



**Protocol A0501104**

***A PHASE 1, SINGLE CENTER RANDOMIZED, THRE-WAY  
CROSSOVER, DOUBLE-BLINDED, PLACEBO- AND  
MOXIFLOXACIN-CONTROLLED THOROUGH QT (TQT)  
STUDY TO DETERMINE THE EFFECTS OF SERTRALINE  
(ZOLOFT<sup>®</sup>) ON THE CARDIAC REPOLARIZATION IN  
HEALTHY SUBJECTS***

**Statistical Analysis Plan  
(SAP)**

**Version:**

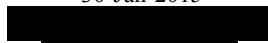
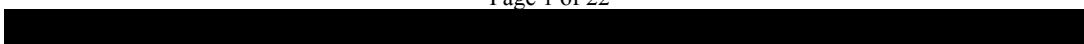


**Author:**



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**List of Reviewers**

Role Name	Reviewer's Name
Clinician/Clinical Pharmacology Lead	[REDACTED]
Clinical Pharmacology Team Lead	[REDACTED]
Regulatory Lead	[REDACTED]
Clinical Programming	[REDACTED]
Clinical Protocol Manager	[REDACTED]
Global Clinical Lead	[REDACTED]
Pharmacometrician	[REDACTED]
Medical Monitor	[REDACTED]
Biostatistician	[REDACTED]

NOTE: *Italicized* text within this document has been taken verbatim from the Protocol.

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## 1. AMENDMENTS FROM PREVIOUS VERSION(S)

None.

## 2. INTRODUCTION

*Sertraline is a selective serotonin reuptake inhibitor (SSRI).*

*ZOLOFT® (Sertraline hydrochloride) is indicated for the treatment of major depressive disorder; obsessions and compulsions in patients with obsessive-compulsive disorder (OCD); panic disorder, with or without agoraphobia, as defined in DSM-I; posttraumatic stress disorder; premenstrual dysphoric disorder (PMDD); and social anxiety disorder, also known as social phobia, in adults (ZOLOFT® USPI Revised August 2014).<sup>1</sup>*

*This study is being conducted to fulfill a US FDA Post Marketing Requirement (PMR) and the study design is in accordance with the ICH E14 Guidance for a thorough QTc (TQT) study. This study is designed to assess effect of sertraline on the QTc interval at supratherapeutic concentrations.*

### 2.1. Study Design

*This will be a Phase 1, single-center, randomized, double-blind, placebo- and moxifloxacin-controlled, 3-period, 6-sequence, 3-treatment (sertraline and placebo blinded; moxifloxacin open label) 3-way crossover thorough QT (TQT) study of the effects of sertraline on cardiac repolarization in 54 healthy subjects.*

#### **Number of Subjects**

*A sample size of approximately 42 subjects (7 per sequence) was estimated to be required for the study to attain statistical power to demonstrate lack of effect of sertraline on QTc and also show assay sensitivity. To allow for dropouts, 54 (9 per sequence) subjects will be randomized to have approximately 42 evaluable subjects. Subjects will not be replaced. However, if the total number of subjects goes below 36, an additional 6 subjects will be randomized.*

#### **Study Treatments**

*The subjects, investigator and site personnel involved in the study (except for the pharmacy staff) will be blinded to study treatments (except open label moxifloxacin), while the sponsor (Pfizer) will be un-blinded.*

*Sertraline (Treatment A), moxifloxacin (Treatment B), and placebo (Treatment C) will be administered in a randomized sequence in Periods 1, 2 or 3 as shown below.*

*The following treatments will be administered:*

- **Treatment A (sertraline hydrochloride - double blinded):** dose titrated from a starting single dose (QD) of 50 mg sertraline in the morning on Day 1 followed by

*BID (given at approximately 12 hours apart) escalating doses administered on Days 2 through 6, followed by 400 mg/day (BID) on Days 7 through 13, and on Day 14 only the morning dose of 200 mg will be administered, and no evening dose will be administered, according to the dose titration scheme below.*

- **Treatment B (moxifloxacin - positive control, open label):** double blinded placebo (matching for sertraline) will be given from Day 1 to Day 13, according to dose titration scheme below. On Day 14, a single dose of 400 mg moxifloxacin (Avelox®) will be administered open label.
- **Treatment C (placebo - double blinded):** placebo control – placebo administered on Days 1 through 14, according to the dose titration scheme below.

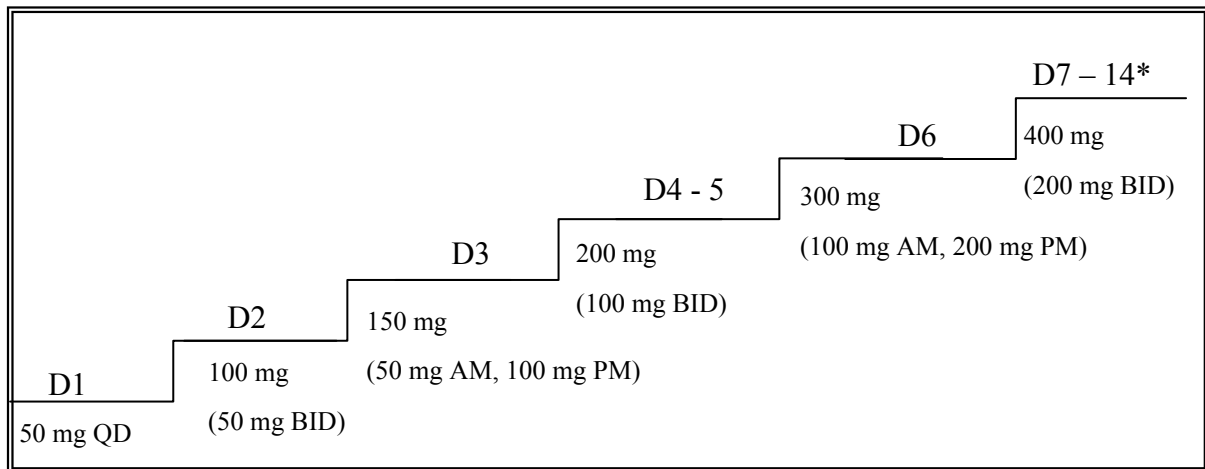
*Sertraline 50 mg tablets and matching placebo tablets will be used in the study.*

**Table 1. Treatment Sequences**

	<i>Treatment</i>		
	<i>Period 1</i>	<i>Period 2</i>	<i>Period 3</i>
<i>Sequence 1 (n=9)</i>	<i>Treatment A</i>	<i>Treatment B</i>	<i>Treatment C</i>
<i>Sequence 2 (n=9)</i>	<i>Treatment C</i>	<i>Treatment B</i>	<i>Treatment A</i>
<i>Sequence 3 (n=9)</i>	<i>Treatment B</i>	<i>Treatment C</i>	<i>Treatment A</i>
<i>Sequence 4 (n=9)</i>	<i>Treatment C</i>	<i>Treatment A</i>	<i>Treatment B</i>
<i>Sequence 5 (n=9)</i>	<i>Treatment A</i>	<i>Treatment C</i>	<i>Treatment B</i>
<i>Sequence 6 (n=9)</i>	<i>Treatment B</i>	<i>Treatment A</i>	<i>Treatment C</i>

*n = number of subjects*

**Dose Titration Scheme for Treatment A – Sertraline Administration:**



\*: On Day 14, only the morning dose of 200 mg will be administered, and no evening dose will be administered.

## 2.2. Study Objectives

### 2.2.1. Primary Objectives

- *To determine the effect of sertraline on QTc intervals relative to time-matched placebo in healthy subjects.*

### 2.2.2. Secondary Objectives

- *To evaluate study sensitivity by evaluating the effect of moxifloxacin on QTc intervals relative to time-matched placebo at moxifloxacin historical  $T_{max}$  (3 hours postdose).*
- *To evaluate the safety and tolerability of sertraline in healthy subjects.*
- *To evaluate the relationship of the QTc interval with plasma concentrations of sertraline and its metabolite, N-desmethylsertraline.*

### 2.2.3. Tertiary Objectives

- *To evaluate the pharmacokinetics of sertraline and its metabolites, N-desmethylsertraline.*

## 3. INTERIM ANALYSES, FINAL ANALYSES AND UNBLINDING

No interim analysis is planned. Final analysis will follow the official database closure.

At the initiation of the study, the study site will be instructed on the method for breaking the blind. The method will be either a manual or electronic process. Blinding codes should only be broken in emergency situations for reasons of subject safety. Whenever possible, the investigator and/or designee should consult with a member of the study team prior to breaking the blind. When the blinding code is broken, the reason must be fully documented and entered on the case report form.

## 4. HYPOTHESES AND DECISION RULES

### 4.1. Statistical Hypotheses

The parameter being tested for each postdose time point  $i$ ,  $i = 1, \dots, 9$  (Day 14 24 hr measurement), is  $\mu(D)_i - \mu(P)_i$  = population mean for QTc on drug (sertraline) at time  $i$  - population mean for QTc on placebo at time  $i$ . The null hypothesis of a positive QT/QTc effect and the alternative hypothesis lack of a QT/QTc effect can be expressed as the following statistical hypotheses:

Ho:  $\mu(D)_i - \mu(P)_i \geq 10$  msec for at least one  $i$

Ha:  $\mu(D)_i - \mu(P)_i < 10$  msec for all  $i$

To establish assay sensitivity, the parameter being tested for 3-hour postdose (historical moxifloxacin median  $T_{max}$ ) is  $\mu(M) - \mu(P)$  = population mean for QTc on drug (moxifloxacin) at time 3-hour postdose - population mean for QTc on placebo at time 3-hour

postdose. The null hypothesis of lack of a QT/QTc effect and the alternative hypothesis of a positive QT/QTc effect can be expressed as the following statistical hypotheses:

Ho:  $\mu(M) - \mu(P) \leq 5$  msec for 3-hour postdose

Ha:  $\mu(M) - \mu(P) > 5$  msec for 3-hour postdose

#### 4.2. Statistical Decision Rules

- **Lack of Effect of sertraline on QTc Intervals Assessment:**

*A lack of an effect of sertraline on QTc intervals will be concluded if the upper bounds of the two-sided 90% (equivalent to one-sided 95%) confidence intervals for all the time-matched mean differences between sertraline and placebo are less than 10 msec.*

- **Assay Sensitivity Assessment:**

*This study will be deemed adequately sensitive to detect QT/QTc prolongation if the lower bound of the two-sided 90% confidence interval for the mean difference between moxifloxacin and placebo is greater than 5 msec at the historic  $T_{max}$  of moxifloxacin (3 hours postdose).*

#### 5. ANALYSIS SETS

Analysis sets may contain different number of subjects.

##### 5.1. Electrocardiogram (ECG) Analysis Set

**Primary ECG Analysis Population:** *The primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period. Analysis sets may contain different numbers of subjects for different ECG parameters based on availability of data.*

**Completer ECG Analysis Population:** *The completer ECG analysis population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.*

##### 5.2. Pharmacokinetic (PK) Analysis Set

###### 5.2.1. Concentration Analysis Set

*The pharmacokinetic (PK) concentration population is defined as all subjects enrolled and treated who have at least 1 concentration determined.*

###### 5.2.2. Parameter Analysis Set

*The PK parameter analysis population is defined as all subjects enrolled and treated who have at least 1 of the pharmacokinetic parameters of primary interest determined.*

### **5.3. Pharmacodynamic Analysis Set**

None.

### **5.4. Safety Analysis Set**

*All subjects who receive at least 1 dose of study medication will be included in the safety analyses and listings.*

### **5.5. Other Analysis Sets**

None.

### **5.6. Treatment Misallocations**

All analyses will be performed on an “as-treated” basis and will not include data from subjects who are randomized but not treated.

If a subject takes a treatment that is not consistent with the treatment they are randomized to, for example takes a treatment out of sequence or takes the same treatment twice, then they will be reported under the treatment that they actually receive for all safety, PK and pharmacodynamic analyses, where applicable.

### **5.7. Protocol Deviations**

Subjects who experience events that may affect their PK profile (eg, lack of compliance with dosing) may be excluded from the PK analysis. At the discretion of the pharmacokineticist a concentration value may also be excluded if the deviation in sampling time is of sufficient concern or if the concentration is anomalous for any other reason.

A full list of protocol deviations will be compiled and reviewed to identify major and minor deviations prior to database closure.

#### **5.7.1. Deviations Assessed Prior to Randomization**

At Screening, the investigator will assess subjects against the inclusion and exclusion criteria as set out in [Sections 4.1](#) and [4.2 of the protocol](#).

#### **5.7.2. Deviations Assessed Post-Randomization**

A full list of protocol deviations for the study report will be compiled prior to database closure. Any significant deviation from the protocol will be reviewed prior to database closure and a decision taken regarding evaluation for each analysis population.

## **6. ENDPOINTS AND COVARIATES**

### **6.1. Efficacy Endpoint(s)**

None.

## 6.2. Safety Endpoints

Any events occurring following start of treatment or increasing in severity will be counted as treatment emergent.

Events that occur in a non-treatment period (for example, Washout or Follow-up) will be counted as treatment emergent and attributed to the previous treatment taken.

Measurements for laboratory (Day 0) and vital signs predose measurements taken on Day 1 of each period will be used as baseline. The following data are considered in standard safety summaries (see [protocol](#) for collection days and list of parameters):

- *adverse events,*
- *laboratory data,*
- *vital signs data.*

The following vital signs endpoints will be determined:

- The maximum decrease and increase from baseline over all measurements taken postdose for supine systolic and diastolic blood pressures,

## 6.3. Other Endpoints

### 6.3.1. PK Endpoints

Blood samples for PK analysis of sertraline will be taken according to the [Schedule of Activities](#) given in the protocol.

The following PK parameters will be calculated for sertraline/metabolite (if possible) from the concentration-time data using standard noncompartmental methods:

**Table 2. Noncompartmental PK Parameters**

Day	Parameter	Analysis Scale
Single Dose (SD)	$C_{max}$ , $C_{max}(dn)$ , $AUC_{24}$ , $AUC_{24}(dn)$ , MR	ln
	$T_{max}$	R
Multiple Dose (MD)	$C_{max}$ , $C_{max}(dn)$ , $AUC_{24}$ , $AUC_{24}(dn)$ , $AUC_{last}$ , Rac [ $R_{ac}$ (obs) and $R_{ac}$ ( $C_{max}$ )] MR and $C_{min}$	ln
	$T_{max}$	R
	$t_{1/2}$	R

Key: ln=natural-log transformed, R=raw (untransformed)

### 6.3.2. ECG Endpoints

For each ECG timepoint, the mean of the triplicate ECG parameters (QT interval, QTcF, PR interval, RR, and QRS), will be used for all analyses.

The baseline will be defined as the mean of the three averaged triplicate measurements taken at the following three timepoints (-1.0 hour, -0.5 hour, 0 hour) prior to dosing on Day 1 of each period.

Primary endpoint:

- Time-matched mean differences in QTcF intervals between sertraline and placebo at each postdose time assessed on Day 14.

Secondary endpoints:

- Time-matched mean differences in QTcF intervals between moxifloxacin and placebo at each postdose time assessed on Day 14. Comparison will be based on 3-hour postdose measurements only.

### **6.3.3. Pharmacokinetic/Pharmacodynamic (PK/PD) Endpoints**

The relationship between plasma concentrations of sertraline/metabolites and QTc will be established.

### **6.4. Covariates**

The baseline QTc from each period will be used as a covariate in the statistical model in [Section 8.1.2](#).

## **7. HANDLING OF MISSING VALUES**

For the analysis of safety endpoints, the sponsor data standard rules for imputation will be applied.

### **7.1. Concentrations Below the Limit of Quantification**

In all data presentations (except listings), concentrations below the limit of quantification (BLQ) will be set to zero. In listings BLQ values will be reported as “<LLQ”, where LLQ will be replaced with the value for the lower limit of quantification.

### **7.2. Deviations, Missing Concentrations and Anomalous Values**

In summary tables and plots of median profiles, statistics will be calculated having set concentrations to missing if 1 of the following cases is true:

1. A concentration has been collected as ND (ie not done) or NS (ie no sample),
2. A deviation in sampling time is of sufficient concern or a concentration has been flagged anomalous by the pharmacokineticist.

Note that summary statistics will not be presented at a particular time point if more than 50% of the data are missing.

### 7.3. Pharmacokinetic Parameters

Actual PK sampling times will be used in the derivation of PK parameters.

If a PK parameter cannot be derived from a subject's concentration data, the parameter will be coded as NC (ie, not calculated). (Note that NC values will not be generated beyond the day that a subject discontinues.)

In summary tables, statistics will be calculated by setting NC values to missing; and statistics will be presented for a particular treatment with  $\geq 3$  evaluable measurements. For statistical analyses (ie, analysis of variance), PK parameters coded as NC will also be set to missing; and analyses will not be performed for a particular parameter if more than 50% of the data are NC.

If an individual subject has a known biased estimate of a PK parameter (due for example to an unexpected event such as vomiting before all the compound is adequately absorbed in the body), this will be footnoted in summary tables and will not be included in the calculation of summary statistics or statistical analyses.

## 8. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

### 8.1. ECG Analysis

During interactions with FDA on design of this TQT study, FDA had indicated concern on possibility of (i) large period effect and (ii) unbalance missing data due to potential large drop-out (i.e., >10%). These FDA concerns are addressed in study [protocol](#) and also in this Statistical Analysis Plan, specifically in Section 8.1.2.

#### 8.1.1. Statistical Methods

The lack of effect on QTcF intervals will be determined by constructing 90% confidence intervals around the estimated difference between the Test (sertraline) and Reference (placebo) treatments using a mixed effects model based on raw postdose QTcF data. The mixed effects model will be implemented using SAS Proc Mixed, with REML estimation method, variance-covariance structure of compound symmetry and Kenward-Roger degrees of freedom algorithm.

#### 8.1.2. Statistical Model

*Averages of triplicate ECG measurements will be used in all statistical analyses. For primary and sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used considering that 24 hour postdose ECG will be sufficient to capture QT prolongation induced by active drug. However, for exposure response analysis all ECG data collected on Day 14, along with Day 1 data will be used.*

*If subjects vomited on Day 14 within 2 hours of dosing, data from these subjects on those days will be excluded from PK and ECG statistical analyses.*

**Primary Analysis:**

*Primary analysis will be conducted in the Primary ECG Analysis Population.*

*The post-dose QTcF intervals will be analyzed (Day 14 data for sertraline, placebo, and moxifloxacin) with baseline as a covariate. Analysis of covariance using a mixed effect model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subject within sequence as a random effect and baseline QTcF as a covariate will be conducted.*

*If there is a significant period effect, a mixed effect model with sequence, period, treatment, period-by-treatment interaction, carry-over, time, treatment-by-time interaction as fixed effects, subject within sequence as a random effect and baseline QTcF as a covariate will be conducted.*

*The 90% confidence intervals (equivalent to a one-sided 95% confidence interval) for time-matched change from placebo in QTcF at each time point on Day 14 will be computed for Sertraline. Similarly, the 90% confidence interval for time-matched change from placebo in QTcF at 3 hours postdose on Day 14 will be computed for moxifloxacin.*

- **Lack of Effect of Sertraline on QTc Intervals Assessment:**

*A lack of an effect of sertraline on QTc intervals will be concluded if the upper bounds of the two-sided 90% (equivalent to one-sided 95%) confidence intervals for all the time-matched mean differences between sertraline and placebo are less than 10 msec.*

- **Assay Sensitivity Assessment:**

*This study will be deemed adequately sensitive to detect QT/QTc prolongation if the lower bound of the two-sided 90% confidence interval for the mean difference between moxifloxacin and placebo is greater than 5 msec at the historic  $T_{max}$  of moxifloxacin (3 hours postdose).*

**Sensitivity Analysis:**

*At the completion of the trial, if more than 10% of subjects dropped out or have missing data for one or more treatment periods, primary analysis outlined above will be conducted in the Completer ECG Analysis Population also.*

**Additional Analyses:**

*Additional analysis will be conducted in the Primary ECG Analysis Population.*

*Relationship between QTc prolongation and sertraline/metabolite plasma concentration will be examined graphically. Exposure response analysis will be performed to establish relationship between change in QTc from baseline and drug concentration.*

*Categorical analysis of QTcF of both absolute post-dose maximum and maximum increase from baseline will be provided.*

*QT, QTcF, PR, HR, and QRS will be summarized by treatment group, study day, and time point – both observed and change from baseline.*

*Analyses conducted on QTcF may be repeated on QTcB, QTcI and QTcN if deemed necessary.*

Graphical presentation of the statistical analyses of QTcF, the estimated mean differences and the associated 90% confidence intervals obtained from the above models, will be plotted against postdose time for sertraline and moxifloxacin on the same plot with horizontal reference lines at 5 and 10 msec.

