Table S4. Summary of adverse events.

Adverse event	ITT (N=173)	≥18 years ITT (N=37)	MPP (N=124)	≥18 years MPP (N=32)
Any AE, n (%)	173 (100.0)	37 (100.0)	124 (100.0)	32 (100.0)
Grade 1	33 (19.1)	6 (16.2)	29 (23.4)	6 (18.8)
Grade 2	89 (51.4)	23 (62.2)	66 (53.2)	21 (65.6)
Grade 3	44 (25.4)	7 (18.9)	27 (21.8)	4 (12.5)
Grade 4	6 (3.5)	1 (2.7)	2 (1.6)	1 (3.1)
Grade 5	1 (0.6)	0	0	0
Number of AEs per patient, mean/median	35.3/28.0	40.6/28.0	36.0/28.5	39.7/28.5
Any study drug–related AE, n (%)[a]	128 (74.0)	27 (73.0)	89 (71.8)	23 (71.9)
Grade 1	64 (37.0)	13 (35.1)	46 (37.1)	11 (34.4)
Grade 2	60 (34.7)	14 (37.8)	41 (33.1)	12 (37.5)
Grade 3	3 (1.7)	0 (0.0)	2 (1.6)	0 (0.0)
Grade 4	1 (0.6)	0	0	0
Any SAE, n (%)	77 (44.5)	14 (37.8)	35 (28.2)	9 (28.1)
Grade 1	11 (6.4)	1 (2.7)	5 (4.0)	1 (3.1)
Grade 2	25 (14.5)	6 (16.2)	11 (8.9)	4 (12.5)
Grade 3	34 (19.7)	6 (16.2)	17 (13.7)	3 (9.4)
Grade 4	6 (3.5)	1 (2.7)	2 (1.6)	1 (3.1)
Grade 5	1 (0.6)	0 (0.0)	2 (1.6)	0
Number of SAEs per patient, mean/median	0.7/0.0	0.5/0.0	0.4/0.0	0.4/0.0
Any study drug–related SAE, n (%)[a]	2 (1.2)	0	1 (0.8)	0
Grade 2	1 (0.6)	0	1 (0.8)	0
Grade 4	1 (0.6)	0	0	0
Any AE leading to study discontinuation, n (%)	3 (1.7)	0	0	0
Grade 3	1 (0.6)	0	0	0
Grade 4	1 (0.6)	0	0	0
Grade 5	1 (0.6)	0	0	0
Any AE leading to permanent study drug discontinuation, n (%)	4 (2.3)	1 (2.7)	1 (0.8)	1 (3.1)
Grade 3	2 (1.2)	1 (2.7)	1 (0.8)	1 (3.1)
Grade 4	1 (0.6)	0	0	0
Grade 5	1 (0.6)	0	0	0
Death	1 (0.6)	0	0	0

SAE, serious adverse event.