

Table 11.32
Frequency of AEs by System Organ Class, and Severity.
SS Sub-population, Primary Enrolment into OLE

MedDRA SOC	Severity	DrugX N=180													
		Treatment Period		Safety Follow-up Period										Overall	
		n (%)		0-6 wks after last dose		>6 wks after last dose		0-8 wks after last dose		>8 wks after last dose		Total		n (%)	
n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Any AE		142 (78.9)	327	56 (31.1)	71	93 (51.7)	122	77 (42.8)	103	75 (41.7)	90	121 (67.2)	193	170 (94.4)	520
	1: Mild	110 (61.1)	159	31 (17.2)	34	59 (32.8)	67	42 (23.3)	49	46 (25.6)	52	84 (46.7)	101	143 (79.4)	260
	2: Moderate	75 (41.7)	94	17 (9.4)	18	25 (13.9)	26	24 (13.3)	25	18 (10.0)	19	38 (21.1)	44	97 (53.9)	138
	3: Severe	48 (26.7)	51	12 (6.7)	12	17 (9.4)	18	20 (11.1)	20	10 (5.6)	10	27 (15.0)	30	66 (36.7)	81
	4: Life-threatening	12 (6.7)	13	4 (2.2)	4	7 (3.9)	7	5 (2.8)	5	6 (3.3)	6	11 (6.1)	11	22 (12.2)	24
	5: Death	9 (5.0)	10	3 (1.7)	3	4 (2.2)	4	4 (2.2)	4	3 (1.7)	3	7 (3.9)	7	16 (8.9)	17

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				0-6 wks after last dose		>6 wks after last dose		0-8 wks after last dose		>8 wks after last dose				Total	
		n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E	n (%)	E
SOC1															
	1: Mild	117 (65.0)	206	34 (18.9)	35	60 (33.3)	71	47 (26.1)	55	46 (25.6)	51	82 (45.6)	106	144 (80.0)	312
	2: Moderate	74 (41.1)	101	18 (10.0)	18	37 (20.6)	39	23 (12.8)	25	30 (16.7)	32	52 (28.9)	57	108 (60.0)	158
	3: Severe	50 (27.8)	57	9 (5.0)	9	15 (8.3)	15	15 (8.3)	15	9 (5.0)	9	23 (12.8)	24	66 (36.7)	81
	4: Life-threatening	31 (17.2)	33	6 (3.3)	6	11 (6.1)	12	13 (7.2)	13	5 (2.8)	5	16 (8.9)	18	44 (24.4)	51
	5: Death	8 (4.4)	8	0 (0.0)	0	3 (1.7)	3	0 (0.0)	0	3 (1.7)	3	3 (1.7)	3	11 (6.1)	11
		7 (3.9)	7	2 (1.1)	2	2 (1.1)	2	2 (1.1)	2	2 (1.1)	2	4 (2.2)	4	11 (6.1)	11
SOC2															
	1: Mild	89 (49.4)	121	31 (17.2)	36	44 (24.4)	51	40 (22.2)	48	34 (18.9)	39	68 (37.8)	87	120 (66.7)	208
	2: Moderate	54 (30.0)	58	13 (7.2)	16	26 (14.4)	28	20 (11.1)	24	18 (10.0)	20	38 (21.1)	44	76 (42.2)	102
	3: Severe	32 (17.8)	37	9 (5.0)	9	10 (5.6)	11	10 (5.6)	10	9 (5.0)	10	18 (10.0)	20	47 (26.1)	57
	4: Life-threatening	18 (10.0)	18	6 (3.3)	6	6 (3.3)	6	7 (3.9)	7	5 (2.8)	5	11 (6.1)	12	27 (15.0)	30
	5: Death	5 (2.8)	5	4 (2.2)	4	4 (2.2)	4	5 (2.8)	5	3 (1.7)	3	8 (4.4)	8	13 (7.2)	13
		2 (1.1)	3	1 (0.6)	1	2 (1.1)	2	2 (1.1)	2	1 (0.6)	1	3 (1.7)	3	5 (2.8)	6