Residuals from the model will be examined for normality and the presence of outliers via visual inspection of plots of residuals vs predicted values and normal probability plots of residuals but these will not be included in the clinical study report. If there are major deviations from normality or outliers then the effect of these on the conclusions will be investigated through alternative transformations and/or analyses excluding outliers. Justification for any alternative to the planned analysis will be given in the report of the study.

### **8.1.3. Statistical Analysis**

#### **8.1.3.1. QT Interval Corrected for Heart Rate**

*The average of the triplicate ECGs collected at each time will be calculated. Baseline will be defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hour, -0.5 hour, 0 hour) before dosing within each period. The QT intervals, QTcF, QTcB, PR intervals, RR, QRS intervals and heart rate will be recorded at each assessment time indicated by the [Schedule of Activities](#) from the protocol. If QTcF is not supplied then it will be derived using Fridericia's heart rate correction formula:*

- $QTcF(msec) = QT(msec)/(RR)^{1/3}$  where  $RR(sec) = 60/HR$  (if not provided)

*If not supplied, QTcB intervals will be derived using Bazett's heart rate correction formula:*

- $QTcB(msec) = QT(msec)/(RR)^{1/2}$  where  $RR(sec) = 60/HR$  (if not provided)

*Changes from baseline for QTcF, QTcB, uncorrected QT, PR, QRS, and heart rate will be calculated for each subject and treatment at each time point.*

*The maximum absolute postdose value and the maximum increase from baseline for QTcF, QTcB, uncorrected QT, PR, QRS, and heart rate will be determined for each subject and treatment.*

*Additionally, QTcI and QTcN may also be computed using individual and population correction methods. Change from baseline, maximum absolute postdose value and the maximum increase from baseline for QTcI and QTcN may also be computed.*

**QTcN (population correction) and QTcI (individual correction):**

Besides using fixed coefficient correction methods (QTcF and QTcB), observed predose data can be used to estimate correction coefficients based on population and individual correction methods. Estimation of correction coefficients can be derived by using either a linear model or a log-linear model depending upon relationship between observed predose QT and RR.

Graphical presentation of predose QT and RR will be provided.

**Linear regression method:**

- Fit a model  $QT = a + b * RR$  to baseline data (predose Day 1 data)
- Use the estimated slope ( $\hat{b}$ ) to correct QT
- Corrected QT for heart rate will be computed as follows:

$$QTc = QT + \hat{b} * (1-RR)$$

**Log-linear regression method:**

- Fit a model  $\text{Loge}(QT) = a + b * \text{Loge}(RR)$  to baseline data (predose Day 1 data)
- Use the estimated slope ( $\hat{b}$ ) to correct QT
- Corrected QT for heart rate will be computed as follows:

$$QTc_{\log} = QT/RR^{\hat{b}}$$

SAS statements to fit these models for individual and population corrections are provided in [Appendix 1](#).

If QTcI and QTcN are used, statistical analysis results will be reported. The correction formula that gives the lowest (in absolute value) Pearson correlation between the corrected QT and heart rate at baseline is the most desirable and will be used in subsequent analysis besides QTcF.

**8.1.3.2. Other Analyses**

Baseline subtracted QTcF, QT and heart rate differences between each treatment and placebo (treatment-placebo) will be summarized (N, mean, 90% confidence interval) and plotted (mean) for each treatment and postdose timepoint.

Observed and changes from baseline for QTcF, QT (uncorrected), PR, RR, QRS, heart rate (and QTcB, QTcN, QTcI, if needed) will be calculated for each subject and summarized descriptively (N, mean, SD, median, minimum and maximum) by treatment and time postdose.

The maximum absolute value (postdose) and the maximum increase from baseline for QTcF, QT (uncorrected), PR, RR, QRS and heart rate will be determined for each subject and treatment. The maximum increase from baseline will be calculated by first subtracting the baseline value from each postdose measurement to give the change from baseline. The maximum of these values over the respective period will then be selected, except in the case where a subject does not show an increase. In such an instance, the minimum decrease will be taken.

Categorization of maximum QTcF and uncorrected QT interval will be provided by treatment using the following criteria:

Absolute Maximum Value (msec)	<450	≥450 to <480	≥480 to <500	≥500
Maximum Increase from Baseline (msec)	<30	≥30 to <60	≥60	

Categorization of maximum heart rate (HR), PR interval and QRS interval will be provided by treatment using the following criteria:

HR (bpm)	Minimum (min.) <40	Maximum (max.) >120
PR (msec)	Max. ≥300	
PR (msec) increase from baseline	Baseline >200 and max. ≥25% increase	Baseline ≤200 and max. ≥50% increase
QRS (msec)	Max. ≥200	
QRS (msec) increase from baseline	Baseline >100 and max. ≥25% increase	Baseline ≤100 and max. ≥50% increase

The mean of the triplicate ECG measurements will be used to represent a single observation at that time point. If any of the three individual ECG tracings has a QTc value ≥500 msec, but the mean of the triplicates is not ≥500 msec, the data from the subject's individual tracing will be described in a safety section of the study report in order to place the ≥500 msec value in appropriate clinical context. However, values from individual tracings within triplicate measurements that are ≥500 msec will not be included in the categorical analysis unless the average from the triplicate measurement is also ≥500 msec. These individual tracings with values of ≥500 msec will be listed.

## 8.2. PK Analysis

The following sertraline/metabolite PK parameters will be summarized:

**Table 3. PK Parameters to be Summarized Descriptively**

Day	Parameter	Descriptive Statistics
Single Dose (SD)	$C_{max}$ , $C_{max}(dn)$ , $AUC_{24}$ , $AUC_{24}(dn)$ , MR	N, arithmetic mean, median, cv%, standard deviation, minimum, maximum, geometric mean and geometric CV%
	$T_{max}$	N, median, minimum, maximum
Multiple Dose (MD)	$C_{max}$ , $C_{max}(dn)$ , $AUC_{24}$ , $AUC_{24}(dn)$ , $AUC_{last}$ , $R_{ac}$ [ $R_{ac}$ (obs) and $R_{ac}$ ( $C_{max}$ )] MR and $C_{min}$	N, arithmetic mean, median, cv%, standard deviation, minimum, maximum, geometric mean and geometric CV%
	$T_{max}$	N, median, minimum, maximum
	$t_{1/2}$	N, arithmetic mean, median, cv%, standard deviation, minimum, maximum

There will be one summary table each for sertraline and metabolite presenting all PK parameters for Days 1 and 14.

Supporting data from the estimation of  $t_{1/2}$  will be listed by analyte: terminal phase rate constant ( $k_{el}$ ), goodness of fit statistic from the log-linear regression ( $r^2$ ) and the first, last, and number of time points used in the estimation of  $k_{el}$ . This data may be included in the clinical study report.

Presentations for sertraline/metabolite concentrations will include:

- A listing of all plasma concentrations sorted by subject id and nominal time postdose by Study Day. The listing of plasma concentrations will include the actual times. Deviations from the nominal time will be given in a separate listing.
- A summary of plasma concentrations by nominal time postdose by Study Day, where the set of statistics will include n, mean, median, standard deviation, coefficient of variation (cv), minimum, maximum and the number of concentrations above the lower limit of quantification.
- Median plasma concentrations time plots (on both linear and semi-log scales) against nominal time postdose. Plots for Study Days 1 and 14 could be combined in to one plot.
- Mean plasma concentrations time plots (on both linear and semi-log scales) against nominal time postdose. Plots for Study Days 1 and 14 could be combined in to one plot.
- Individual plasma concentration time plots (on both linear and semi-log scales) against actual time postdose. Plots for Study Days 1 and 14 could be combined in to one plot.

- Individual plasma concentration time plots by subject (on both linear and semi-log scales) against actual time postdose, (there will be separate plots for each subject per scale). Plots for Study Days 1 and 14 could be combined in to one plot.
- Dose normalized plot for individual subject parameters ( $C_{\max}$  and  $AUC_{24}$ ) will be presented by Study Day and overlaid with geometric means.

For summary statistics and mean plots by sampling time, the nominal PK sampling time will be used, for individual subject plots by time, the actual PK sampling time will be used.

### **8.3. Pharmacokinetic/Pharmacodynamic (PK/PD) Analysis**

Tables and figures described in this section will be provided by the Clinical Pharmacology group, if applicable.

*Relationship between QTc prolongation and sertraline/metabolite plasma concentration will be examined graphically. Exposure response analysis will be performed to establish relationship between change in QTc from baseline and drug concentration.*

Figures showing relationship between QTcF, QT, and Change from baseline in QTcF and plasma concentration of sertraline/metabolite will be provided.

A repeated measure mixed model will be fitted to establish this relationship where change from baseline in QTcF will be related to sertraline/metabolite plasma concentration. SAS codes to fit mixed model for this analysis is provided in [Appendix 1](#).

### **8.4. Safety Analysis**

A set of summary tables split by treatment will be produced to evaluate any potential risk associated with the safety and toleration of administering sertraline and moxifloxacin.

#### **8.4.1. Treatment and Disposition of Subjects**

Subject evaluation groups will show end of study subject disposition and will show which subjects were analyzed for pharmacokinetics, as well as for safety (adverse events and laboratory data). Frequency counts will be supplied for subject discontinuation(s) by treatment.

Data will be reported in accordance with the sponsor's reporting standards.

#### **8.4.2. Demographic and Clinical Examination Data**

A breakdown of demographic data will be provided for age, race, weight, body mass index, and height. Each will be summarized by sex at birth and 'All Subjects' in accordance with the sponsor's reporting standards.

#### **8.4.3. Discontinuation(s)**

Subject discontinuations, temporary discontinuations or dose reductions due to adverse events will be detailed and summarized by treatment.

Data will be reported in accordance with the sponsor reporting standards.

#### **8.4.4. Adverse Events**

Adverse events will be reported in accordance with the sponsor's reporting standards.

#### **8.4.5. Laboratory Data**

Laboratory data will be listed in accordance with the sponsor's reporting standards.

#### **8.4.6. Vital Signs**

The baseline measurement is the average of the predose measurements taken on Day 1 of each period.

For each planned timepoint, baseline values and change from baseline in vital signs (supine blood pressure and pulse rate) will be summarized with descriptive statistics (using sponsor default standards) by treatment.

These data will be listed in accordance with the sponsor reporting standards. Additionally, standing vital signs will be listed only.

#### **8.4.7. Other Safety Data**

Assessment of Suicidal Ideation and Behavior (SIB) based on Columbia Suicide Severity Rating Scale will be listed by treatment as per the sponsor's reporting standards.

#### **8.4.8. Concomitant Treatments**

All concomitant medication(s) as well as non-drug treatment(s) will be provided in the listings.

#### **8.4.9. Screening and Other Special Purpose Data**

Prior medication(s) and non-drug treatment(s), serum FSH concentrations (female only), urine drug screen, and serum B-hCG for all females of childbearing potential will be obtained at Screening. These data will not be brought in-house, and therefore will not be listed.

### **9. REFERENCES**

1. [REDACTED]

## 10. APPENDICES

### Appendix 1. SAS CODE FOR ANALYSES

#### A. An example of the PROC MIXED code is provided below for primary analysis:

```
proc mixed data=ecg method=REML;
  class subject sequence period time treat;
  model &var = sequence period treat baseline time time*treat/ddfm=kr;
  random subject(sequence);
  repeated / subject = subject(sequence) type=cs;
  lsmeans treat*time/cl diff alpha=0.1;
run;
```

**Note:** The response variable (&var) in the model is the absolute postdose QTcF interval.

#### B. An example of the PROC MIXED code is provided below for primary analysis that included terms for carryover effect and treatment by period interaction. This model will be fitted only if model in A has a significant ( $p < 0.05$ ) period effect:

Create a dummy variable for carryover effect;

- For each subject
  - determine treatment assigned (A, B, C) for each period.
  - For Periods 2 and 3 only:
    - Assign carryover = 1 if treatment assigned in previous period is 'A', carryover = 2 if treatment assigned in previous period = 'B', carryover = 3 if treatment assigned in previous period = 'C'
  - Assign carryover = 1 for all obs in Period 1

```
proc mixed data=ecg method=REML;
  class subject sequence period time treat carryover;
  model &var = sequence period treat period*treat carryover baseline time
  time*treat/ddfm=kr;
  random subject(sequence);
  repeated / subject = subject(sequence) type=cs;
  lsmeans treat*time/cl diff alpha=0.1;
run;
```

**Note:**

The response variables (&var) in the model is the absolute postdose QTcF interval.

**C. An example of the PROC MIXED code is provided below for establishing relationship between QT and RR for computing QTcI and QTcN: Only predose Day 1 data to be use**

```
proc mixed data=ecg method=REML;
  class subject;
  model &var = &var2/ddfm=kr;
  random int &var2 / subject = subject type=un;
run;
```

**Note:**

Both population correction and individual correction coefficients can be obtained from this model fit.

Linear regression model: &var = absolute QTcF interval; &var2 = absolute RR

Log-linear regression model: &var = log (absolute QTcF interval); &var2 = log (absolute RR)

**D. An example of the PROC MIXED code is provided below for establishing relationship between QTcF and sertraline/metabolite plasma concentration; Postdose data from sertraline/metabolite group only.**

```
proc mixed data=ecg method=REML;
  class subject;
  model &var = &var2/ddfm=kr;
  repeated / subject = subject type=un;
run;
```

**Note:**

&var = postdose change from baseline in QTcF interval

&var2 = corresponding plasma concentration

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drggroup period egstmnum leg_sort;
model stresnm = drggroup period leg_sort egbase egstmnum egstmnum*leg_sort/ddfm=kr;
random subjid(drggroup);
repeated / subject =period*subjid(drggroup) type=cs;
lsmeans egstmnum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Model Information

Data Set WORK.ECG3  
 Dependent Variable STRESNM  
 Covariance Structures Variance Components,  
 Compound Symmetry  
 Subject Effect SUBJI\*PERIOD(DRGGRO)  
 Estimation Method REML  
 Residual Variance Method Profile  
 Fixed Effects SE Method Kenward-Roger  
 Degrees of Freedom Method Kenward-Roger

Class Level Information

Class	Levels	Values		
SUBJID	54	10011001 10011002 10011003		
		10011004 10011005 10011006		
		10011007 10011008 10011009		
		10011010 10011011 10011012		
		10011013 10011014 10011015		
		10011016 10011017 10011018		
		10011019 10011020 10011021		
		10011022 10011023 10011024		
		10011025 10011026 10011027		
		10011028 10011029 10011030		
		10011031 10011032 10011033		
		10011034 10011035 10011036		
		10011037 10011038 10011039		
		10011040 10011041 10011042		
		10011043 10011044 10011045		
		10011046 10011047 10011048		
		10011049 10011050 10011051		
		10011052 10011053 10011054		
		DRGGROUP	6	ABC ACB BAC BCA CAB CBA
		PERIOD	3	Period 1 Period 2 Period 3
		EGSTMNUM	9	1 2 3 4 5 6 8 12 24
LEG_SORT	3	201 202 203		

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	54
Subjects	1
Max Obs Per Subject	1351

Number of Observations

Number of Observations Read	1351
Number of Observations Used	1351
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	9662.48289495	
1	3	8613.87062266	0.00152315
2	1	8607.59045696	0.00083658
3	1	8604.44134180	0.00020428
4	1	8603.95439250	0.00008347
5	1	8603.66734522	0.00000317
6	1	8603.65728154	0.00000001

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		138.04
CS	SUBJI*PERIOD(DRGGRO)	9.7239
Residual		27.3390

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	8603.7
AIC (smaller is better)	8609.7
AICC (smaller is better)	8609.7
BIC (smaller is better)	8615.6

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	26.4	0.32	0.8955
PERIOD	2	67.4	1.25	0.2941
LEG_SORT	2	66.1	95.36	<.0001
EGBASE	1	129	28.34	<.0001
EGSTMNUM	8	1176	60.36	<.0001
EGSTMNUM*LEG_SORT	16	1176	4.02	<.0001

Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	414.30	1.8198	42.2	227.67	<.0001	0.1	411.24	417.36
EGSTMNUM*LEG_SORT	1	202	418.89	1.8225	42.4	229.85	<.0001	0.1	415.82	421.95
EGSTMNUM*LEG_SORT	1	203	407.34	1.8225	42.4	223.51	<.0001	0.1	404.28	410.41
EGSTMNUM*LEG_SORT	2	201	415.63	1.8198	42.2	228.40	<.0001	0.1	412.56	418.69
EGSTMNUM*LEG_SORT	2	202	419.90	1.8225	42.4	230.40	<.0001	0.1	416.83	422.96
EGSTMNUM*LEG_SORT	2	203	407.77	1.8225	42.4	223.75	<.0001	0.1	404.71	410.84
EGSTMNUM*LEG_SORT	3	201	416.47	1.8198	42.2	228.86	<.0001	0.1	413.40	419.53
EGSTMNUM*LEG_SORT	3	202	420.47	1.8225	42.4	230.72	<.0001	0.1	417.41	423.54
EGSTMNUM*LEG_SORT	3	203	408.64	1.8225	42.4	224.22	<.0001	0.1	405.58	411.71
EGSTMNUM*LEG_SORT	4	201	418.25	1.8198	42.2	229.84	<.0001	0.1	415.19	421.31
EGSTMNUM*LEG_SORT	4	202	421.80	1.8225	42.4	231.45	<.0001	0.1	418.73	424.86
EGSTMNUM*LEG_SORT	4	203	408.60	1.8225	42.4	224.20	<.0001	0.1	405.54	411.67
EGSTMNUM*LEG_SORT	5	201	411.29	1.8198	42.2	226.01	<.0001	0.1	408.22	414.35
EGSTMNUM*LEG_SORT	5	202	413.41	1.8225	42.4	226.84	<.0001	0.1	410.35	416.48

