

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	14	(16.3)	16	(19.0)	18	(21.4)	48	(18.9)
Adverse Event	2	(2.3)	12	(14.3)	10	(11.9)	24	(9.4)
I/E Not Met	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Protocol Violation	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Withdrew Consent	2	(2.3)	1	(1.2)	3	(3.6)	6	(2.4)
Status Not Recorded	8	(9.3)	3	(3.6)	5	(6.0)	16	(6.3)
Participants Ongoing	72	(83.7)	68	(81.0)	66	(78.6)	206	(81.1)
Adverse Event	6	(7.0)	32	(38.1)	30	(35.7)	68	(26.8)
Death	2	(2.3)	1	(1.2)	0	(0.0)	3	(1.2)
I/E Not Met	0	(0.0)	0	(0.0)	2	(2.4)	2	(0.8)
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)	3	(3.6)	7	(2.8)
Withdrew Consent	7	(8.1)	9	(10.7)	5	(6.0)	21	(8.3)

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	n	(%)	n	(%)	n	(%)	n	(%)
Trial Disposition								
Status Not Recorded	50	(58.1)	22	(26.2)	22	(26.2)	94	(37.0)
Participant Study Medication Disposition								
Completed	71	(82.6)	74	(88.1)	73	(86.9)	218	(85.8)
Adverse Event	5	(5.8)	40	(47.6)	35	(41.7)	80	(31.5)
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	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)	1	(1.2)	3	(3.6)	6	(2.4)
Withdrew Consent	8	(9.3)	9	(10.7)	6	(7.1)	23	(9.1)
Status Not Recorded	48	(55.8)	22	(26.2)	23	(27.4)	93	(36.6)
Discontinued	15	(17.4)	10	(11.9)	11	(13.1)	36	(14.2)
Adverse Event	3	(3.5)	4	(4.8)	5	(6.0)	12	(4.7)
Death	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)

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	n	(%)	n	(%)	n	(%)	n	(%)
Participant Study Medication Disposition								
Sponsor Decision	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Withdrew Consent	1	(1.2)	1	(1.2)	2	(2.4)	4	(1.6)
Status Not Recorded	10	(11.6)	3	(3.6)	4	(4.8)	17	(6.7)

Source: [CDISCpilot: adam-adsI]