

Disposition of Participant
All Participants as Treated

	Placebo		Low Dose		High Dose		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Participants in population	86		84		84		254	
Trial Disposition								
Discontinued	19	(22.1)	21	(25.0)	19	(22.6)	59	(23.2)
Adverse Event	3	(3.5)	12	(14.3)	9	(10.7)	24	(9.4)
Death	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Lack of Efficacy	2	(2.3)	0	(0.0)	0	(0.0)	2	(0.8)
Physician Decision	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Withdrew Consent	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Status Not Recorded	13	(15.1)	7	(8.3)	8	(9.5)	28	(11.0)
Participants Ongoing	67	(77.9)	63	(75.0)	65	(77.4)	195	(76.8)
Adverse Event	5	(5.8)	32	(38.1)	31	(36.9)	68	(26.8)
Death	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
I/E Not Met	1	(1.2)	0	(0.0)	2	(2.4)	3	(1.2)
Lack of Efficacy	1	(1.2)	0	(0.0)	1	(1.2)	2	(0.8)
Lost to Follow-up	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Physician Decision	1	(1.2)	0	(0.0)	1	(1.2)	2	(0.8)
Protocol Violation	1	(1.2)	1	(1.2)	1	(1.2)	3	(1.2)
Sponsor Decision	2	(2.3)	2	(2.4)	3	(3.6)	7	(2.8)
Withdrew Consent	9	(10.5)	9	(10.7)	7	(8.3)	25	(9.8)
Status Not Recorded	45	(52.3)	18	(21.4)	19	(22.6)	82	(32.3)
Participant Study Medication Disposition								
Completed	73	(84.9)	67	(79.8)	70	(83.3)	210	(82.7)
Adverse Event	7	(8.1)	34	(40.5)	35	(41.7)	76	(29.9)
Death	2	(2.3)	1	(1.2)	0	(0.0)	3	(1.2)
I/E Not Met	1	(1.2)	0	(0.0)	2	(2.4)	3	(1.2)
Lack of Efficacy	3	(3.5)	0	(0.0)	1	(1.2)	4	(1.6)
Lost to Follow-up	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Physician Decision	1	(1.2)	0	(0.0)	2	(2.4)	3	(1.2)
Protocol Violation	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Sponsor Decision	2	(2.3)	2	(2.4)	2	(2.4)	6	(2.4)
Withdrew Consent	7	(8.1)	9	(10.7)	5	(6.0)	21	(8.3)
Status Not Recorded	49	(57.0)	19	(22.6)	22	(26.2)	90	(35.4)
Discontinued	13	(15.1)	17	(20.2)	14	(16.7)	44	(17.3)
Adverse Event	1	(1.2)	10	(11.9)	5	(6.0)	16	(6.3)

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	n	(%)	n	(%)	n	(%)	n	(%)
Participant Study Medication Disposition								
Protocol Violation	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Sponsor Decision	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Withdrew Consent	2	(2.3)	1	(1.2)	3	(3.6)	6	(2.4)
Status Not Recorded	9	(10.5)	6	(7.1)	5	(6.0)	20	(7.9)

Source: [CDISCpilot: adam-adsl]