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	203	403.91	1.8225	42.4	221.63	<.0001	0.1	400.84	406.97
EGSTMNUM*LEG_SORT	6	201	408.99	1.8198	42.2	224.75	<.0001	0.1	405.92	412.05
EGSTMNUM*LEG_SORT	6	202	411.49	1.8225	42.4	225.79	<.0001	0.1	408.43	414.56
EGSTMNUM*LEG_SORT	6	203	402.47	1.8225	42.4	220.84	<.0001	0.1	399.41	405.54
EGSTMNUM*LEG_SORT	8	201	408.73	1.8198	42.2	224.61	<.0001	0.1	405.67	411.79
EGSTMNUM*LEG_SORT	8	202	410.64	1.8225	42.4	225.32	<.0001	0.1	407.57	413.70
EGSTMNUM*LEG_SORT	8	203	403.13	1.8225	42.4	221.20	<.0001	0.1	400.07	406.20
EGSTMNUM*LEG_SORT	12	201	411.02	1.8198	42.2	225.86	<.0001	0.1	407.96	414.08
EGSTMNUM*LEG_SORT	12	202	411.49	1.8225	42.4	225.79	<.0001	0.1	408.43	414.56
EGSTMNUM*LEG_SORT	12	203	405.34	1.8225	42.4	222.41	<.0001	0.1	402.28	408.41
EGSTMNUM*LEG_SORT	24	201	414.29	1.8145	41.7	228.32	<.0001	0.1	411.24	417.35
EGSTMNUM*LEG_SORT	24	202	412.60	1.8225	42.4	226.40	<.0001	0.1	409.53	415.66
EGSTMNUM*LEG_SORT	24	203	406.95	1.8225	42.4	223.29	<.0001	0.1	403.88	410.01

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-4.5872	1.2268	445	-3.74	0.0002	0.1	-6.6093	-2.5651
EGSTMNUM*LEG_SORT	1	201	1	203	6.9573	1.2230	451	5.69	<.0001	0.1	4.9415	8.9731
EGSTMNUM*LEG_SORT	1	201	2	201	-1.3267	1.0457	1175	-1.27	0.2048	0.1	-3.0481	0.3948
EGSTMNUM*LEG_SORT	1	201	2	202	-5.6005	1.2268	445	-4.57	<.0001	0.1	-7.6226	-3.5784
EGSTMNUM*LEG_SORT	1	201	2	203	6.5240	1.2230	451	5.33	<.0001	0.1	4.5082	8.5398
EGSTMNUM*LEG_SORT	1	201	3	201	-2.1667	1.0457	1175	-2.07	0.0385	0.1	-3.8881	-0.4452
EGSTMNUM*LEG_SORT	1	201	3	202	-6.1738	1.2268	445	-5.03	<.0001	0.1	-8.1959	-4.1517
EGSTMNUM*LEG_SORT	1	201	3	203	5.6573	1.2230	451	4.63	<.0001	0.1	3.6415	7.6731
EGSTMNUM*LEG_SORT	1	201	4	201	-3.9533	1.0457	1175	-3.78	0.0002	0.1	-5.6748	-2.2319
EGSTMNUM*LEG_SORT	1	201	4	202	-7.5005	1.2268	445	-6.11	<.0001	0.1	-9.5226	-5.4784
EGSTMNUM*LEG_SORT	1	201	4	203	5.6973	1.2230	451	4.66	<.0001	0.1	3.6815	7.7131
EGSTMNUM*LEG_SORT	1	201	5	201	3.0133	1.0457	1175	2.88	0.0040	0.1	1.2919	4.7348
EGSTMNUM*LEG_SORT	1	201	5	202	0.8862	1.2268	445	0.72	0.4705	0.1	-1.1359	2.9083

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	5	203	10.3906	1.2230	451	8.50	<.0001	0.1	8.3748	12.4064
EGSTMNUM*LEG_SORT	1	201	6	201	5.3133	1.0457	1175	5.08	<.0001	0.1	3.5919	7.0348
EGSTMNUM*LEG_SORT	1	201	6	202	2.8062	1.2268	445	2.29	0.0226	0.1	0.7841	4.8283
EGSTMNUM*LEG_SORT	1	201	6	203	11.8240	1.2230	451	9.67	<.0001	0.1	9.8082	13.8398
EGSTMNUM*LEG_SORT	1	201	8	201	5.5667	1.0457	1175	5.32	<.0001	0.1	3.8452	7.2881
EGSTMNUM*LEG_SORT	1	201	8	202	3.6595	1.2268	445	2.98	0.0030	0.1	1.6374	5.6816
EGSTMNUM*LEG_SORT	1	201	8	203	11.1640	1.2230	451	9.13	<.0001	0.1	9.1482	13.1798
EGSTMNUM*LEG_SORT	1	201	12	201	3.2800	1.0457	1175	3.14	0.0018	0.1	1.5586	5.0014
EGSTMNUM*LEG_SORT	1	201	12	202	2.8062	1.2268	445	2.29	0.0226	0.1	0.7841	4.8283
EGSTMNUM*LEG_SORT	1	201	12	203	8.9573	1.2230	451	7.32	<.0001	0.1	6.9415	10.9731
EGSTMNUM*LEG_SORT	1	201	24	201	0.004942	1.0451	1178	0.00	0.9962	0.1	-1.7154	1.7253
EGSTMNUM*LEG_SORT	1	201	24	202	1.6995	1.2268	445	1.39	0.1666	0.1	-0.3226	3.7216
EGSTMNUM*LEG_SORT	1	201	24	203	7.3506	1.2230	451	6.01	<.0001	0.1	5.3348	9.3664
EGSTMNUM*LEG_SORT	1	202	1	203	11.5445	1.2245	449	9.43	<.0001	0.1	9.5261	13.5628
EGSTMNUM*LEG_SORT	1	202	2	201	3.2605	1.2268	445	2.66	0.0081	0.1	1.2384	5.2826
EGSTMNUM*LEG_SORT	1	202	2	202	-1.0133	1.0457	1175	-0.97	0.3327	0.1	-2.7348	0.7081
EGSTMNUM*LEG_SORT	1	202	2	203	11.1111	1.2245	449	9.07	<.0001	0.1	9.0928	13.1294
EGSTMNUM*LEG_SORT	1	202	3	201	2.4205	1.2268	445	1.97	0.0491	0.1	0.3984	4.4426
EGSTMNUM*LEG_SORT	1	202	3	202	-1.5867	1.0457	1175	-1.52	0.1295	0.1	-3.3081	0.1348
EGSTMNUM*LEG_SORT	1	202	3	203	10.2445	1.2245	449	8.37	<.0001	0.1	8.2261	12.2628
EGSTMNUM*LEG_SORT	1	202	4	201	0.6338	1.2268	445	0.52	0.6057	0.1	-1.3883	2.6559
EGSTMNUM*LEG_SORT	1	202	4	202	-2.9133	1.0457	1175	-2.79	0.0054	0.1	-4.6348	-1.1919
EGSTMNUM*LEG_SORT	1	202	4	203	10.2845	1.2245	449	8.40	<.0001	0.1	8.2661	12.3028
EGSTMNUM*LEG_SORT	1	202	5	201	7.6005	1.2268	445	6.20	<.0001	0.1	5.5784	9.6226
EGSTMNUM*LEG_SORT	1	202	5	202	5.4733	1.0457	1175	5.23	<.0001	0.1	3.7519	7.1948
EGSTMNUM*LEG_SORT	1	202	5	203	14.9778	1.2245	449	12.23	<.0001	0.1	12.9595	16.9961
EGSTMNUM*LEG_SORT	1	202	6	201	9.9005	1.2268	445	8.07	<.0001	0.1	7.8784	11.9226
EGSTMNUM*LEG_SORT	1	202	6	202	7.3933	1.0457	1175	7.07	<.0001	0.1	5.6719	9.1148
EGSTMNUM*LEG_SORT	1	202	6	203	16.4111	1.2245	449	13.40	<.0001	0.1	14.3928	18.4294
EGSTMNUM*LEG_SORT	1	202	8	201	10.1538	1.2268	445	8.28	<.0001	0.1	8.1317	12.1759
EGSTMNUM*LEG_SORT	1	202	8	202	8.2467	1.0457	1175	7.89	<.0001	0.1	6.5252	9.9681
EGSTMNUM*LEG_SORT	1	202	8	203	15.7511	1.2245	449	12.86	<.0001	0.1	13.7328	17.7694
EGSTMNUM*LEG_SORT	1	202	12	201	7.8672	1.2268	445	6.41	<.0001	0.1	5.8451	9.8893
EGSTMNUM*LEG_SORT	1	202	12	202	7.3933	1.0457	1175	7.07	<.0001	0.1	5.6719	9.1148
EGSTMNUM*LEG_SORT	1	202	12	203	13.5445	1.2245	449	11.06	<.0001	0.1	11.5261	15.5628

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	24	201	4.5921	1.2257	448	3.75	0.0002	0.1	2.5718	6.6124
EGSTMNUM*LEG_SORT	1	202	24	202	6.2867	1.0457	1175	6.01	<.0001	0.1	4.5652	8.0081
EGSTMNUM*LEG_SORT	1	202	24	203	11.9378	1.2245	449	9.75	<.0001	0.1	9.9195	13.9561
EGSTMNUM*LEG_SORT	1	203	2	201	-8.2840	1.2230	451	-6.77	<.0001	0.1	-10.2998	-6.2682
EGSTMNUM*LEG_SORT	1	203	2	202	-12.5578	1.2245	449	-10.26	<.0001	0.1	-14.5761	-10.5395
EGSTMNUM*LEG_SORT	1	203	2	203	-0.4333	1.0457	1175	-0.41	0.6787	0.1	-2.1548	1.2881
EGSTMNUM*LEG_SORT	1	203	3	201	-9.1240	1.2230	451	-7.46	<.0001	0.1	-11.1398	-7.1082
EGSTMNUM*LEG_SORT	1	203	3	202	-13.1311	1.2245	449	-10.72	<.0001	0.1	-15.1494	-11.1128
EGSTMNUM*LEG_SORT	1	203	3	203	-1.3000	1.0457	1175	-1.24	0.2141	0.1	-3.0214	0.4214
EGSTMNUM*LEG_SORT	1	203	4	201	-10.9106	1.2230	451	-8.92	<.0001	0.1	-12.9264	-8.8948
EGSTMNUM*LEG_SORT	1	203	4	202	-14.4578	1.2245	449	-11.81	<.0001	0.1	-16.4761	-12.4395
EGSTMNUM*LEG_SORT	1	203	4	203	-1.2600	1.0457	1175	-1.20	0.2285	0.1	-2.9814	0.4614
EGSTMNUM*LEG_SORT	1	203	5	201	-3.9440	1.2230	451	-3.22	0.0014	0.1	-5.9598	-1.9282
EGSTMNUM*LEG_SORT	1	203	5	202	-6.0711	1.2245	449	-4.96	<.0001	0.1	-8.0894	-4.0528
EGSTMNUM*LEG_SORT	1	203	5	203	3.4333	1.0457	1175	3.28	0.0011	0.1	1.7119	5.1548
EGSTMNUM*LEG_SORT	1	203	6	201	-1.6440	1.2230	451	-1.34	0.1796	0.1	-3.6598	0.3718
EGSTMNUM*LEG_SORT	1	203	6	202	-4.1511	1.2245	449	-3.39	0.0008	0.1	-6.1694	-2.1328
EGSTMNUM*LEG_SORT	1	203	6	203	4.8667	1.0457	1175	4.65	<.0001	0.1	3.1452	6.5881
EGSTMNUM*LEG_SORT	1	203	8	201	-1.3906	1.2230	451	-1.14	0.2561	0.1	-3.4064	0.6252
EGSTMNUM*LEG_SORT	1	203	8	202	-3.2978	1.2245	449	-2.69	0.0073	0.1	-5.3161	-1.2795
EGSTMNUM*LEG_SORT	1	203	8	203	4.2067	1.0457	1175	4.02	<.0001	0.1	2.4852	5.9281
EGSTMNUM*LEG_SORT	1	203	12	201	-3.6773	1.2230	451	-3.01	0.0028	0.1	-5.6931	-1.6615
EGSTMNUM*LEG_SORT	1	203	12	202	-4.1511	1.2245	449	-3.39	0.0008	0.1	-6.1694	-2.1328
EGSTMNUM*LEG_SORT	1	203	12	203	2.0000	1.0457	1175	1.91	0.0561	0.1	0.2786	3.7214
EGSTMNUM*LEG_SORT	1	203	24	201	-6.9524	1.2221	453	-5.69	<.0001	0.1	-8.9666	-4.9381
EGSTMNUM*LEG_SORT	1	203	24	202	-5.2578	1.2245	449	-4.29	<.0001	0.1	-7.2761	-3.2395
EGSTMNUM*LEG_SORT	1	203	24	203	0.3933	1.0457	1175	0.38	0.7069	0.1	-1.3281	2.1148
EGSTMNUM*LEG_SORT	2	201	2	202	-4.2738	1.2268	445	-3.48	0.0005	0.1	-6.2959	-2.2517
EGSTMNUM*LEG_SORT	2	201	2	203	7.8506	1.2230	451	6.42	<.0001	0.1	5.8348	9.8664
EGSTMNUM*LEG_SORT	2	201	3	201	-0.8400	1.0457	1175	-0.80	0.4220	0.1	-2.5614	0.8814
EGSTMNUM*LEG_SORT	2	201	3	202	-4.8472	1.2268	445	-3.95	<.0001	0.1	-6.8693	-2.8251
EGSTMNUM*LEG_SORT	2	201	3	203	6.9840	1.2230	451	5.71	<.0001	0.1	4.9682	8.9998
EGSTMNUM*LEG_SORT	2	201	4	201	-2.6267	1.0457	1175	-2.51	0.0121	0.1	-4.3481	-0.9052
EGSTMNUM*LEG_SORT	2	201	4	202	-6.1738	1.2268	445	-5.03	<.0001	0.1	-8.1959	-4.1517
EGSTMNUM*LEG_SORT	2	201	4	203	7.0240	1.2230	451	5.74	<.0001	0.1	5.0082	9.0398

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	5	201	4.3400	1.0457	1175	4.15	<.0001	0.1	2.6186	6.0614
EGSTMNUM*LEG_SORT	2	201	5	202	2.2128	1.2268	445	1.80	0.0719	0.1	0.1907	4.2349
EGSTMNUM*LEG_SORT	2	201	5	203	11.7173	1.2230	451	9.58	<.0001	0.1	9.7015	13.7331
EGSTMNUM*LEG_SORT	2	201	6	201	6.6400	1.0457	1175	6.35	<.0001	0.1	4.9186	8.3614
EGSTMNUM*LEG_SORT	2	201	6	202	4.1328	1.2268	445	3.37	0.0008	0.1	2.1107	6.1549
EGSTMNUM*LEG_SORT	2	201	6	203	13.1506	1.2230	451	10.75	<.0001	0.1	11.1348	15.1664
EGSTMNUM*LEG_SORT	2	201	8	201	6.8933	1.0457	1175	6.59	<.0001	0.1	5.1719	8.6148
EGSTMNUM*LEG_SORT	2	201	8	202	4.9862	1.2268	445	4.06	<.0001	0.1	2.9641	7.0083
EGSTMNUM*LEG_SORT	2	201	8	203	12.4906	1.2230	451	10.21	<.0001	0.1	10.4748	14.5064
EGSTMNUM*LEG_SORT	2	201	12	201	4.6067	1.0457	1175	4.41	<.0001	0.1	2.8852	6.3281
EGSTMNUM*LEG_SORT	2	201	12	202	4.1328	1.2268	445	3.37	0.0008	0.1	2.1107	6.1549
EGSTMNUM*LEG_SORT	2	201	12	203	10.2840	1.2230	451	8.41	<.0001	0.1	8.2682	12.2998
EGSTMNUM*LEG_SORT	2	201	24	201	1.3316	1.0451	1178	1.27	0.2029	0.1	-0.3887	3.0520
EGSTMNUM*LEG_SORT	2	201	24	202	3.0262	1.2268	445	2.47	0.0140	0.1	1.0041	5.0483
EGSTMNUM*LEG_SORT	2	201	24	203	8.6773	1.2230	451	7.10	<.0001	0.1	6.6615	10.6931
EGSTMNUM*LEG_SORT	2	202	2	203	12.1245	1.2245	449	9.90	<.0001	0.1	10.1061	14.1428
EGSTMNUM*LEG_SORT	2	202	3	201	3.4338	1.2268	445	2.80	0.0053	0.1	1.4117	5.4559
EGSTMNUM*LEG_SORT	2	202	3	202	-0.5733	1.0457	1175	-0.55	0.5836	0.1	-2.2948	1.1481
EGSTMNUM*LEG_SORT	2	202	3	203	11.2578	1.2245	449	9.19	<.0001	0.1	9.2395	13.2761
EGSTMNUM*LEG_SORT	2	202	4	201	1.6472	1.2268	445	1.34	0.1801	0.1	-0.3749	3.6693
EGSTMNUM*LEG_SORT	2	202	4	202	-1.9000	1.0457	1175	-1.82	0.0695	0.1	-3.6214	-0.1786
EGSTMNUM*LEG_SORT	2	202	4	203	11.2978	1.2245	449	9.23	<.0001	0.1	9.2795	13.3161
EGSTMNUM*LEG_SORT	2	202	5	201	8.6138	1.2268	445	7.02	<.0001	0.1	6.5917	10.6359
EGSTMNUM*LEG_SORT	2	202	5	202	6.4867	1.0457	1175	6.20	<.0001	0.1	4.7652	8.2081
EGSTMNUM*LEG_SORT	2	202	5	203	15.9911	1.2245	449	13.06	<.0001	0.1	13.9728	18.0094
EGSTMNUM*LEG_SORT	2	202	6	201	10.9138	1.2268	445	8.90	<.0001	0.1	8.8917	12.9359
EGSTMNUM*LEG_SORT	2	202	6	202	8.4067	1.0457	1175	8.04	<.0001	0.1	6.6852	10.1281
EGSTMNUM*LEG_SORT	2	202	6	203	17.4245	1.2245	449	14.23	<.0001	0.1	15.4061	19.4428
EGSTMNUM*LEG_SORT	2	202	8	201	11.1672	1.2268	445	9.10	<.0001	0.1	9.1451	13.1893
EGSTMNUM*LEG_SORT	2	202	8	202	9.2600	1.0457	1175	8.86	<.0001	0.1	7.5386	10.9814
EGSTMNUM*LEG_SORT	2	202	8	203	16.7645	1.2245	449	13.69	<.0001	0.1	14.7461	18.7828
EGSTMNUM*LEG_SORT	2	202	12	201	8.8805	1.2268	445	7.24	<.0001	0.1	6.8584	10.9026
EGSTMNUM*LEG_SORT	2	202	12	202	8.4067	1.0457	1175	8.04	<.0001	0.1	6.6852	10.1281
EGSTMNUM*LEG_SORT	2	202	12	203	14.5578	1.2245	449	11.89	<.0001	0.1	12.5395	16.5761
EGSTMNUM*LEG_SORT	2	202	24	201	5.6054	1.2257	448	4.57	<.0001	0.1	3.5851	7.6257

