

**Table 14.5.1.2: Adverse Events by preferred term and System organ class
Safety Population**

	Placebo (N=22) n (%)	Treatment A (N=19) n (%)	Treatment B (N=26) n (%)	Treatment A & B (N=45) n (%)	Total (N=67) n (%)
Any Adverse Event	22 (100.0)	19 (100.0)	26 (100.0)	45 (100.0)	67 (100.0)
Gastrointestinal disorders	18 (81.8)	10 (52.6)	9 (34.6)	19 (42.2)	37 (55.2)
Diarrhea	15 (68.2)	7 (36.8)	5 (19.2)	12 (26.7)	27 (40.3)
Vomiting	6 (27.3)	3 (15.8)	4 (15.4)	7 (15.6)	13 (19.4)
Nervous system disorder	15 (68.2)	8 (42.1)	17 (65.4)	25 (55.6)	40 (59.7)
Headache	14 (63.6)	7 (36.8)	14 (53.8)	21 (46.7)	35 (52.2)
Tremor	1 (4.5)	1 (5.3)	3 (11.5)	4 (8.9)	5 (7.5)
Vascular disorders	5 (22.7)	6 (31.6)	8 (30.8)	14 (31.1)	19 (28.4)
Hypotension	4 (18.2)	2 (10.5)	5 (19.2)	7 (15.6)	11 (16.4)
Flushing	1 (4.5)	1 (5.3)	2 (7.7)	3 (6.7)	4 (6.0)
Poor venous access	0	3 (15.8)	2 (7.7)	5 (11.1)	5 (7.5)
Cardiac disorders	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Tachycardia	2 (9.1)	1 (5.3)	0	1 (2.2)	3 (4.5)
Eye disorders	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)
Conjunctivitis allergic	0	4 (21.1)	2 (7.7)	6 (13.3)	6 (9.0)