

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	21	(24.4)	14	(16.7)	24	(28.6)	59	(23.2)
Adverse Event	15	(17.4)	13	(15.5)	14	(16.7)	42	(16.5)
I/E Not Met	2	(2.3)	0	(0.0)	4	(4.8)	6	(2.4)
Lack of Efficacy	2	(2.3)	0	(0.0)	3	(3.6)	5	(2.0)
Withdrew Consent	2	(2.3)	1	(1.2)	3	(3.6)	6	(2.4)
Participants Ongoing	65	(75.6)	70	(83.3)	60	(71.4)	195	(76.8)
Participant Study Medication Disposition								
Completed	58	(67.4)	25	(29.8)	27	(32.1)	110	(43.3)
Discontinued	28	(32.6)	59	(70.2)	57	(67.9)	144	(56.7)
Adverse Event	8	(9.3)	44	(52.4)	40	(47.6)	92	(36.2)
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	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)	10	(11.9)	8	(9.5)	27	(10.6)

Source: [CDISCpilot: adam-ads]