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	202	24	202	7.3000	1.0457	1175	6.98	<.0001	0.1	5.5786	9.0214
EGSTMNUM*LEG_SORT	2	202	24	203	12.9511	1.2245	449	10.58	<.0001	0.1	10.9328	14.9694
EGSTMNUM*LEG_SORT	2	203	3	201	-8.6906	1.2230	451	-7.11	<.0001	0.1	-10.7064	-6.6748
EGSTMNUM*LEG_SORT	2	203	3	202	-12.6978	1.2245	449	-10.37	<.0001	0.1	-14.7161	-10.6795
EGSTMNUM*LEG_SORT	2	203	3	203	-0.8667	1.0457	1175	-0.83	0.4074	0.1	-2.5881	0.8548
EGSTMNUM*LEG_SORT	2	203	4	201	-10.4773	1.2230	451	-8.57	<.0001	0.1	-12.4931	-8.4615
EGSTMNUM*LEG_SORT	2	203	4	202	-14.0245	1.2245	449	-11.45	<.0001	0.1	-16.0428	-12.0061
EGSTMNUM*LEG_SORT	2	203	4	203	-0.8267	1.0457	1175	-0.79	0.4294	0.1	-2.5481	0.8948
EGSTMNUM*LEG_SORT	2	203	5	201	-3.5106	1.2230	451	-2.87	0.0043	0.1	-5.5264	-1.4948
EGSTMNUM*LEG_SORT	2	203	5	202	-5.6378	1.2245	449	-4.60	<.0001	0.1	-7.6561	-3.6195
EGSTMNUM*LEG_SORT	2	203	5	203	3.8667	1.0457	1175	3.70	0.0002	0.1	2.1452	5.5881
EGSTMNUM*LEG_SORT	2	203	6	201	-1.2106	1.2230	451	-0.99	0.3228	0.1	-3.2264	0.8052
EGSTMNUM*LEG_SORT	2	203	6	202	-3.7178	1.2245	449	-3.04	0.0025	0.1	-5.7361	-1.6995
EGSTMNUM*LEG_SORT	2	203	6	203	5.3000	1.0457	1175	5.07	<.0001	0.1	3.5786	7.0214
EGSTMNUM*LEG_SORT	2	203	8	201	-0.9573	1.2230	451	-0.78	0.4342	0.1	-2.9731	1.0585
EGSTMNUM*LEG_SORT	2	203	8	202	-2.8645	1.2245	449	-2.34	0.0198	0.1	-4.8828	-0.8461
EGSTMNUM*LEG_SORT	2	203	8	203	4.6400	1.0457	1175	4.44	<.0001	0.1	2.9186	6.3614
EGSTMNUM*LEG_SORT	2	203	12	201	-3.2440	1.2230	451	-2.65	0.0083	0.1	-5.2598	-1.2282
EGSTMNUM*LEG_SORT	2	203	12	202	-3.7178	1.2245	449	-3.04	0.0025	0.1	-5.7361	-1.6995
EGSTMNUM*LEG_SORT	2	203	12	203	2.4333	1.0457	1175	2.33	0.0201	0.1	0.7119	4.1548
EGSTMNUM*LEG_SORT	2	203	24	201	-6.5190	1.2221	453	-5.33	<.0001	0.1	-8.5332	-4.5048
EGSTMNUM*LEG_SORT	2	203	24	202	-4.8245	1.2245	449	-3.94	<.0001	0.1	-6.8428	-2.8061
EGSTMNUM*LEG_SORT	2	203	24	203	0.8267	1.0457	1175	0.79	0.4294	0.1	-0.8948	2.5481
EGSTMNUM*LEG_SORT	3	201	3	202	-4.0072	1.2268	445	-3.27	0.0012	0.1	-6.0293	-1.9851
EGSTMNUM*LEG_SORT	3	201	3	203	7.8240	1.2230	451	6.40	<.0001	0.1	5.8082	9.8398
EGSTMNUM*LEG_SORT	3	201	4	201	-1.7867	1.0457	1175	-1.71	0.0878	0.1	-3.5081	-0.06523
EGSTMNUM*LEG_SORT	3	201	4	202	-5.3338	1.2268	445	-4.35	<.0001	0.1	-7.3559	-3.3117
EGSTMNUM*LEG_SORT	3	201	4	203	7.8640	1.2230	451	6.43	<.0001	0.1	5.8482	9.8798
EGSTMNUM*LEG_SORT	3	201	5	201	5.1800	1.0457	1175	4.95	<.0001	0.1	3.4586	6.9014
EGSTMNUM*LEG_SORT	3	201	5	202	3.0528	1.2268	445	2.49	0.0132	0.1	1.0307	5.0749
EGSTMNUM*LEG_SORT	3	201	5	203	12.5573	1.2230	451	10.27	<.0001	0.1	10.5415	14.5731
EGSTMNUM*LEG_SORT	3	201	6	201	7.4800	1.0457	1175	7.15	<.0001	0.1	5.7586	9.2014
EGSTMNUM*LEG_SORT	3	201	6	202	4.9728	1.2268	445	4.05	<.0001	0.1	2.9507	6.9949
EGSTMNUM*LEG_SORT	3	201	6	203	13.9906	1.2230	451	11.44	<.0001	0.1	11.9748	16.0064
EGSTMNUM*LEG_SORT	3	201	8	201	7.7333	1.0457	1175	7.40	<.0001	0.1	6.0119	9.4548

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	8	202	5.8262	1.2268	445	4.75	<.0001	0.1	3.8041	7.8483
EGSTMNUM*LEG_SORT	3	201	8	203	13.3306	1.2230	451	10.90	<.0001	0.1	11.3148	15.3464
EGSTMNUM*LEG_SORT	3	201	12	201	5.4467	1.0457	1175	5.21	<.0001	0.1	3.7252	7.1681
EGSTMNUM*LEG_SORT	3	201	12	202	4.9728	1.2268	445	4.05	<.0001	0.1	2.9507	6.9949
EGSTMNUM*LEG_SORT	3	201	12	203	11.1240	1.2230	451	9.10	<.0001	0.1	9.1082	13.1398
EGSTMNUM*LEG_SORT	3	201	24	201	2.1716	1.0451	1178	2.08	0.0379	0.1	0.4513	3.8920
EGSTMNUM*LEG_SORT	3	201	24	202	3.8662	1.2268	445	3.15	0.0017	0.1	1.8441	5.8883
EGSTMNUM*LEG_SORT	3	201	24	203	9.5173	1.2230	451	7.78	<.0001	0.1	7.5015	11.5331
EGSTMNUM*LEG_SORT	3	202	3	203	11.8311	1.2245	449	9.66	<.0001	0.1	9.8128	13.8494
EGSTMNUM*LEG_SORT	3	202	4	201	2.2205	1.2268	445	1.81	0.0710	0.1	0.1984	4.2426
EGSTMNUM*LEG_SORT	3	202	4	202	-1.3267	1.0457	1175	-1.27	0.2048	0.1	-3.0481	0.3948
EGSTMNUM*LEG_SORT	3	202	4	203	11.8711	1.2245	449	9.69	<.0001	0.1	9.8528	13.8894
EGSTMNUM*LEG_SORT	3	202	5	201	9.1872	1.2268	445	7.49	<.0001	0.1	7.1651	11.2093
EGSTMNUM*LEG_SORT	3	202	5	202	7.0600	1.0457	1175	6.75	<.0001	0.1	5.3386	8.7814
EGSTMNUM*LEG_SORT	3	202	5	203	16.5645	1.2245	449	13.53	<.0001	0.1	14.5461	18.5828
EGSTMNUM*LEG_SORT	3	202	6	201	11.4872	1.2268	445	9.36	<.0001	0.1	9.4651	13.5093
EGSTMNUM*LEG_SORT	3	202	6	202	8.9800	1.0457	1175	8.59	<.0001	0.1	7.2586	10.7014
EGSTMNUM*LEG_SORT	3	202	6	203	17.9978	1.2245	449	14.70	<.0001	0.1	15.9795	20.0161
EGSTMNUM*LEG_SORT	3	202	8	201	11.7405	1.2268	445	9.57	<.0001	0.1	9.7184	13.7626
EGSTMNUM*LEG_SORT	3	202	8	202	9.8333	1.0457	1175	9.40	<.0001	0.1	8.1119	11.5548
EGSTMNUM*LEG_SORT	3	202	8	203	17.3378	1.2245	449	14.16	<.0001	0.1	15.3195	19.3561
EGSTMNUM*LEG_SORT	3	202	12	201	9.4538	1.2268	445	7.71	<.0001	0.1	7.4317	11.4759
EGSTMNUM*LEG_SORT	3	202	12	202	8.9800	1.0457	1175	8.59	<.0001	0.1	7.2586	10.7014
EGSTMNUM*LEG_SORT	3	202	12	203	15.1311	1.2245	449	12.36	<.0001	0.1	13.1128	17.1494
EGSTMNUM*LEG_SORT	3	202	24	201	6.1788	1.2257	448	5.04	<.0001	0.1	4.1585	8.1991
EGSTMNUM*LEG_SORT	3	202	24	202	7.8733	1.0457	1175	7.53	<.0001	0.1	6.1519	9.5948
EGSTMNUM*LEG_SORT	3	202	24	203	13.5245	1.2245	449	11.04	<.0001	0.1	11.5061	15.5428
EGSTMNUM*LEG_SORT	3	203	4	201	-9.6106	1.2230	451	-7.86	<.0001	0.1	-11.6264	-7.5948
EGSTMNUM*LEG_SORT	3	203	4	202	-13.1578	1.2245	449	-10.75	<.0001	0.1	-15.1761	-11.1395
EGSTMNUM*LEG_SORT	3	203	4	203	0.04000	1.0457	1175	0.04	0.9695	0.1	-1.6814	1.7614
EGSTMNUM*LEG_SORT	3	203	5	201	-2.6440	1.2230	451	-2.16	0.0312	0.1	-4.6598	-0.6282
EGSTMNUM*LEG_SORT	3	203	5	202	-4.7711	1.2245	449	-3.90	0.0001	0.1	-6.7894	-2.7528
EGSTMNUM*LEG_SORT	3	203	5	203	4.7333	1.0457	1175	4.53	<.0001	0.1	3.0119	6.4548
EGSTMNUM*LEG_SORT	3	203	6	201	-0.3440	1.2230	451	-0.28	0.7787	0.1	-2.3598	1.6718
EGSTMNUM*LEG_SORT	3	203	6	202	-2.8511	1.2245	449	-2.33	0.0203	0.1	-4.8694	-0.8328

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	6	203	6.1667	1.0457	1175	5.90	<.0001	0.1	4.4452	7.8881
EGSTMNUM*LEG_SORT	3	203	8	201	-0.09063	1.2230	451	-0.07	0.9410	0.1	-2.1064	1.9252
EGSTMNUM*LEG_SORT	3	203	8	202	-1.9978	1.2245	449	-1.63	0.1035	0.1	-4.0161	0.02054
EGSTMNUM*LEG_SORT	3	203	8	203	5.5067	1.0457	1175	5.27	<.0001	0.1	3.7852	7.2281
EGSTMNUM*LEG_SORT	3	203	12	201	-2.3773	1.2230	451	-1.94	0.0525	0.1	-4.3931	-0.3615
EGSTMNUM*LEG_SORT	3	203	12	202	-2.8511	1.2245	449	-2.33	0.0203	0.1	-4.8694	-0.8328
EGSTMNUM*LEG_SORT	3	203	12	203	3.3000	1.0457	1175	3.16	0.0016	0.1	1.5786	5.0214
EGSTMNUM*LEG_SORT	3	203	24	201	-5.6524	1.2221	453	-4.63	<.0001	0.1	-7.6666	-3.6381
EGSTMNUM*LEG_SORT	3	203	24	202	-3.9578	1.2245	449	-3.23	0.0013	0.1	-5.9761	-1.9395
EGSTMNUM*LEG_SORT	3	203	24	203	1.6933	1.0457	1175	1.62	0.1057	0.1	-0.02810	3.4148
EGSTMNUM*LEG_SORT	4	201	4	202	-3.5472	1.2268	445	-2.89	0.0040	0.1	-5.5693	-1.5251
EGSTMNUM*LEG_SORT	4	201	4	203	9.6506	1.2230	451	7.89	<.0001	0.1	7.6348	11.6664
EGSTMNUM*LEG_SORT	4	201	5	201	6.9667	1.0457	1175	6.66	<.0001	0.1	5.2452	8.6881
EGSTMNUM*LEG_SORT	4	201	5	202	4.8395	1.2268	445	3.94	<.0001	0.1	2.8174	6.8616
EGSTMNUM*LEG_SORT	4	201	5	203	14.3440	1.2230	451	11.73	<.0001	0.1	12.3282	16.3598
EGSTMNUM*LEG_SORT	4	201	6	201	9.2667	1.0457	1175	8.86	<.0001	0.1	7.5452	10.9881
EGSTMNUM*LEG_SORT	4	201	6	202	6.7595	1.2268	445	5.51	<.0001	0.1	4.7374	8.7816
EGSTMNUM*LEG_SORT	4	201	6	203	15.7773	1.2230	451	12.90	<.0001	0.1	13.7615	17.7931
EGSTMNUM*LEG_SORT	4	201	8	201	9.5200	1.0457	1175	9.10	<.0001	0.1	7.7986	11.2414
EGSTMNUM*LEG_SORT	4	201	8	202	7.6128	1.2268	445	6.21	<.0001	0.1	5.5907	9.6349
EGSTMNUM*LEG_SORT	4	201	8	203	15.1173	1.2230	451	12.36	<.0001	0.1	13.1015	17.1331
EGSTMNUM*LEG_SORT	4	201	12	201	7.2333	1.0457	1175	6.92	<.0001	0.1	5.5119	8.9548
EGSTMNUM*LEG_SORT	4	201	12	202	6.7595	1.2268	445	5.51	<.0001	0.1	4.7374	8.7816
EGSTMNUM*LEG_SORT	4	201	12	203	12.9106	1.2230	451	10.56	<.0001	0.1	10.8948	14.9264
EGSTMNUM*LEG_SORT	4	201	24	201	3.9583	1.0451	1178	3.79	0.0002	0.1	2.2379	5.6786
EGSTMNUM*LEG_SORT	4	201	24	202	5.6528	1.2268	445	4.61	<.0001	0.1	3.6307	7.6749
EGSTMNUM*LEG_SORT	4	201	24	203	11.3040	1.2230	451	9.24	<.0001	0.1	9.2882	13.3198
EGSTMNUM*LEG_SORT	4	202	4	203	13.1978	1.2245	449	10.78	<.0001	0.1	11.1795	15.2161
EGSTMNUM*LEG_SORT	4	202	5	201	10.5138	1.2268	445	8.57	<.0001	0.1	8.4917	12.5359
EGSTMNUM*LEG_SORT	4	202	5	202	8.3867	1.0457	1175	8.02	<.0001	0.1	6.6652	10.1081
EGSTMNUM*LEG_SORT	4	202	5	203	17.8911	1.2245	449	14.61	<.0001	0.1	15.8728	19.9094
EGSTMNUM*LEG_SORT	4	202	6	201	12.8138	1.2268	445	10.45	<.0001	0.1	10.7917	14.8359
EGSTMNUM*LEG_SORT	4	202	6	202	10.3067	1.0457	1175	9.86	<.0001	0.1	8.5852	12.0281
EGSTMNUM*LEG_SORT	4	202	6	203	19.3245	1.2245	449	15.78	<.0001	0.1	17.3061	21.3428
EGSTMNUM*LEG_SORT	4	202	8	201	13.0672	1.2268	445	10.65	<.0001	0.1	11.0451	15.0893

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	8	202	11.1600	1.0457	1175	10.67	<.0001	0.1	9.4386	12.8814
EGSTMNUM*LEG_SORT	4	202	8	203	18.6645	1.2245	449	15.24	<.0001	0.1	16.6461	20.6828
EGSTMNUM*LEG_SORT	4	202	12	201	10.7805	1.2268	445	8.79	<.0001	0.1	8.7584	12.8026
EGSTMNUM*LEG_SORT	4	202	12	202	10.3067	1.0457	1175	9.86	<.0001	0.1	8.5852	12.0281
EGSTMNUM*LEG_SORT	4	202	12	203	16.4578	1.2245	449	13.44	<.0001	0.1	14.4395	18.4761
EGSTMNUM*LEG_SORT	4	202	24	201	7.5054	1.2257	448	6.12	<.0001	0.1	5.4851	9.5257
EGSTMNUM*LEG_SORT	4	202	24	202	9.2000	1.0457	1175	8.80	<.0001	0.1	7.4786	10.9214
EGSTMNUM*LEG_SORT	4	202	24	203	14.8511	1.2245	449	12.13	<.0001	0.1	12.8328	16.8694
EGSTMNUM*LEG_SORT	4	203	5	201	-2.6840	1.2230	451	-2.19	0.0287	0.1	-4.6998	-0.6682
EGSTMNUM*LEG_SORT	4	203	5	202	-4.8111	1.2245	449	-3.93	<.0001	0.1	-6.8294	-2.7928
EGSTMNUM*LEG_SORT	4	203	5	203	4.6933	1.0457	1175	4.49	<.0001	0.1	2.9719	6.4148
EGSTMNUM*LEG_SORT	4	203	6	201	-0.3840	1.2230	451	-0.31	0.7537	0.1	-2.3998	1.6318
EGSTMNUM*LEG_SORT	4	203	6	202	-2.8911	1.2245	449	-2.36	0.0187	0.1	-4.9094	-0.8728
EGSTMNUM*LEG_SORT	4	203	6	203	6.1267	1.0457	1175	5.86	<.0001	0.1	4.4052	7.8481
EGSTMNUM*LEG_SORT	4	203	8	201	-0.1306	1.2230	451	-0.11	0.9150	0.1	-2.1464	1.8852
EGSTMNUM*LEG_SORT	4	203	8	202	-2.0378	1.2245	449	-1.66	0.0968	0.1	-4.0561	-0.01946
EGSTMNUM*LEG_SORT	4	203	8	203	5.4667	1.0457	1175	5.23	<.0001	0.1	3.7452	7.1881
EGSTMNUM*LEG_SORT	4	203	12	201	-2.4173	1.2230	451	-1.98	0.0487	0.1	-4.4331	-0.4015
EGSTMNUM*LEG_SORT	4	203	12	202	-2.8911	1.2245	449	-2.36	0.0187	0.1	-4.9094	-0.8728
EGSTMNUM*LEG_SORT	4	203	12	203	3.2600	1.0457	1175	3.12	0.0019	0.1	1.5386	4.9814
EGSTMNUM*LEG_SORT	4	203	24	201	-5.6924	1.2221	453	-4.66	<.0001	0.1	-7.7066	-3.6781
EGSTMNUM*LEG_SORT	4	203	24	202	-3.9978	1.2245	449	-3.26	0.0012	0.1	-6.0161	-1.9795
EGSTMNUM*LEG_SORT	4	203	24	203	1.6533	1.0457	1175	1.58	0.1141	0.1	-0.06810	3.3748
EGSTMNUM*LEG_SORT	5	201	5	202	-2.1272	1.2268	445	-1.73	0.0836	0.1	-4.1493	-0.1051
EGSTMNUM*LEG_SORT	5	201	5	203	7.3773	1.2230	451	6.03	<.0001	0.1	5.3615	9.3931
EGSTMNUM*LEG_SORT	5	201	6	201	2.3000	1.0457	1175	2.20	0.0280	0.1	0.5786	4.0214
EGSTMNUM*LEG_SORT	5	201	6	202	-0.2072	1.2268	445	-0.17	0.8660	0.1	-2.2293	1.8149
EGSTMNUM*LEG_SORT	5	201	6	203	8.1066	1.2230	451	7.20	<.0001	0.1	6.7948	10.8264
EGSTMNUM*LEG_SORT	5	201	8	201	2.5533	1.0457	1175	2.44	0.0148	0.1	0.8319	4.2748
EGSTMNUM*LEG_SORT	5	201	8	202	0.6462	1.2268	445	0.53	0.5987	0.1	-1.3759	2.6683
EGSTMNUM*LEG_SORT	5	201	8	203	8.1506	1.2230	451	6.66	<.0001	0.1	6.1348	10.1664
EGSTMNUM*LEG_SORT	5	201	12	201	0.2667	1.0457	1175	0.26	0.7988	0.1	-1.4548	1.9881
EGSTMNUM*LEG_SORT	5	201	12	202	-0.2072	1.2268	445	-0.17	0.8660	0.1	-2.2293	1.8149
EGSTMNUM*LEG_SORT	5	201	12	203	5.9440	1.2230	451	4.86	<.0001	0.1	3.9282	7.9598
EGSTMNUM*LEG_SORT	5	201	24	201	-3.0084	1.0451	1178	-2.88	0.0041	0.1	-4.7287	-1.2880

