Table 5.4
Adverse Events
By Body System, Preferred Term, and Greatest Severity

Body System Preferred Term Severity	Active N= 45	Placebo N= 25	Overall N= 70
Any Event	9 (20.0%)	5 (20.0%)	14 (20.0%)
Mild	4 (8.9%)	1 (4.0%)	5 (7.1%)
Moderate	1 (2.2%)	4 (16.0%)	5 (7.1%)
Severe	4 (8.9%)		4 (5.7%)
Cardiac disorders	2 (4.4%)	2 (8.0%)	4 (5.7%)
Mild	1 (2.2%)		1 (1.4%)
Moderate		2 (8.0%)	2 (2.9%)
Severe	1 (2.2%)		1 (1.4%)
Atrial flutter	1 (2.2%)		1 (1.4%)
Mild	1 (2.2%)		1 (1.4%)
Cardiac failure		1 (4.0%)	1 (1.4%)
Moderate		1 (4.0%)	1 (1.4%)
Palpitations	1 (2.2%)	1 (4.0%)	2 (2.9%)
Moderate		1 (4.0%)	1 (1.4%)
Severe	1 (2.2%)		1 (1.4%)
Tachycardia		1 (4.0%)	1 (1.4%)
Moderate		1 (4.0%)	1 (1.4%)
Gastrointestinal disorders	4 (8.9%)	2 (8.0%)	6 (8.6%)
Mild	2 (4.4%)		2 (2.9%)
Moderate		2 (8.0%)	2 (2.9%)
Severe	2 (4.4%)		2 (2.9%)
Abdominal pain		1 (4.0%)	1 (1.4%)
Moderate		1 (4.0%)	1 (1.4%)
Anal ulcer		1 (4.0%)	1 (1.4%)
Mild		1 (4.0%)	1 (1.4%)
Constipation	2 (4.4%)		2 (2.9%)
Mild	2 (4.4%)		2 (2.9%)
Flatulence	1 (2.2%)		1 (1.4%)
Severe	1 (2.2%)		1 (1.4%)

* Other includes Asian, Native American, and other races.
** P-values: Age = Wilcoxon rank-sum, Sex = Pearson's chi-square, Race = Fisher's exact test.
Created by on 06MAR2018.

Table 5.4
Adverse Events
By Body System, Preferred Term, and Greatest Severity

Body System Preferred Term Severity	Active N= 45	Placebo N= 25	Overall N= 70
Hiatus hernia	1 (2.2%)		1 (1.4%)
Severe	1 (2.2%)		1 (1.4%)
dyspepsia		1 (4.0%)	1 (1.4%)
Moderate		1 (4.0%)	1 (1.4%)
Nervous system disorders	2 (4.4%)	1 (4.0%)	3 (4.3%)
Mild	1 (2.2%)	1 (4.0%)	2 (2.9%)
Moderate	1 (2.2%)		1 (1.4%)
Convulsion	1 (2.2%)		1 (1.4%)
Mild	1 (2.2%)		1 (1.4%)
Essential tremor		1 (4.0%)	1 (1.4%)
Mild		1 (4.0%)	1 (1.4%)
dizziness	1 (2.2%)		1 (1.4%)
Moderate	1 (2.2%)		1 (1.4%)
Psychiatric disorders	2 (4.4%)	1 (4.0%)	3 (4.3%)
Mild	1 (2.2%)	1 (4.0%)	2 (2.9%)
Severe	1 (2.2%)		1 (1.4%)
Confusional state	1 (2.2%)		1 (1.4%)
Severe	1 (2.2%)		1 (1.4%)
Sleep disorder	1 (2.2%)		1 (1.4%)
Mild	1 (2.2%)		1 (1.4%)
delirium	1 (2.2%)	1 (4.0%)	2 (2.9%)
Mild	1 (2.2%)	1 (4.0%)	2 (2.9%)