

Table 15.9.1.1: Change from Baseline in Mean Daytime QTcF in Lead V5 (Standard 12-Lead ECG)
Full Analysis Set

	Total (N=41)
Week 24	
N	35
Mean (SD)	504.0 (32.65)
Median	501.4
Q1, Q3	484.5, 520.6
Min, Max	443.8, 591.9
Change from Baseline at Week 24	
N	35
Mean (SD)	-8.5 (18.03)
Median	-8.0
Q1, Q3	-22.2, 2.1
Min, Max	-54.1, 31.8
95% CI	(-14.7 , -2.3)
p-value	0.0087

Baseline was the Day 1 value.

QTcF is corrected QT interval using Fridericia's formula. $QTcF = QT / \text{cube root } (RR)$.
AUC(0-6) for QTcF was calculated using the trapezoidal rule, mean of triplicate values, and actual time (latest of triplicate times).
Mean daytime QTcF (AUC 0-6/6) was computed by dividing AUC(0-6) by the time from dosing to the 6 hour postdose time point.
p-values and 95% Confidence Intervals (CI) for the mean change were based on the paired t-test.

Data Extracted: 16May2017

Source: .../final/version1/prog/t-eg-auc06.sas v9.4 Output file: t-eg-auc06-v5.out 25MAY2017:10:15