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	201	24	202	-1.3138	1.2268	445	-1.07	0.2848	0.1	-3.3359	0.7083
EGSTMNUM*LEG_SORT	5	201	24	203	4.3373	1.2230	451	3.55	0.0004	0.1	2.3215	6.3531
EGSTMNUM*LEG_SORT	5	202	5	203	9.5045	1.2245	449	7.76	<.0001	0.1	7.4861	11.5228
EGSTMNUM*LEG_SORT	5	202	6	201	4.4272	1.2268	445	3.61	0.0003	0.1	2.4051	6.4493
EGSTMNUM*LEG_SORT	5	202	6	202	1.9200	1.0457	1175	1.84	0.0666	0.1	0.1986	3.6414
EGSTMNUM*LEG_SORT	5	202	6	203	10.9378	1.2245	449	8.93	<.0001	0.1	8.9195	12.9561
EGSTMNUM*LEG_SORT	5	202	8	201	4.6805	1.2268	445	3.82	0.0002	0.1	2.6584	6.7026
EGSTMNUM*LEG_SORT	5	202	8	202	2.7733	1.0457	1175	2.65	0.0081	0.1	1.0519	4.4948
EGSTMNUM*LEG_SORT	5	202	8	203	10.2778	1.2245	449	8.39	<.0001	0.1	8.2595	12.2961
EGSTMNUM*LEG_SORT	5	202	12	201	2.3938	1.2268	445	1.95	0.0516	0.1	0.3717	4.4159
EGSTMNUM*LEG_SORT	5	202	12	202	1.9200	1.0457	1175	1.84	0.0666	0.1	0.1986	3.6414
EGSTMNUM*LEG_SORT	5	202	12	203	8.0711	1.2245	449	6.59	<.0001	0.1	6.0528	10.0894
EGSTMNUM*LEG_SORT	5	202	24	201	-0.8812	1.2257	448	-0.72	0.4725	0.1	-2.9015	1.1391
EGSTMNUM*LEG_SORT	5	202	24	202	0.8133	1.0457	1175	0.78	0.4369	0.1	-0.9081	2.5348
EGSTMNUM*LEG_SORT	5	202	24	203	6.4645	1.2245	449	5.28	<.0001	0.1	4.4461	8.4828
EGSTMNUM*LEG_SORT	5	203	6	201	-5.0773	1.2230	451	-4.15	<.0001	0.1	-7.0931	-3.0615
EGSTMNUM*LEG_SORT	5	203	6	202	-7.5845	1.2245	449	-6.19	<.0001	0.1	-9.6028	-5.5661
EGSTMNUM*LEG_SORT	5	203	6	203	1.4333	1.0457	1175	1.37	0.1707	0.1	-0.2881	3.1548
EGSTMNUM*LEG_SORT	5	203	8	201	-4.8240	1.2230	451	-3.94	<.0001	0.1	-6.8398	-2.8082
EGSTMNUM*LEG_SORT	5	203	8	202	-6.7311	1.2245	449	-5.50	<.0001	0.1	-8.7494	-4.7128
EGSTMNUM*LEG_SORT	5	203	8	203	0.7733	1.0457	1175	0.74	0.4597	0.1	-0.9481	2.4948
EGSTMNUM*LEG_SORT	5	203	12	201	-7.1106	1.2230	451	-5.81	<.0001	0.1	-9.1264	-5.0948
EGSTMNUM*LEG_SORT	5	203	12	202	-7.5845	1.2245	449	-6.19	<.0001	0.1	-9.6028	-5.5661
EGSTMNUM*LEG_SORT	5	203	12	203	-1.4333	1.0457	1175	-1.37	0.1707	0.1	-3.1548	0.2881
EGSTMNUM*LEG_SORT	5	203	24	201	-10.3857	1.2221	453	-8.50	<.0001	0.1	-12.3999	-8.3715
EGSTMNUM*LEG_SORT	5	203	24	202	-8.6911	1.2245	449	-7.10	<.0001	0.1	-10.7094	-6.6728
EGSTMNUM*LEG_SORT	5	203	24	203	-3.0400	1.0457	1175	-2.91	0.0037	0.1	-4.7614	-1.3186
EGSTMNUM*LEG_SORT	6	201	6	202	-2.5072	1.2268	445	-2.04	0.0416	0.1	-4.5293	-0.4851
EGSTMNUM*LEG_SORT	6	201	6	203	6.5106	1.2230	451	5.32	<.0001	0.1	4.4948	8.5264
EGSTMNUM*LEG_SORT	6	201	8	201	0.2533	1.0457	1175	0.24	0.8086	0.1	-1.4681	1.9748
EGSTMNUM*LEG_SORT	6	201	8	202	-1.6538	1.2268	445	-1.35	0.1783	0.1	-3.6759	0.3683
EGSTMNUM*LEG_SORT	6	201	8	203	5.8506	1.2230	451	4.78	<.0001	0.1	3.8348	7.8664
EGSTMNUM*LEG_SORT	6	201	12	201	-2.0333	1.0457	1175	-1.94	0.0521	0.1	-3.7548	-0.3119
EGSTMNUM*LEG_SORT	6	201	12	202	-2.5072	1.2268	445	-2.04	0.0416	0.1	-4.5293	-0.4851
EGSTMNUM*LEG_SORT	6	201	12	203	3.6440	1.2230	451	2.98	0.0030	0.1	1.6282	5.6598

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	6	201	24	201	-5.3084	1.0451	1178	-5.08	<.0001	0.1	-7.0287	-3.5880
EGSTMNUM*LEG_SORT	6	201	24	202	-3.6138	1.2268	445	-2.95	0.0034	0.1	-5.6359	-1.5917
EGSTMNUM*LEG_SORT	6	201	24	203	2.0373	1.2230	451	1.67	0.0964	0.1	0.02150	4.0531
EGSTMNUM*LEG_SORT	6	202	6	203	9.0178	1.2245	449	7.36	<.0001	0.1	6.9995	11.0361
EGSTMNUM*LEG_SORT	6	202	8	201	2.7605	1.2268	445	2.25	0.0249	0.1	0.7384	4.7826
EGSTMNUM*LEG_SORT	6	202	8	202	0.8533	1.0457	1175	0.82	0.4147	0.1	-0.8681	2.5748
EGSTMNUM*LEG_SORT	6	202	8	203	8.3578	1.2245	449	6.83	<.0001	0.1	6.3395	10.3761
EGSTMNUM*LEG_SORT	6	202	12	201	0.4738	1.2268	445	0.39	0.6995	0.1	-1.5483	2.4959
EGSTMNUM*LEG_SORT	6	202	12	202	1.8E-13	1.0457	1175	0.00	1.0000	0.1	-1.7214	1.7214
EGSTMNUM*LEG_SORT	6	202	12	203	6.1511	1.2245	449	5.02	<.0001	0.1	4.1328	8.1694
EGSTMNUM*LEG_SORT	6	202	24	201	-2.8012	1.2257	448	-2.29	0.0228	0.1	-4.8215	-0.7809
EGSTMNUM*LEG_SORT	6	202	24	202	-1.1067	1.0457	1175	-1.06	0.2902	0.1	-2.8281	0.6148
EGSTMNUM*LEG_SORT	6	202	24	203	4.5445	1.2245	449	3.71	0.0002	0.1	2.5261	6.5628
EGSTMNUM*LEG_SORT	6	203	8	201	-6.2573	1.2230	451	-5.12	<.0001	0.1	-8.2731	-4.2415
EGSTMNUM*LEG_SORT	6	203	8	202	-8.1645	1.2245	449	-6.67	<.0001	0.1	-10.1828	-6.1461
EGSTMNUM*LEG_SORT	6	203	8	203	-0.6600	1.0457	1175	-0.63	0.5281	0.1	-2.3814	1.0614
EGSTMNUM*LEG_SORT	6	203	12	201	-8.5440	1.2230	451	-6.99	<.0001	0.1	-10.5598	-6.5282
EGSTMNUM*LEG_SORT	6	203	12	202	-9.0178	1.2245	449	-7.36	<.0001	0.1	-11.0361	-6.9995
EGSTMNUM*LEG_SORT	6	203	12	203	-2.8667	1.0457	1175	-2.74	0.0062	0.1	-4.5881	-1.1452
EGSTMNUM*LEG_SORT	6	203	24	201	-11.8190	1.2221	453	-9.67	<.0001	0.1	-13.8332	-9.8048
EGSTMNUM*LEG_SORT	6	203	24	202	-10.1245	1.2245	449	-8.27	<.0001	0.1	-12.1428	-8.1061
EGSTMNUM*LEG_SORT	6	203	24	203	-4.4733	1.0457	1175	-4.28	<.0001	0.1	-6.1948	-2.7519
EGSTMNUM*LEG_SORT	8	201	8	202	-1.9072	1.2268	445	-1.55	0.1208	0.1	-3.9293	0.1149
EGSTMNUM*LEG_SORT	8	201	8	203	5.5973	1.2230	451	4.58	<.0001	0.1	3.5815	7.6131
EGSTMNUM*LEG_SORT	8	201	12	201	-2.2867	1.0457	1175	-2.19	0.0290	0.1	-4.0081	-0.5652
EGSTMNUM*LEG_SORT	8	201	12	202	-2.7605	1.2268	445	-2.25	0.0249	0.1	-4.7826	-0.7384
EGSTMNUM*LEG_SORT	8	201	12	203	3.3906	1.2230	451	2.77	0.0058	0.1	1.3748	5.4064
EGSTMNUM*LEG_SORT	8	201	24	201	-5.5617	1.0451	1178	-5.32	<.0001	0.1	-7.2821	-3.8414
EGSTMNUM*LEG_SORT	8	201	24	202	-3.8672	1.2268	445	-3.15	0.0017	0.1	-5.8893	-1.8451
EGSTMNUM*LEG_SORT	8	201	24	203	1.7840	1.2230	451	1.46	0.1453	0.1	-0.2318	3.7998
EGSTMNUM*LEG_SORT	8	202	8	203	7.5045	1.2245	449	6.13	<.0001	0.1	5.4861	9.5228
EGSTMNUM*LEG_SORT	8	202	12	201	-0.3795	1.2268	445	-0.31	0.7572	0.1	-2.4016	1.6426
EGSTMNUM*LEG_SORT	8	202	12	202	-0.8533	1.0457	1175	-0.82	0.4147	0.1	-2.5748	0.8681
EGSTMNUM*LEG_SORT	8	202	12	203	5.2978	1.2245	449	4.33	<.0001	0.1	3.2795	7.3161
EGSTMNUM*LEG_SORT	8	202	24	201	-3.6546	1.2257	448	-2.98	0.0030	0.1	-5.6749	-1.6343

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	202	24	202	-1.9600	1.0457	1175	-1.87	0.0611	0.1	-3.6814	-0.2386
EGSTMNUM*LEG_SORT	8	202	24	203	3.6911	1.2245	449	3.01	0.0027	0.1	1.6728	5.7094
EGSTMNUM*LEG_SORT	8	203	12	201	-7.8840	1.2230	451	-6.45	<.0001	0.1	-9.8998	-5.8682
EGSTMNUM*LEG_SORT	8	203	12	202	-8.3578	1.2245	449	-6.83	<.0001	0.1	-10.3761	-6.3395
EGSTMNUM*LEG_SORT	8	203	12	203	-2.2067	1.0457	1175	-2.11	0.0351	0.1	-3.9281	-0.4852
EGSTMNUM*LEG_SORT	8	203	24	201	-11.1590	1.2221	453	-9.13	<.0001	0.1	-13.1732	-9.1448
EGSTMNUM*LEG_SORT	8	203	24	202	-9.4645	1.2245	449	-7.73	<.0001	0.1	-11.4828	-7.4461
EGSTMNUM*LEG_SORT	8	203	24	203	-3.8133	1.0457	1175	-3.65	0.0003	0.1	-5.5348	-2.0919
EGSTMNUM*LEG_SORT	12	201	12	202	-0.4738	1.2268	445	-0.39	0.6995	0.1	-2.4959	1.5483
EGSTMNUM*LEG_SORT	12	201	12	203	5.6773	1.2230	451	4.64	<.0001	0.1	3.6615	7.6931
EGSTMNUM*LEG_SORT	12	201	24	201	-3.2751	1.0451	1178	-3.13	0.0018	0.1	-4.9954	-1.5547
EGSTMNUM*LEG_SORT	12	201	24	202	-1.5805	1.2268	445	-1.29	0.1983	0.1	-3.6026	0.4416
EGSTMNUM*LEG_SORT	12	201	24	203	4.0706	1.2230	451	3.33	0.0009	0.1	2.0548	6.0864
EGSTMNUM*LEG_SORT	12	202	12	203	6.1511	1.2245	449	5.02	<.0001	0.1	4.1328	8.1694
EGSTMNUM*LEG_SORT	12	202	24	201	-2.8012	1.2257	448	-2.29	0.0228	0.1	-4.8215	-0.7809
EGSTMNUM*LEG_SORT	12	202	24	202	-1.1067	1.0457	1175	-1.06	0.2902	0.1	-2.8281	0.6148
EGSTMNUM*LEG_SORT	12	202	24	203	4.5445	1.2245	449	3.71	0.0002	0.1	2.5261	6.5628
EGSTMNUM*LEG_SORT	12	203	24	201	-8.9524	1.2221	453	-7.33	<.0001	0.1	-10.9666	-6.9381
EGSTMNUM*LEG_SORT	12	203	24	202	-7.2578	1.2245	449	-5.93	<.0001	0.1	-9.2761	-5.2395
EGSTMNUM*LEG_SORT	12	203	24	203	-1.6067	1.0457	1175	-1.54	0.1247	0.1	-3.3281	0.1148
EGSTMNUM*LEG_SORT	24	201	24	202	1.6946	1.2257	448	1.38	0.1675	0.1	-0.3257	3.7149
EGSTMNUM*LEG_SORT	24	201	24	203	7.3457	1.2221	453	6.01	<.0001	0.1	5.3315	9.3599
EGSTMNUM*LEG_SORT	24	202	24	203	5.6511	1.2245	449	4.61	<.0001	0.1	3.6328	7.6694

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:57)

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drggroup period egstmnum leg_sort;
model stresnm = drggroup period leg_sort egbase egstmnum egstmnum*leg_sort/ddfm=kr;
random subjid(drggroup);
repeated / subject =period*subjid(drggroup) type=cs;
lsmeans egstmnum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (00:56)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Model Information

Data Set WORK.ECG3  
 Dependent Variable STRESNM  
 Covariance Structures Variance Components,  
 Compound Symmetry  
 Subject Effect SUBJI\*PERIOD(DRGGRO)  
 Estimation Method REML  
 Residual Variance Method Profile  
 Fixed Effects SE Method Kenward-Roger  
 Degrees of Freedom Method Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	46	10011001 10011002 10011003
		10011004 10011005 10011006
		10011008 10011009 10011010
		10011011 10011012 10011013
		10011014 10011015 10011016
		10011017 10011018 10011019
		10011020 10011021 10011023
		10011024 10011025 10011026
		10011027 10011028 10011029
		10011031 10011032 10011033
		10011034 10011035 10011037
		10011038 10011039 10011040
		10011041 10011042 10011043
		10011046 10011047 10011049
		10011051 10011052 10011053
		10011054
		DRGGROUP
PERIOD	3	Period 1 Period 2 Period 3
EGSTMNUM	9	1 2 3 4 5 6 8 12 24
LEG_SORT	3	201 202 203

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

Supporting SAS Output for Statistical Summary (1) of QTcF between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	46
Subjects	1
Max Obs Per Subject	1242

Number of Observations

Number of Observations Read	1242
Number of Observations Used	1242
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	8810.80227289	
1	2	7875.86518233	0.00175707
2	1	7869.69487543	0.00073896
3	1	7867.12676266	0.00016993
4	1	7866.91553038	0.00011320
5	1	7866.55450602	0.00000601
6	1	7866.53690740	0.00000002
7	1	7866.53684896	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		118.90
CS	SUBJI*PERIOD(DRGGRO)	8.6869
Residual		27.0662

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	7866.5
AIC (smaller is better)	7872.5
AICC (smaller is better)	7872.6
BIC (smaller is better)	7878.0

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	24.7	0.38	0.8582
PERIOD	2	69.9	1.80	0.1737
LEG_SORT	2	68.3	104.74	<.0001
EGBASE	1	121	27.81	<.0001
EGSTMNUM	8	1080	57.91	<.0001
EGSTMNUM*LEG_SORT	16	1080	4.08	<.0001

Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	415.40	1.8365	39.6	226.19	<.0001	0.1	412.31	418.50
EGSTMNUM*LEG_SORT	1	202	419.81	1.8369	39.7	228.54	<.0001	0.1	416.71	422.90
EGSTMNUM*LEG_SORT	1	203	408.28	1.8371	39.7	222.25	<.0001	0.1	405.19	411.38
EGSTMNUM*LEG_SORT	2	201	417.00	1.8365	39.6	227.06	<.0001	0.1	413.91	420.09
EGSTMNUM*LEG_SORT	2	202	421.18	1.8369	39.7	229.29	<.0001	0.1	418.09	424.28
EGSTMNUM*LEG_SORT	2	203	408.62	1.8371	39.7	222.43	<.0001	0.1	405.52	411.71
EGSTMNUM*LEG_SORT	3	201	417.17	1.8365	39.6	227.15	<.0001	0.1	414.08	420.27
EGSTMNUM*LEG_SORT	3	202	421.88	1.8369	39.7	229.67	<.0001	0.1	418.78	424.97
EGSTMNUM*LEG_SORT	3	203	409.71	1.8371	39.7	223.02	<.0001	0.1	406.62	412.80
EGSTMNUM*LEG_SORT	4	201	419.45	1.8365	39.6	228.39	<.0001	0.1	416.36	422.54
EGSTMNUM*LEG_SORT	4	202	423.10	1.8369	39.7	230.33	<.0001	0.1	420.00	426.19
EGSTMNUM*LEG_SORT	4	203	409.63	1.8371	39.7	222.98	<.0001	0.1	406.54	412.72
EGSTMNUM*LEG_SORT	5	201	412.06	1.8365	39.6	224.37	<.0001	0.1	408.96	415.15

