

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