Table 14.3.1.1
Overall Summary of Adverse Events
Safety Population

	Treatments				
Adverse Events	Dose Group 1 0.25 mg/kg/day (N=12) N (%)	Dose Group 2 0.75 mg/kg/day (N=12) N (%)	Dose Group 3 2.0 mg/kg/day (N=12) N (%)	Dose Group 4 6.0 mg/kg/day (N=12) N (%)	Total (N=48) N (%)
Total Number of AEs	16	18	13	11	58
Total Number of TEAEs	13	13	11	9	46
Subjects with					
Any TEAE	7 (58.3)	6 (50.0)	8 (66.7)	7 (58.3)	28 (58.3)
Any Drug Related TEAE	1 (8.3)	2 (16.7)	2 (16.7)	3 (25.0)	8 (16.7)
Any CTCAE Grade 3 or Higher TEAE	0	0	0	0	0
Discontinuation of Study Drug due to a TEAE	0	0	0	0	0
Any Serious TEAE	0	0	0	0	0
Death	0	0	0	0	0

Treatment-emergent adverse events (TEAEs) are defined as any adverse event or worsening of an existing condition after initiation of the investigational product and through the subject's last study visit (study completion or early termination).
Serious adverse events were recorded for up to 30 days after the final administration of study drug.
Related TEAEs include those considered possibly, probably, and definitely related.

Program: t-ae-overall.sas, Final, 21MAR2018 18:06