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	202	414.75	1.8369	39.7	225.78	<.0001	0.1	411.65	417.84
EGSTMNUM*LEG_SORT	5	203	404.43	1.8371	39.7	220.15	<.0001	0.1	401.33	407.52
EGSTMNUM*LEG_SORT	6	201	409.94	1.8365	39.6	223.22	<.0001	0.1	406.85	413.03
EGSTMNUM*LEG_SORT	6	202	412.81	1.8369	39.7	224.73	<.0001	0.1	409.72	415.91
EGSTMNUM*LEG_SORT	6	203	402.90	1.8371	39.7	219.32	<.0001	0.1	399.81	406.00
EGSTMNUM*LEG_SORT	8	201	409.93	1.8365	39.6	223.21	<.0001	0.1	406.83	413.02
EGSTMNUM*LEG_SORT	8	202	412.31	1.8369	39.7	224.46	<.0001	0.1	409.22	415.41
EGSTMNUM*LEG_SORT	8	203	404.09	1.8371	39.7	219.96	<.0001	0.1	400.99	407.18
EGSTMNUM*LEG_SORT	12	201	412.26	1.8365	39.6	224.48	<.0001	0.1	409.17	415.35
EGSTMNUM*LEG_SORT	12	202	412.12	1.8369	39.7	224.36	<.0001	0.1	409.03	415.22
EGSTMNUM*LEG_SORT	12	203	405.99	1.8371	39.7	221.00	<.0001	0.1	402.90	409.09
EGSTMNUM*LEG_SORT	24	201	415.57	1.8365	39.6	226.28	<.0001	0.1	412.48	418.66
EGSTMNUM*LEG_SORT	24	202	413.48	1.8369	39.7	225.09	<.0001	0.1	410.39	416.57
EGSTMNUM*LEG_SORT	24	203	407.90	1.8371	39.7	222.04	<.0001	0.1	404.81	411.00

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-4.4006	1.2479	501	-3.53	0.0005	0.1	-6.4570	-2.3442
EGSTMNUM*LEG_SORT	1	201	1	203	7.1229	1.2474	501	5.71	<.0001	0.1	5.0673	9.1785
EGSTMNUM*LEG_SORT	1	201	2	201	-1.5942	1.0848	1080	-1.47	0.1420	0.1	-3.3801	0.1917
EGSTMNUM*LEG_SORT	1	201	2	202	-5.7774	1.2479	501	-4.63	<.0001	0.1	-7.8339	-3.7210
EGSTMNUM*LEG_SORT	1	201	2	203	6.7895	1.2474	501	5.44	<.0001	0.1	4.7339	8.8451
EGSTMNUM*LEG_SORT	1	201	3	201	-1.7681	1.0848	1080	-1.63	0.1034	0.1	-3.5540	0.01775
EGSTMNUM*LEG_SORT	1	201	3	202	-6.4731	1.2479	501	-5.19	<.0001	0.1	-8.5295	-4.4166
EGSTMNUM*LEG_SORT	1	201	3	203	5.6953	1.2474	501	4.57	<.0001	0.1	3.6397	7.7509
EGSTMNUM*LEG_SORT	1	201	4	201	-4.0435	1.0848	1080	-3.73	0.0002	0.1	-5.8293	-2.2576
EGSTMNUM*LEG_SORT	1	201	4	202	-7.6905	1.2479	501	-6.16	<.0001	0.1	-9.7469	-5.6340
EGSTMNUM*LEG_SORT	1	201	4	203	5.7750	1.2474	501	4.63	<.0001	0.1	3.7194	7.8306

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	5	201	3.3478	1.0848	1080	3.09	0.0021	0.1	1.5620	5.1337
EGSTMNUM*LEG_SORT	1	201	5	202	0.6574	1.2479	501	0.53	0.5986	0.1	-1.3991	2.7138
EGSTMNUM*LEG_SORT	1	201	5	203	10.9779	1.2474	501	8.80	<.0001	0.1	8.9223	13.0335
EGSTMNUM*LEG_SORT	1	201	6	201	5.4638	1.0848	1080	5.04	<.0001	0.1	3.6779	7.2496
EGSTMNUM*LEG_SORT	1	201	6	202	2.5921	1.2479	501	2.08	0.0383	0.1	0.5357	4.6486
EGSTMNUM*LEG_SORT	1	201	6	203	12.4997	1.2474	501	10.02	<.0001	0.1	10.4441	14.5553
EGSTMNUM*LEG_SORT	1	201	8	201	5.4783	1.0848	1080	5.05	<.0001	0.1	3.6924	7.2641
EGSTMNUM*LEG_SORT	1	201	8	202	3.0921	1.2479	501	2.48	0.0135	0.1	1.0357	5.1486
EGSTMNUM*LEG_SORT	1	201	8	203	11.3185	1.2474	501	9.07	<.0001	0.1	9.2629	13.3741
EGSTMNUM*LEG_SORT	1	201	12	201	3.1449	1.0848	1080	2.90	0.0038	0.1	1.3591	4.9308
EGSTMNUM*LEG_SORT	1	201	12	202	3.2805	1.2479	501	2.63	0.0088	0.1	1.2241	5.3370
EGSTMNUM*LEG_SORT	1	201	12	203	9.4127	1.2474	501	7.55	<.0001	0.1	7.3571	11.4683
EGSTMNUM*LEG_SORT	1	201	24	201	-0.1667	1.0848	1080	-0.15	0.8779	0.1	-1.9525	1.6192
EGSTMNUM*LEG_SORT	1	201	24	202	1.9255	1.2479	501	1.54	0.1235	0.1	-0.1310	3.9819
EGSTMNUM*LEG_SORT	1	201	24	203	7.4997	1.2474	501	6.01	<.0001	0.1	5.4441	9.5553
EGSTMNUM*LEG_SORT	1	202	1	203	11.5235	1.2499	499	9.22	<.0001	0.1	9.4638	13.5832
EGSTMNUM*LEG_SORT	1	202	2	201	2.8064	1.2479	501	2.25	0.0250	0.1	0.7500	4.8628
EGSTMNUM*LEG_SORT	1	202	2	202	-1.3768	1.0848	1080	-1.27	0.2046	0.1	-3.1627	0.4091
EGSTMNUM*LEG_SORT	1	202	2	203	11.1901	1.2499	499	8.95	<.0001	0.1	9.1305	13.2498
EGSTMNUM*LEG_SORT	1	202	3	201	2.6325	1.2479	501	2.11	0.0354	0.1	0.5761	4.6889
EGSTMNUM*LEG_SORT	1	202	3	202	-2.0725	1.0848	1080	-1.91	0.0563	0.1	-3.8583	-0.2866
EGSTMNUM*LEG_SORT	1	202	3	203	10.0959	1.2499	499	8.08	<.0001	0.1	8.0363	12.1556
EGSTMNUM*LEG_SORT	1	202	4	201	0.3571	1.2479	501	0.29	0.7749	0.1	-1.6993	2.4136
EGSTMNUM*LEG_SORT	1	202	4	202	-3.2899	1.0848	1080	-3.03	0.0025	0.1	-5.0757	-1.5040
EGSTMNUM*LEG_SORT	1	202	4	203	10.1757	1.2499	499	8.14	<.0001	0.1	8.1160	12.2353
EGSTMNUM*LEG_SORT	1	202	5	201	7.7484	1.2479	501	6.21	<.0001	0.1	5.6920	9.8049
EGSTMNUM*LEG_SORT	1	202	5	202	5.0580	1.0848	1080	4.66	<.0001	0.1	3.2721	6.8438
EGSTMNUM*LEG_SORT	1	202	5	203	15.3785	1.2499	499	12.30	<.0001	0.1	13.3189	17.4382
EGSTMNUM*LEG_SORT	1	202	6	201	9.8644	1.2479	501	7.90	<.0001	0.1	7.8079	11.9208
EGSTMNUM*LEG_SORT	1	202	6	202	6.9928	1.0848	1080	6.45	<.0001	0.1	5.2069	8.7786
EGSTMNUM*LEG_SORT	1	202	6	203	16.9003	1.2499	499	13.52	<.0001	0.1	14.8406	18.9600
EGSTMNUM*LEG_SORT	1	202	8	201	9.8789	1.2479	501	7.92	<.0001	0.1	7.8224	11.9353
EGSTMNUM*LEG_SORT	1	202	8	202	7.4928	1.0848	1080	6.91	<.0001	0.1	5.7069	9.2786
EGSTMNUM*LEG_SORT	1	202	8	203	15.7191	1.2499	499	12.58	<.0001	0.1	13.6594	17.7788

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	12	201	7.5455	1.2479	501	6.05	<.0001	0.1	5.4891	9.6020
EGSTMNUM*LEG_SORT	1	202	12	202	7.6812	1.0848	1080	7.08	<.0001	0.1	5.8953	9.4670
EGSTMNUM*LEG_SORT	1	202	12	203	13.8133	1.2499	499	11.05	<.0001	0.1	11.7536	15.8730
EGSTMNUM*LEG_SORT	1	202	24	201	4.2339	1.2479	501	3.39	0.0007	0.1	2.1775	6.2904
EGSTMNUM*LEG_SORT	1	202	24	202	6.3261	1.0848	1080	5.83	<.0001	0.1	4.5402	8.1120
EGSTMNUM*LEG_SORT	1	202	24	203	11.9003	1.2499	499	9.52	<.0001	0.1	9.8406	13.9600
EGSTMNUM*LEG_SORT	1	203	2	201	-8.7171	1.2474	501	-6.99	<.0001	0.1	-10.7727	-6.6615
EGSTMNUM*LEG_SORT	1	203	2	202	-12.9003	1.2499	499	-10.32	<.0001	0.1	-14.9600	-10.8406
EGSTMNUM*LEG_SORT	1	203	2	203	-0.3333	1.0848	1080	-0.31	0.7587	0.1	-2.1192	1.4525
EGSTMNUM*LEG_SORT	1	203	3	201	-8.8910	1.2474	501	-7.13	<.0001	0.1	-10.9466	-6.8354
EGSTMNUM*LEG_SORT	1	203	3	202	-13.5959	1.2499	499	-10.88	<.0001	0.1	-15.6556	-11.5363
EGSTMNUM*LEG_SORT	1	203	3	203	-1.4275	1.0848	1080	-1.32	0.1885	0.1	-3.2134	0.3583
EGSTMNUM*LEG_SORT	1	203	4	201	-11.1663	1.2474	501	-8.95	<.0001	0.1	-13.2219	-9.1108
EGSTMNUM*LEG_SORT	1	203	4	202	-14.8133	1.2499	499	-11.85	<.0001	0.1	-16.8730	-12.7536
EGSTMNUM*LEG_SORT	1	203	4	203	-1.3478	1.0848	1080	-1.24	0.2143	0.1	-3.1337	0.4380
EGSTMNUM*LEG_SORT	1	203	5	201	-3.7750	1.2474	501	-3.03	0.0026	0.1	-5.8306	-1.7194
EGSTMNUM*LEG_SORT	1	203	5	202	-6.4655	1.2499	499	-5.17	<.0001	0.1	-8.5252	-4.4058
EGSTMNUM*LEG_SORT	1	203	5	203	3.8551	1.0848	1080	3.55	0.0004	0.1	2.0692	5.6409
EGSTMNUM*LEG_SORT	1	203	6	201	-1.6591	1.2474	501	-1.33	0.1841	0.1	-3.7147	0.3965
EGSTMNUM*LEG_SORT	1	203	6	202	-4.5307	1.2499	499	-3.62	0.0003	0.1	-6.5904	-2.4710
EGSTMNUM*LEG_SORT	1	203	6	203	5.3768	1.0848	1080	4.96	<.0001	0.1	3.5909	7.1627
EGSTMNUM*LEG_SORT	1	203	8	201	-1.6446	1.2474	501	-1.32	0.1880	0.1	-3.7002	0.4110
EGSTMNUM*LEG_SORT	1	203	8	202	-4.0307	1.2499	499	-3.22	0.0013	0.1	-6.0904	-1.9710
EGSTMNUM*LEG_SORT	1	203	8	203	4.1957	1.0848	1080	3.87	0.0001	0.1	2.4098	5.9815
EGSTMNUM*LEG_SORT	1	203	12	201	-3.9779	1.2474	501	-3.19	0.0015	0.1	-6.0335	-1.9223
EGSTMNUM*LEG_SORT	1	203	12	202	-3.8423	1.2499	499	-3.07	0.0022	0.1	-5.9020	-1.7826
EGSTMNUM*LEG_SORT	1	203	12	203	2.2899	1.0848	1080	2.11	0.0350	0.1	0.5040	4.0757
EGSTMNUM*LEG_SORT	1	203	24	201	-7.2895	1.2474	501	-5.84	<.0001	0.1	-9.3451	-5.2339
EGSTMNUM*LEG_SORT	1	203	24	202	-5.1974	1.2499	499	-4.16	<.0001	0.1	-7.2571	-3.1377
EGSTMNUM*LEG_SORT	1	203	24	203	0.3768	1.0848	1080	0.35	0.7284	0.1	-1.4091	2.1627
EGSTMNUM*LEG_SORT	2	201	2	202	-4.1832	1.2479	501	-3.35	0.0009	0.1	-6.2397	-2.1268
EGSTMNUM*LEG_SORT	2	201	2	203	8.3837	1.2474	501	6.72	<.0001	0.1	6.3281	10.4393
EGSTMNUM*LEG_SORT	2	201	3	201	-0.1739	1.0848	1080	-0.16	0.8727	0.1	-1.9598	1.6120
EGSTMNUM*LEG_SORT	2	201	3	202	-4.8789	1.2479	501	-3.91	0.0001	0.1	-6.9353	-2.8224

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	3	203	7.2895	1.2474	501	5.84	<.0001	0.1	5.2339	9.3451
EGSTMNUM*LEG_SORT	2	201	4	201	-2.4493	1.0848	1080	-2.26	0.0242	0.1	-4.2351	-0.6634
EGSTMNUM*LEG_SORT	2	201	4	202	-6.0963	1.2479	501	-4.89	<.0001	0.1	-8.1527	-4.0398
EGSTMNUM*LEG_SORT	2	201	4	203	7.3692	1.2474	501	5.91	<.0001	0.1	5.3137	9.4248
EGSTMNUM*LEG_SORT	2	201	5	201	4.9420	1.0848	1080	4.56	<.0001	0.1	3.1562	6.7279
EGSTMNUM*LEG_SORT	2	201	5	202	2.2516	1.2479	501	1.80	0.0718	0.1	0.1951	4.3080
EGSTMNUM*LEG_SORT	2	201	5	203	12.5721	1.2474	501	10.08	<.0001	0.1	10.5166	14.6277
EGSTMNUM*LEG_SORT	2	201	6	201	7.0580	1.0848	1080	6.51	<.0001	0.1	5.2721	8.8438
EGSTMNUM*LEG_SORT	2	201	6	202	4.1863	1.2479	501	3.35	0.0009	0.1	2.1299	6.2428
EGSTMNUM*LEG_SORT	2	201	6	203	14.0939	1.2474	501	11.30	<.0001	0.1	12.0383	16.1495
EGSTMNUM*LEG_SORT	2	201	8	201	7.0725	1.0848	1080	6.52	<.0001	0.1	5.2866	8.8583
EGSTMNUM*LEG_SORT	2	201	8	202	4.6863	1.2479	501	3.76	0.0002	0.1	2.6299	6.7428
EGSTMNUM*LEG_SORT	2	201	8	203	12.9127	1.2474	501	10.35	<.0001	0.1	10.8571	14.9683
EGSTMNUM*LEG_SORT	2	201	12	201	4.7391	1.0848	1080	4.37	<.0001	0.1	2.9533	6.5250
EGSTMNUM*LEG_SORT	2	201	12	202	4.8748	1.2479	501	3.91	0.0001	0.1	2.8183	6.9312
EGSTMNUM*LEG_SORT	2	201	12	203	11.0069	1.2474	501	8.82	<.0001	0.1	8.9513	13.0625
EGSTMNUM*LEG_SORT	2	201	24	201	1.4275	1.0848	1080	1.32	0.1885	0.1	-0.3583	3.2134
EGSTMNUM*LEG_SORT	2	201	24	202	3.5197	1.2479	501	2.82	0.0050	0.1	1.4632	5.5761
EGSTMNUM*LEG_SORT	2	201	24	203	9.0939	1.2474	501	7.29	<.0001	0.1	7.0383	11.1495
EGSTMNUM*LEG_SORT	2	202	2	203	12.5670	1.2499	499	10.05	<.0001	0.1	10.5073	14.6266
EGSTMNUM*LEG_SORT	2	202	3	201	4.0093	1.2479	501	3.21	0.0014	0.1	1.9529	6.0657
EGSTMNUM*LEG_SORT	2	202	3	202	-0.6957	1.0848	1080	-0.64	0.5215	0.1	-2.4815	1.0902
EGSTMNUM*LEG_SORT	2	202	3	203	11.4728	1.2499	499	9.18	<.0001	0.1	9.4131	13.5324
EGSTMNUM*LEG_SORT	2	202	4	201	1.7339	1.2479	501	1.39	0.1653	0.1	-0.3225	3.7904
EGSTMNUM*LEG_SORT	2	202	4	202	-1.9130	1.0848	1080	-1.76	0.0781	0.1	-3.6989	-0.1272
EGSTMNUM*LEG_SORT	2	202	4	203	11.5525	1.2499	499	9.24	<.0001	0.1	9.4928	13.6121
EGSTMNUM*LEG_SORT	2	202	5	201	9.1252	1.2479	501	7.31	<.0001	0.1	7.0688	11.1817
EGSTMNUM*LEG_SORT	2	202	5	202	6.4348	1.0848	1080	5.93	<.0001	0.1	4.6489	8.2207
EGSTMNUM*LEG_SORT	2	202	5	203	16.7554	1.2499	499	13.41	<.0001	0.1	14.6957	18.8150
EGSTMNUM*LEG_SORT	2	202	6	201	11.2412	1.2479	501	9.01	<.0001	0.1	9.1848	13.2976
EGSTMNUM*LEG_SORT	2	202	6	202	8.3696	1.0848	1080	7.72	<.0001	0.1	6.5837	10.1554
EGSTMNUM*LEG_SORT	2	202	6	203	18.2771	1.2499	499	14.62	<.0001	0.1	16.2174	20.3368
EGSTMNUM*LEG_SORT	2	202	8	201	11.2557	1.2479	501	9.02	<.0001	0.1	9.1992	13.3121
EGSTMNUM*LEG_SORT	2	202	8	202	8.8696	1.0848	1080	8.18	<.0001	0.1	7.0837	10.6554

