Table 14.1.1.1 Baseline Characteristics
(Safety Analysis Set)

Parameter		Placebo N=XX	Active N=XX
Parameter 1	n	xx	xx
	Mean	xx.x	xx.x
	SD	xx.x	xx.x
	Median	xx.x	xx.x
	Q1 , Q3	xx.x , xx.x	xx.x , xx.x
	Min , Max	xx , xx	xx , xx
Parameter 2	n	xx	xx
	Mean	xx.x	xx.x
	SD	xx.x	xx.x
	Median	xx.x	xx.x
	Q1 , Q3	xx.x , xx.x	xx.x , xx.x
	Min , Max	xx , xx	xx , xx
Parameter 3	n	xx	xx
	Mean	xx.x	xx.x
	SD	xx.x	xx.x
	Median	xx.x	xx.x
	Q1 , Q3	xx.x , xx.x	xx.x , xx.x
	Min , Max	xx , xx	xx , xx
Continue for the rest of the parameters...			

N=Number of subjects in the analysis set
SD= Standard deviation, Q1= First quartile, Q3= Third quartile
Min= Minimum, Max= Maximum

Table 14.1.1.2 Treatment-emergent Adverse Events by Preferred Term
(Safety Analysis Set)

Preferred Term	Placebo N=XX n (%)	Active N=XX n (%)
Number of subjects reporting treatment-emergent adverse events	xx (xx.x)	xx (xx.x)
Preferred term 1	xx (xx.x)	xx (xx.x)
Preferred term 2	xx (xx.x)	xx (xx.x)
Preferred term n	xx (xx.x)	xx (xx.x)

N=Number of subjects in the analysis set
Adverse events are coded using MedDRA version 20.0