.3 (16.0–59.1)	28.2 (16.0–59.1)	24.9 (17.4–58.8)	24.9 (14.2–53.1)	24.9 (14.2–58.8)	24.6 (18.0–29.9)	24.8 (17.7–29.8)	24.7 (17.7–29.9)
Missing	0 (0)	0 (0)	0 (0)	1 (0.2)	1 (0.2)	2 (0.2)	0 (0)	0 (0)	0 (0)
BMI Category									
< 25	208 (20.0)	206 (19.6)	414 (19.8)	278 (51.5)	268 (50.8)	546 (51.1)	59 (51.8)	55 (51.9)	114 (51.8)
25 to <30	466 (44.9)	464 (44.1)	930 (44.5)	152 (28.1)	138 (26.1)	290 (27.2)	55 (48.2)	51 (48.1)	106 (48.2)
30 to <35	247 (23.8)	249 (23.6)	496 (23.7)	71 (13.1)	80 (15.2)	151 (14.1)	0 (0)	0 (0)	0 (0)
35 to <40	70 (6.7)	77 (7.3)	147 (7.0)	28 (5.2)	26 (4.9)	54 (5.1)	0 (0)	0 (0)	0 (0)
≥40	47 (4.5)	57 (5.4)	104 (5.0)	10 (1.9)	15 (2.8)	25 (2.3)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	0 (0)	0 (0)	1 (0.2)	1 (0.2)	2 (0.2)	0 (0)	0 (0)	0 (0)
Days since first symptom									
≤3	715 (68.9)	687 (65.2)	1402 (67.0)	397 (73.5)	388 (73.5)	785 (73.5)	77 (67.5)	73 (68.9)	150 (68.2)
>3	323 (31.1)	366 (34.8)	689 (33.0)	143 (26.5)	140 (26.5)	283 (26.5)	37 (32.5)	33 (31.1)	70 (31.8)
Baseline risk factors for severe COVID-19									
None	0 (0)	0 (0)	0 (0)	219 (40.6)	211 (40.0)	430 (40.3)	114 (100)	102 (96.2)	216 (98.2)
Any	1,038 (100.0)	1,053 (100.0)	2,091 (100.0)	321 (59.4)	317 (60.0)	638 (59.7)	0 (0)	4 (3.8)*	4 (1.8)*
Baseline SARS-CoV-2 serology (anti-N and/or anti-S)									
Negative	504 (48.6)	526 (50.0)	1030 (49.3)	133 (24.6)	128 (24.2)	261 (24.4)	28 (24.6)	20 (18.9)	48 (21.8)
Positive	521 (50.2)	514 (48.8)	1035 (49.5)	397 (73.5)	390 (73.9)	787 (73.7)	85 (74.6)	84 (79.2)	169 (76.8)
Missing	13 (1.3)	13 (1.2)	26 (1.2)	10 (1.9)	10 (1.9)	20 (1.9)	1 (0.9)	2 (1.9)	3 (1.4)
Baseline Viral RNA (log₁₀ copies/mL)									
Mean (SD)	4.76 (2.89)	4.66 (2.88)	4.71 (2.89)	5.19 (2.88)	4.85 (2.95)	5.02 (2.92)	5.52 (2.30)	5.85 (1.96)	5.68 (2.15)
Median (range)	5.52 (0–9.16)	5.39 (0–9.15)	5.44 (0–9.16)	6.20 (0–9.47)	5.80 (0–9.37)	5.99 (0–9.47)	6.20 (0–9.06)	6.42 (0–8.65)	6.31 (0–9.06)
Missing	28 (2.7)	29 (2.8)	57 (2.7)	11 (2.0)	9 (1.7)	20 (1.9)	1 (0.9)	2 (1.9)	3 (1.4)
COVID-19 Vaccination Status									
Vaccinated	0 (0)	0 (0)	0 (0)	330 (61.1)	322 (61.0)	652 (61.0)	42 (36.8)	39 (36.8)	81 (36.8)
Not Vaccinated	1,038 (100.0)	1,053 (100.0)	2,091 (100.0)	210 (38.9)	206 (39.0)	416 (39.0)	72 (63.2)	67 (63.2)	139 (63.2)
COVID-19 mAb treatment									
Not received/ not expected to receive	977 (94.1)	989 (93.9)	1966 (94.0)	540 (100.0)	528 (100.0)	1068 (100.0)	114 (100.0)	106 (100.0)	220 (100.0)
Received/ expected to receive	61 (5.9)	64 (6.1)	125 (6.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Primary SARS-CoV-2 Variant, n/N (% of sequenced samples)									
Delta	755/765 (98.7)	750/757 (99.1)	1505/1522 (98.9)	412/418 (98.6)	384/393 (97.7)	796/811 (98.2)	—	—	—
Omicron	—	—	—	—	—	—	98/98 (100)	97/97 (100)	195/195 (100)

Abbreviations: AI/AN = American Indian or Alaska Native; anti-N = anti-nucleocapsid protein; anti-S = anti-spike protein; BMI = body mass index; EPIC-HR = Evaluation of Protease Inhibition for Covid-19 in High-Risk Patients; EPIC-SR = Evaluation of Protease Inhibition for Covid-19 in Standard-Risk Patients; mAb = monoclonal antibody; SD = standard deviation.

*Subjects enrolled but subsequently found to have met the severe COVID-19 risk factor exclusion criterion for the EPIC-SR/2022 enrollment period.