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	202	8	203	17.0959	1.2499	499	13.68	<.0001	0.1	15.0363	19.1556
EGSTMNUM*LEG_SORT	2	202	12	201	8.9224	1.2479	501	7.15	<.0001	0.1	6.8659	10.9788
EGSTMNUM*LEG_SORT	2	202	12	202	9.0580	1.0848	1080	8.35	<.0001	0.1	7.2721	10.8438
EGSTMNUM*LEG_SORT	2	202	12	203	15.1901	1.2499	499	12.15	<.0001	0.1	13.1305	17.2498
EGSTMNUM*LEG_SORT	2	202	24	201	5.6108	1.2479	501	4.50	<.0001	0.1	3.5543	7.6672
EGSTMNUM*LEG_SORT	2	202	24	202	7.7029	1.0848	1080	7.10	<.0001	0.1	5.9170	9.4888
EGSTMNUM*LEG_SORT	2	202	24	203	13.2771	1.2499	499	10.62	<.0001	0.1	11.2174	15.3368
EGSTMNUM*LEG_SORT	2	203	3	201	-8.5576	1.2474	501	-6.86	<.0001	0.1	-10.6132	-6.5021
EGSTMNUM*LEG_SORT	2	203	3	202	-13.2626	1.2499	499	-10.61	<.0001	0.1	-15.3223	-11.2029
EGSTMNUM*LEG_SORT	2	203	3	203	-1.0942	1.0848	1080	-1.01	0.3134	0.1	-2.8801	0.6917
EGSTMNUM*LEG_SORT	2	203	4	201	-10.8330	1.2474	501	-8.68	<.0001	0.1	-12.8886	-8.7774
EGSTMNUM*LEG_SORT	2	203	4	202	-14.4800	1.2499	499	-11.59	<.0001	0.1	-16.5397	-12.4203
EGSTMNUM*LEG_SORT	2	203	4	203	-1.0145	1.0848	1080	-0.94	0.3499	0.1	-2.8004	0.7714
EGSTMNUM*LEG_SORT	2	203	5	201	-3.4417	1.2474	501	-2.76	0.0060	0.1	-5.4973	-1.3861
EGSTMNUM*LEG_SORT	2	203	5	202	-6.1322	1.2499	499	-4.91	<.0001	0.1	-8.1919	-4.0725
EGSTMNUM*LEG_SORT	2	203	5	203	4.1884	1.0848	1080	3.86	0.0001	0.1	2.4025	5.9743
EGSTMNUM*LEG_SORT	2	203	6	201	-1.3258	1.2474	501	-1.06	0.2884	0.1	-3.3814	0.7298
EGSTMNUM*LEG_SORT	2	203	6	202	-4.1974	1.2499	499	-3.36	0.0008	0.1	-6.2571	-2.1377
EGSTMNUM*LEG_SORT	2	203	6	203	5.7101	1.0848	1080	5.26	<.0001	0.1	3.9243	7.4960
EGSTMNUM*LEG_SORT	2	203	8	201	-1.3113	1.2474	501	-1.05	0.2937	0.1	-3.3669	0.7443
EGSTMNUM*LEG_SORT	2	203	8	202	-3.6974	1.2499	499	-2.96	0.0032	0.1	-5.7571	-1.6377
EGSTMNUM*LEG_SORT	2	203	8	203	4.5290	1.0848	1080	4.17	<.0001	0.1	2.7431	6.3149
EGSTMNUM*LEG_SORT	2	203	12	201	-3.6446	1.2474	501	-2.92	0.0036	0.1	-5.7002	-1.5890
EGSTMNUM*LEG_SORT	2	203	12	202	-3.5090	1.2499	499	-2.81	0.0052	0.1	-5.5687	-1.4493
EGSTMNUM*LEG_SORT	2	203	12	203	2.6232	1.0848	1080	2.42	0.0158	0.1	0.8373	4.4091
EGSTMNUM*LEG_SORT	2	203	24	201	-6.9562	1.2474	501	-5.58	<.0001	0.1	-9.0118	-4.9006
EGSTMNUM*LEG_SORT	2	203	24	202	-4.8641	1.2499	499	-3.89	0.0001	0.1	-6.9237	-2.8044
EGSTMNUM*LEG_SORT	2	203	24	203	0.7101	1.0848	1080	0.65	0.5128	0.1	-1.0757	2.4960
EGSTMNUM*LEG_SORT	3	201	3	202	-4.7050	1.2479	501	-3.77	0.0002	0.1	-6.7614	-2.6485
EGSTMNUM*LEG_SORT	3	201	3	203	7.4634	1.2474	501	5.98	<.0001	0.1	5.4079	9.5190
EGSTMNUM*LEG_SORT	3	201	4	201	-2.2754	1.0848	1080	-2.10	0.0362	0.1	-4.0612	-0.4895
EGSTMNUM*LEG_SORT	3	201	4	202	-5.9224	1.2479	501	-4.75	<.0001	0.1	-7.9788	-3.8659
EGSTMNUM*LEG_SORT	3	201	4	203	7.5432	1.2474	501	6.05	<.0001	0.1	5.4876	9.5987
EGSTMNUM*LEG_SORT	3	201	5	201	5.1159	1.0848	1080	4.72	<.0001	0.1	3.3301	6.9018

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.  
 Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.  
 Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.  
 Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	5	202	2.4255	1.2479	501	1.94	0.0525	0.1	0.3690	4.4819
EGSTMNUM*LEG_SORT	3	201	5	203	12.7461	1.2474	501	10.22	<.0001	0.1	10.6905	14.8016
EGSTMNUM*LEG_SORT	3	201	6	201	7.2319	1.0848	1080	6.67	<.0001	0.1	5.4460	9.0178
EGSTMNUM*LEG_SORT	3	201	6	202	4.3603	1.2479	501	3.49	0.0005	0.1	2.3038	6.4167
EGSTMNUM*LEG_SORT	3	201	6	203	14.2678	1.2474	501	11.44	<.0001	0.1	12.2122	16.3234
EGSTMNUM*LEG_SORT	3	201	8	201	7.2464	1.0848	1080	6.68	<.0001	0.1	5.4605	9.0322
EGSTMNUM*LEG_SORT	3	201	8	202	4.8603	1.2479	501	3.89	0.0001	0.1	2.8038	6.9167
EGSTMNUM*LEG_SORT	3	201	8	203	13.0866	1.2474	501	10.49	<.0001	0.1	11.0310	15.1422
EGSTMNUM*LEG_SORT	3	201	12	201	4.9130	1.0848	1080	4.53	<.0001	0.1	3.1272	6.6989
EGSTMNUM*LEG_SORT	3	201	12	202	5.0487	1.2479	501	4.05	<.0001	0.1	2.9922	7.1051
EGSTMNUM*LEG_SORT	3	201	12	203	11.1808	1.2474	501	8.96	<.0001	0.1	9.1252	13.2364
EGSTMNUM*LEG_SORT	3	201	24	201	1.6014	1.0848	1080	1.48	0.1402	0.1	-0.1844	3.3873
EGSTMNUM*LEG_SORT	3	201	24	202	3.6936	1.2479	501	2.96	0.0032	0.1	1.6372	5.7500
EGSTMNUM*LEG_SORT	3	201	24	203	9.2678	1.2474	501	7.43	<.0001	0.1	7.2122	11.3234
EGSTMNUM*LEG_SORT	3	202	3	203	12.1684	1.2499	499	9.74	<.0001	0.1	10.1087	14.2281
EGSTMNUM*LEG_SORT	3	202	4	201	2.4296	1.2479	501	1.95	0.0521	0.1	0.3732	4.4860
EGSTMNUM*LEG_SORT	3	202	4	202	-1.2174	1.0848	1080	-1.12	0.2620	0.1	-3.0033	0.5685
EGSTMNUM*LEG_SORT	3	202	4	203	12.2481	1.2499	499	9.80	<.0001	0.1	10.1884	14.3078
EGSTMNUM*LEG_SORT	3	202	5	201	9.8209	1.2479	501	7.87	<.0001	0.1	7.7645	11.8773
EGSTMNUM*LEG_SORT	3	202	5	202	7.1304	1.0848	1080	6.57	<.0001	0.1	5.3446	8.9163
EGSTMNUM*LEG_SORT	3	202	5	203	17.4510	1.2499	499	13.96	<.0001	0.1	15.3913	19.5107
EGSTMNUM*LEG_SORT	3	202	6	201	11.9368	1.2479	501	9.57	<.0001	0.1	9.8804	13.9933
EGSTMNUM*LEG_SORT	3	202	6	202	9.0652	1.0848	1080	8.36	<.0001	0.1	7.2793	10.8511
EGSTMNUM*LEG_SORT	3	202	6	203	18.9728	1.2499	499	15.18	<.0001	0.1	16.9131	21.0324
EGSTMNUM*LEG_SORT	3	202	8	201	11.9513	1.2479	501	9.58	<.0001	0.1	9.8949	14.0078
EGSTMNUM*LEG_SORT	3	202	8	202	9.5652	1.0848	1080	8.82	<.0001	0.1	7.7793	11.3511
EGSTMNUM*LEG_SORT	3	202	8	203	17.7916	1.2499	499	14.23	<.0001	0.1	15.7319	19.8513
EGSTMNUM*LEG_SORT	3	202	12	201	9.6180	1.2479	501	7.71	<.0001	0.1	7.5616	11.6744
EGSTMNUM*LEG_SORT	3	202	12	202	9.7536	1.0848	1080	8.99	<.0001	0.1	7.9678	11.5395
EGSTMNUM*LEG_SORT	3	202	12	203	15.8858	1.2499	499	12.71	<.0001	0.1	13.8261	17.9455
EGSTMNUM*LEG_SORT	3	202	24	201	6.3064	1.2479	501	5.05	<.0001	0.1	4.2500	8.3628
EGSTMNUM*LEG_SORT	3	202	24	202	8.3986	1.0848	1080	7.74	<.0001	0.1	6.6127	10.1844
EGSTMNUM*LEG_SORT	3	202	24	203	13.9728	1.2499	499	11.18	<.0001	0.1	11.9131	16.0324
EGSTMNUM*LEG_SORT	3	203	4	201	-9.7388	1.2474	501	-7.81	<.0001	0.1	-11.7944	-7.6832

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	4	202	-13.3858	1.2499	499	-10.71	<.0001	0.1	-15.4455	-11.3261
EGSTMNUM*LEG_SORT	3	203	4	203	0.07971	1.0848	1080	0.07	0.9414	0.1	-1.7062	1.8656
EGSTMNUM*LEG_SORT	3	203	5	201	-2.3475	1.2474	501	-1.88	0.0604	0.1	-4.4031	-0.2919
EGSTMNUM*LEG_SORT	3	203	5	202	-5.0380	1.2499	499	-4.03	<.0001	0.1	-7.0977	-2.9783
EGSTMNUM*LEG_SORT	3	203	5	203	5.2826	1.0848	1080	4.87	<.0001	0.1	3.4967	7.0685
EGSTMNUM*LEG_SORT	3	203	6	201	-0.2316	1.2474	501	-0.19	0.8528	0.1	-2.2872	1.8240
EGSTMNUM*LEG_SORT	3	203	6	202	-3.1032	1.2499	499	-2.48	0.0134	0.1	-5.1629	-1.0435
EGSTMNUM*LEG_SORT	3	203	6	203	6.8043	1.0848	1080	6.27	<.0001	0.1	5.0185	8.5902
EGSTMNUM*LEG_SORT	3	203	8	201	-0.2171	1.2474	501	-0.17	0.8619	0.1	-2.2727	1.8385
EGSTMNUM*LEG_SORT	3	203	8	202	-2.6032	1.2499	499	-2.08	0.0378	0.1	-4.6629	-0.5435
EGSTMNUM*LEG_SORT	3	203	8	203	5.6232	1.0848	1080	5.18	<.0001	0.1	3.8373	7.4091
EGSTMNUM*LEG_SORT	3	203	12	201	-2.5504	1.2474	501	-2.04	0.0414	0.1	-4.6060	-0.4948
EGSTMNUM*LEG_SORT	3	203	12	202	-2.4148	1.2499	499	-1.93	0.0539	0.1	-4.4745	-0.3551
EGSTMNUM*LEG_SORT	3	203	12	203	3.7174	1.0848	1080	3.43	0.0006	0.1	1.9315	5.5033
EGSTMNUM*LEG_SORT	3	203	24	201	-5.8620	1.2474	501	-4.70	<.0001	0.1	-7.9176	-3.8064
EGSTMNUM*LEG_SORT	3	203	24	202	-3.7699	1.2499	499	-3.02	0.0027	0.1	-5.8295	-1.7102
EGSTMNUM*LEG_SORT	3	203	24	203	1.8043	1.0848	1080	1.66	0.0965	0.1	0.01848	3.5902
EGSTMNUM*LEG_SORT	4	201	4	202	-3.6470	1.2479	501	-2.92	0.0036	0.1	-5.7034	-1.5906
EGSTMNUM*LEG_SORT	4	201	4	203	9.8185	1.2474	501	7.87	<.0001	0.1	7.7629	11.8741
EGSTMNUM*LEG_SORT	4	201	5	201	7.3913	1.0848	1080	6.81	<.0001	0.1	5.6054	9.1772
EGSTMNUM*LEG_SORT	4	201	5	202	4.7008	1.2479	501	3.77	0.0002	0.1	2.6444	6.7573
EGSTMNUM*LEG_SORT	4	201	5	203	15.0214	1.2474	501	12.04	<.0001	0.1	12.9658	17.0770
EGSTMNUM*LEG_SORT	4	201	6	201	9.5072	1.0848	1080	8.76	<.0001	0.1	7.7214	11.2931
EGSTMNUM*LEG_SORT	4	201	6	202	6.6356	1.2479	501	5.32	<.0001	0.1	4.5792	8.6921
EGSTMNUM*LEG_SORT	4	201	6	203	16.5432	1.2474	501	13.26	<.0001	0.1	14.4876	18.5987
EGSTMNUM*LEG_SORT	4	201	8	201	9.5217	1.0848	1080	8.78	<.0001	0.1	7.7359	11.3076
EGSTMNUM*LEG_SORT	4	201	8	202	7.1356	1.2479	501	5.72	<.0001	0.1	5.0792	9.1921
EGSTMNUM*LEG_SORT	4	201	8	203	15.3620	1.2474	501	12.32	<.0001	0.1	13.3064	17.4176
EGSTMNUM*LEG_SORT	4	201	12	201	7.1884	1.0848	1080	6.63	<.0001	0.1	5.4025	8.9743
EGSTMNUM*LEG_SORT	4	201	12	202	7.3240	1.2479	501	5.87	<.0001	0.1	5.2676	9.3805
EGSTMNUM*LEG_SORT	4	201	12	203	13.4562	1.2474	501	10.79	<.0001	0.1	11.4006	15.5118
EGSTMNUM*LEG_SORT	4	201	24	201	3.8768	1.0848	1080	3.57	0.0004	0.1	2.0909	5.6627
EGSTMNUM*LEG_SORT	4	201	24	202	5.9690	1.2479	501	4.78	<.0001	0.1	3.9125	8.0254
EGSTMNUM*LEG_SORT	4	201	24	203	11.5432	1.2474	501	9.25	<.0001	0.1	9.4876	13.5987

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	4	203	13.4655	1.2499	499	10.77	<.0001	0.1	11.4058	15.5252
EGSTMNUM*LEG_SORT	4	202	5	201	11.0383	1.2479	501	8.85	<.0001	0.1	8.9819	13.0947
EGSTMNUM*LEG_SORT	4	202	5	202	8.3478	1.0848	1080	7.70	<.0001	0.1	6.5620	10.1337
EGSTMNUM*LEG_SORT	4	202	5	203	18.6684	1.2499	499	14.94	<.0001	0.1	16.6087	20.7281
EGSTMNUM*LEG_SORT	4	202	6	201	13.1542	1.2479	501	10.54	<.0001	0.1	11.0978	15.2107
EGSTMNUM*LEG_SORT	4	202	6	202	10.2826	1.0848	1080	9.48	<.0001	0.1	8.4967	12.0685
EGSTMNUM*LEG_SORT	4	202	6	203	20.1901	1.2499	499	16.15	<.0001	0.1	18.1305	22.2498
EGSTMNUM*LEG_SORT	4	202	8	201	13.1687	1.2479	501	10.55	<.0001	0.1	11.1123	15.2252
EGSTMNUM*LEG_SORT	4	202	8	202	10.7826	1.0848	1080	9.94	<.0001	0.1	8.9967	12.5685
EGSTMNUM*LEG_SORT	4	202	8	203	19.0090	1.2499	499	15.21	<.0001	0.1	16.9493	21.0687
EGSTMNUM*LEG_SORT	4	202	12	201	10.8354	1.2479	501	8.68	<.0001	0.1	8.7790	12.8918
EGSTMNUM*LEG_SORT	4	202	12	202	10.9710	1.0848	1080	10.11	<.0001	0.1	9.1851	12.7569
EGSTMNUM*LEG_SORT	4	202	12	203	17.1032	1.2499	499	13.68	<.0001	0.1	15.0435	19.1629
EGSTMNUM*LEG_SORT	4	202	24	201	7.5238	1.2479	501	6.03	<.0001	0.1	5.4674	9.5802
EGSTMNUM*LEG_SORT	4	202	24	202	9.6159	1.0848	1080	8.86	<.0001	0.1	7.8301	11.4018
EGSTMNUM*LEG_SORT	4	202	24	203	15.1901	1.2499	499	12.15	<.0001	0.1	13.1305	17.2498
EGSTMNUM*LEG_SORT	4	203	5	201	-2.4272	1.2474	501	-1.95	0.0522	0.1	-4.4828	-0.3716
EGSTMNUM*LEG_SORT	4	203	5	202	-5.1177	1.2499	499	-4.09	<.0001	0.1	-7.1774	-3.0580
EGSTMNUM*LEG_SORT	4	203	5	203	5.2029	1.0848	1080	4.80	<.0001	0.1	3.4170	6.9888
EGSTMNUM*LEG_SORT	4	203	6	201	-0.3113	1.2474	501	-0.25	0.8030	0.1	-2.3669	1.7443
EGSTMNUM*LEG_SORT	4	203	6	202	-3.1829	1.2499	499	-2.55	0.0112	0.1	-5.2426	-1.1232
EGSTMNUM*LEG_SORT	4	203	6	203	6.7246	1.0848	1080	6.20	<.0001	0.1	4.9388	8.5105
EGSTMNUM*LEG_SORT	4	203	8	201	-0.2968	1.2474	501	-0.24	0.8120	0.1	-2.3524	1.7588
EGSTMNUM*LEG_SORT	4	203	8	202	-2.6829	1.2499	499	-2.15	0.0323	0.1	-4.7426	-0.6232
EGSTMNUM*LEG_SORT	4	203	8	203	5.5435	1.0848	1080	5.11	<.0001	0.1	3.7576	7.3293
EGSTMNUM*LEG_SORT	4	203	12	201	-2.6301	1.2474	501	-2.11	0.0355	0.1	-4.6857	-0.5745
EGSTMNUM*LEG_SORT	4	203	12	202	-2.4945	1.2499	499	-2.00	0.0465	0.1	-4.5542	-0.4348
EGSTMNUM*LEG_SORT	4	203	12	203	3.6377	1.0848	1080	3.35	0.0008	0.1	1.8518	5.4236
EGSTMNUM*LEG_SORT	4	203	24	201	-5.9417	1.2474	501	-4.76	<.0001	0.1	-7.9973	-3.8861
EGSTMNUM*LEG_SORT	4	203	24	202	-3.8496	1.2499	499	-3.08	0.0022	0.1	-5.9092	-1.7899
EGSTMNUM*LEG_SORT	4	203	24	203	1.7246	1.0848	1080	1.59	0.1122	0.1	-0.06123	3.5105
EGSTMNUM*LEG_SORT	5	201	5	202	-2.6905	1.2479	501	-2.16	0.0316	0.1	-4.7469	-0.6340
EGSTMNUM*LEG_SORT	5	201	5	203	7.6301	1.2474	501	6.12	<.0001	0.1	5.5745	9.6857
EGSTMNUM*LEG_SORT	5	201	6	201	2.1159	1.0848	1080	1.95	0.0514	0.1	0.3301	3.9018

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	201	6	202	-0.7557	1.2479	501	-0.61	0.5451	0.1	-2.8121	1.3008
EGSTMNUM*LEG_SORT	5	201	6	203	9.1519	1.2474	501	7.34	<.0001	0.1	7.0963	11.2074
EGSTMNUM*LEG_SORT	5	201	8	201	2.1304	1.0848	1080	1.96	0.0498	0.1	0.3446	3.9163
EGSTMNUM*LEG_SORT	5	201	8	202	-0.2557	1.2479	501	-0.20	0.8377	0.1	-2.3121	1.8008
EGSTMNUM*LEG_SORT	5	201	8	203	7.9707	1.2474	501	6.39	<.0001	0.1	5.9151	10.0263
EGSTMNUM*LEG_SORT	5	201	12	201	-0.2029	1.0848	1080	-0.19	0.8517	0.1	-1.9888	1.5830
EGSTMNUM*LEG_SORT	5	201	12	202	-0.06728	1.2479	501	-0.05	0.9570	0.1	-2.1237	1.9892
EGSTMNUM*LEG_SORT	5	201	12	203	6.0649	1.2474	501	4.86	<.0001	0.1	4.0093	8.1205
EGSTMNUM*LEG_SORT	5	201	24	201	-3.5145	1.0848	1080	-3.24	0.0012	0.1	-5.3004	-1.7286
EGSTMNUM*LEG_SORT	5	201	24	202	-1.4224	1.2479	501	-1.14	0.2549	0.1	-3.4788	0.6341
EGSTMNUM*LEG_SORT	5	201	24	203	4.1519	1.2474	501	3.33	0.0009	0.1	2.0963	6.2074
EGSTMNUM*LEG_SORT	5	202	5	203	10.3206	1.2499	499	8.26	<.0001	0.1	8.2609	12.3803
EGSTMNUM*LEG_SORT	5	202	6	201	4.8064	1.2479	501	3.85	0.0001	0.1	2.7500	6.8628
EGSTMNUM*LEG_SORT	5	202	6	202	1.9348	1.0848	1080	1.78	0.0748	0.1	0.1489	3.7207
EGSTMNUM*LEG_SORT	5	202	6	203	11.8423	1.2499	499	9.47	<.0001	0.1	9.7826	13.9020
EGSTMNUM*LEG_SORT	5	202	8	201	4.8209	1.2479	501	3.86	0.0001	0.1	2.7645	6.8773
EGSTMNUM*LEG_SORT	5	202	8	202	2.4348	1.0848	1080	2.24	0.0250	0.1	0.6489	4.2207
EGSTMNUM*LEG_SORT	5	202	8	203	10.6612	1.2499	499	8.53	<.0001	0.1	8.6015	12.7208
EGSTMNUM*LEG_SORT	5	202	12	201	2.4876	1.2479	501	1.99	0.0468	0.1	0.4311	4.5440
EGSTMNUM*LEG_SORT	5	202	12	202	2.6232	1.0848	1080	2.42	0.0158	0.1	0.8373	4.4091
EGSTMNUM*LEG_SORT	5	202	12	203	8.7554	1.2499	499	7.00	<.0001	0.1	6.6957	10.8150
EGSTMNUM*LEG_SORT	5	202	24	201	-0.8240	1.2479	501	-0.66	0.5093	0.1	-2.8805	1.2324
EGSTMNUM*LEG_SORT	5	202	24	202	1.2681	1.0848	1080	1.17	0.2427	0.1	-0.5178	3.0540
EGSTMNUM*LEG_SORT	5	202	24	203	6.8423	1.2499	499	5.47	<.0001	0.1	4.7826	8.9020
EGSTMNUM*LEG_SORT	5	203	6	201	-5.5142	1.2474	501	-4.42	<.0001	0.1	-7.5698	-3.4586
EGSTMNUM*LEG_SORT	5	203	6	202	-8.3858	1.2499	499	-6.71	<.0001	0.1	-10.4455	-6.3261
EGSTMNUM*LEG_SORT	5	203	6	203	1.5217	1.0848	1080	1.40	0.1610	0.1	-0.2641	3.3076
EGSTMNUM*LEG_SORT	5	203	8	201	-5.4997	1.2474	501	-4.41	<.0001	0.1	-7.5553	-3.4441
EGSTMNUM*LEG_SORT	5	203	8	202	-7.8858	1.2499	499	-6.31	<.0001	0.1	-9.9455	-5.8261
EGSTMNUM*LEG_SORT	5	203	8	203	0.3406	1.0848	1080	0.31	0.7536	0.1	-1.4453	2.1264
EGSTMNUM*LEG_SORT	5	203	12	201	-7.8330	1.2474	501	-6.28	<.0001	0.1	-9.8886	-5.7774
EGSTMNUM*LEG_SORT	5	203	12	202	-7.6974	1.2499	499	-6.16	<.0001	0.1	-9.7571	-5.6377
EGSTMNUM*LEG_SORT	5	203	12	203	-1.5652	1.0848	1080	-1.44	0.1493	0.1	-3.3511	0.2207
EGSTMNUM*LEG_SORT	5	203	24	201	-11.1446	1.2474	501	-8.93	<.0001	0.1	-13.2002	-9.0890

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	203	24	202	-9.0525	1.2499	499	-7.24	<.0001	0.1	-11.1121	-6.9928
EGSTMNUM*LEG_SORT	5	203	24	203	-3.4783	1.0848	1080	-3.21	0.0014	0.1	-5.2641	-1.6924
EGSTMNUM*LEG_SORT	6	201	6	202	-2.8716	1.2479	501	-2.30	0.0218	0.1	-4.9281	-0.8152
EGSTMNUM*LEG_SORT	6	201	6	203	7.0359	1.2474	501	5.64	<.0001	0.1	4.9803	9.0915
EGSTMNUM*LEG_SORT	6	201	8	201	0.01449	1.0848	1080	0.01	0.9893	0.1	-1.7714	1.8004
EGSTMNUM*LEG_SORT	6	201	8	202	-2.3716	1.2479	501	-1.90	0.0579	0.1	-4.4281	-0.3152
EGSTMNUM*LEG_SORT	6	201	8	203	5.8548	1.2474	501	4.69	<.0001	0.1	3.7992	7.9103
EGSTMNUM*LEG_SORT	6	201	12	201	-2.3188	1.0848	1080	-2.14	0.0328	0.1	-4.1047	-0.5330
EGSTMNUM*LEG_SORT	6	201	12	202	-2.1832	1.2479	501	-1.75	0.0808	0.1	-4.2397	-0.1268
EGSTMNUM*LEG_SORT	6	201	12	203	3.9490	1.2474	501	3.17	0.0016	0.1	1.8934	6.0045
EGSTMNUM*LEG_SORT	6	201	24	201	-5.6304	1.0848	1080	-5.19	<.0001	0.1	-7.4163	-3.8446
EGSTMNUM*LEG_SORT	6	201	24	202	-3.5383	1.2479	501	-2.84	0.0048	0.1	-5.5947	-1.4819
EGSTMNUM*LEG_SORT	6	201	24	203	2.0359	1.2474	501	1.63	0.1033	0.1	-0.01968	4.0915
EGSTMNUM*LEG_SORT	6	202	6	203	9.9075	1.2499	499	7.93	<.0001	0.1	7.8478	11.9672
EGSTMNUM*LEG_SORT	6	202	8	201	2.8861	1.2479	501	2.31	0.0211	0.1	0.8297	4.9426
EGSTMNUM*LEG_SORT	6	202	8	202	0.5000	1.0848	1080	0.46	0.6450	0.1	-1.2859	2.2859
EGSTMNUM*LEG_SORT	6	202	8	203	8.7264	1.2499	499	6.98	<.0001	0.1	6.6667	10.7861
EGSTMNUM*LEG_SORT	6	202	12	201	0.5528	1.2479	501	0.44	0.6580	0.1	-1.5036	2.6092
EGSTMNUM*LEG_SORT	6	202	12	202	0.6884	1.0848	1080	0.63	0.5258	0.1	-1.0975	2.4743
EGSTMNUM*LEG_SORT	6	202	12	203	6.8206	1.2499	499	5.46	<.0001	0.1	4.7609	8.8803
EGSTMNUM*LEG_SORT	6	202	24	201	-2.7588	1.2479	501	-2.21	0.0275	0.1	-4.8152	-0.7024
EGSTMNUM*LEG_SORT	6	202	24	202	-0.6667	1.0848	1080	-0.61	0.5390	0.1	-2.4525	1.1192
EGSTMNUM*LEG_SORT	6	202	24	203	4.9075	1.2499	499	3.93	<.0001	0.1	2.8478	6.9672
EGSTMNUM*LEG_SORT	6	203	8	201	-7.0214	1.2474	501	-5.63	<.0001	0.1	-9.0770	-4.9658
EGSTMNUM*LEG_SORT	6	203	8	202	-9.4075	1.2499	499	-7.53	<.0001	0.1	-11.4672	-7.3478
EGSTMNUM*LEG_SORT	6	203	8	203	-1.1812	1.0848	1080	-1.09	0.2765	0.1	-2.9670	0.6047
EGSTMNUM*LEG_SORT	6	203	12	201	-9.3548	1.2474	501	-7.50	<.0001	0.1	-11.4103	-7.2992
EGSTMNUM*LEG_SORT	6	203	12	202	-9.2191	1.2499	499	-7.38	<.0001	0.1	-11.2788	-7.1594
EGSTMNUM*LEG_SORT	6	203	12	203	-3.0870	1.0848	1080	-2.85	0.0045	0.1	-4.8728	-1.3011
EGSTMNUM*LEG_SORT	6	203	24	201	-12.6663	1.2474	501	-10.15	<.0001	0.1	-14.7219	-10.6108
EGSTMNUM*LEG_SORT	6	203	24	202	-10.5742	1.2499	499	-8.46	<.0001	0.1	-12.6339	-8.5145
EGSTMNUM*LEG_SORT	6	203	24	203	-5.0000	1.0848	1080	-4.61	<.0001	0.1	-6.7859	-3.2141
EGSTMNUM*LEG_SORT	8	201	8	202	-2.3861	1.2479	501	-1.91	0.0564	0.1	-4.4426	-0.3297
EGSTMNUM*LEG_SORT	8	201	8	203	5.8403	1.2474	501	4.68	<.0001	0.1	3.7847	7.8958

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

The Mixed Procedure

Differences of Least Squares Means

Effect	Nominal Timepoint	Treatment group sort order	Nominal Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	201	12	201	-2.3333	1.0848	1080	-2.15	0.0317	0.1	-4.1192	-0.5475
EGSTMNUM*LEG_SORT	8	201	12	202	-2.1977	1.2479	501	-1.76	0.0788	0.1	-4.2541	-0.1413
EGSTMNUM*LEG_SORT	8	201	12	203	3.9345	1.2474	501	3.15	0.0017	0.1	1.8789	5.9901
EGSTMNUM*LEG_SORT	8	201	24	201	-5.6449	1.0848	1080	-5.20	<.0001	0.1	-7.4308	-3.8591
EGSTMNUM*LEG_SORT	8	201	24	202	-3.5528	1.2479	501	-2.85	0.0046	0.1	-5.6092	-1.4964
EGSTMNUM*LEG_SORT	8	201	24	203	2.0214	1.2474	501	1.62	0.1058	0.1	-0.03417	4.0770
EGSTMNUM*LEG_SORT	8	202	8	203	8.2264	1.2499	499	6.58	<.0001	0.1	6.1667	10.2861
EGSTMNUM*LEG_SORT	8	202	12	201	0.05278	1.2479	501	0.04	0.9663	0.1	-2.0036	2.1092
EGSTMNUM*LEG_SORT	8	202	12	202	0.1884	1.0848	1080	0.17	0.8622	0.1	-1.5975	1.9743
EGSTMNUM*LEG_SORT	8	202	12	203	6.3206	1.2499	499	5.06	<.0001	0.1	4.2609	8.3803
EGSTMNUM*LEG_SORT	8	202	24	201	-3.2588	1.2479	501	-2.61	0.0093	0.1	-5.3152	-1.2024
EGSTMNUM*LEG_SORT	8	202	24	202	-1.1667	1.0848	1080	-1.08	0.2824	0.1	-2.9525	0.6192
EGSTMNUM*LEG_SORT	8	202	24	203	4.4075	1.2499	499	3.53	0.0005	0.1	2.3478	6.4672
EGSTMNUM*LEG_SORT	8	203	12	201	-8.1736	1.2474	501	-6.55	<.0001	0.1	-10.2292	-6.1180
EGSTMNUM*LEG_SORT	8	203	12	202	-8.0380	1.2499	499	-6.43	<.0001	0.1	-10.0977	-5.9783
EGSTMNUM*LEG_SORT	8	203	12	203	-1.9058	1.0848	1080	-1.76	0.0792	0.1	-3.6917	-0.1199
EGSTMNUM*LEG_SORT	8	203	24	201	-11.4852	1.2474	501	-9.21	<.0001	0.1	-13.5408	-9.4296
EGSTMNUM*LEG_SORT	8	203	24	202	-9.3930	1.2499	499	-7.52	<.0001	0.1	-11.4527	-7.3334
EGSTMNUM*LEG_SORT	8	203	24	203	-3.8188	1.0848	1080	-3.52	0.0004	0.1	-5.6047	-2.0330
EGSTMNUM*LEG_SORT	12	201	12	202	0.1356	1.2479	501	0.11	0.9135	0.1	-1.9208	2.1921
EGSTMNUM*LEG_SORT	12	201	12	203	6.2678	1.2474	501	5.02	<.0001	0.1	4.2122	8.3234
EGSTMNUM*LEG_SORT	12	201	24	201	-3.3116	1.0848	1080	-3.05	0.0023	0.1	-5.0975	-1.5257
EGSTMNUM*LEG_SORT	12	201	24	202	-1.2195	1.2479	501	-0.98	0.3289	0.1	-3.2759	0.8370
EGSTMNUM*LEG_SORT	12	201	24	203	4.3548	1.2474	501	3.49	0.0005	0.1	2.2992	6.4103
EGSTMNUM*LEG_SORT	12	202	12	203	6.1322	1.2499	499	4.91	<.0001	0.1	4.0725	8.1919
EGSTMNUM*LEG_SORT	12	202	24	201	-3.4472	1.2479	501	-2.76	0.0059	0.1	-5.5036	-1.3908
EGSTMNUM*LEG_SORT	12	202	24	202	-1.3551	1.0848	1080	-1.25	0.2119	0.1	-3.1409	0.4308
EGSTMNUM*LEG_SORT	12	202	24	203	4.2191	1.2499	499	3.38	0.0008	0.1	2.1594	6.2788
EGSTMNUM*LEG_SORT	12	203	24	201	-9.5794	1.2474	501	-7.68	<.0001	0.1	-11.6350	-7.5238
EGSTMNUM*LEG_SORT	12	203	24	202	-7.4872	1.2499	499	-5.99	<.0001	0.1	-9.5469	-5.4276
EGSTMNUM*LEG_SORT	12	203	24	203	-1.9130	1.0848	1080	-1.76	0.0781	0.1	-3.6989	-0.1272
EGSTMNUM*LEG_SORT	24	201	24	202	2.0921	1.2479	501	1.68	0.0943	0.1	0.03571	4.1486
EGSTMNUM*LEG_SORT	24	201	24	203	7.6663	1.2474	501	6.15	<.0001	0.1	5.6108	9.7219
EGSTMNUM*LEG_SORT	24	202	24	203	5.5742	1.2499	499	4.46	<.0001	0.1	3.5145	7.6339

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcF as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:56)

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drgggroup period egstmnum leg_sort;
model QTcI = drgggroup period leg_sort egbase_QTcI egstmnum egstmnum*leg_sort/ddfm=kr;
random subjid(drgggroup);
repeated / subject = period*subjid(drgggroup) type=cs;
lsmeans egstmnum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (00:59)

SERTRALINE Protocol A0501104

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Model Information

```
Data Set                WORK.ECG3
Dependent Variable      QTcI
Covariance Structures  Variance Components,
                        Compound Symmetry
Subject Effect          SUBJI*PERIOD(DRGGRO)
Estimation Method       REML
Residual Variance Method Profile
Fixed Effects SE Method Kenward-Roger
Degrees of Freedom Method Kenward-Roger
```

Class Level Information

```
Class      Levels  Values
SUBJID      54    10011001 10011002 10011003
            10011004 10011005 10011006
            10011007 10011008 10011009
            10011010 10011011 10011012
            10011013 10011014 10011015
            10011016 10011017 10011018
            10011019 10011020 10011021
            10011022 10011023 10011024
            10011025 10011026 10011027
            10011028 10011029 10011030
            10011031 10011032 10011033
            10011034 10011035 10011036
            10011037 10011038 10011039
            10011040 10011041 10011042
            10011043 10011044 10011045
            10011046 10011047 10011048
            10011049 10011050 10011051
            10011052 10011053 10011054
DRGGROUP     6    ABC ACB BAC BCA CAB CBA
PERIOD       3    Period 1 Period 2 Period 3
EGSTMNUM     9    1 2 3 4 5 6 8 12 24
LEG_SORT     3    201 202 203
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1      Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (00:59)

SERTRALINE Protocol A0501104

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

## The Mixed Procedure

## Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	54
Subjects	1
Max Obs Per Subject	1351

## Number of Observations

Number of Observations Read	1351
Number of Observations Used	1351
Number of Observations Not Used	0

## Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	9838.99038427	
1	2	8964.06171239	0.00005264
2	1	8963.87805970	0.00000069
3	1	8963.87575564	0.00000000

Convergence criteria met.

## Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		50.9864
CS	SUBJI*PERIOD(DRGGRO)	19.2888
Residual		36.6802

## Fit Statistics

-2 Res Log Likelihood	8963.9
AIC (smaller is better)	8969.9

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Fit Statistics

AICC (smaller is better) 8969.9  
 BIC (smaller is better) 8975.8

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	27.8	0.59	0.7084
PERIOD	2	71.2	0.46	0.6309
LEG_SORT	2	70.8	65.74	<.0001
EGBASE_QTCI	1	58.1	155.94	<.0001
EGSTMNUM	8	1176	49.60	<.0001
EGSTMNUM*LEG_SORT	16	1176	2.44	0.0013

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	414.70	1.4421	105	287.56	<.0001	0.1	412.31	417.09
EGSTMNUM*LEG_SORT	1	202	420.08	1.4469	105	290.34	<.0001	0.1	417.68	422.48
EGSTMNUM*LEG_SORT	1	203	407.09	1.4473	105	281.27	<.0001	0.1	404.69	409.49
EGSTMNUM*LEG_SORT	2	201	416.13	1.4421	105	288.55	<.0001	0.1	413.73	418.52
EGSTMNUM*LEG_SORT	2	202	420.58	1.4469	105	290.69	<.0001	0.1	418.18	422.98
EGSTMNUM*LEG_SORT	2	203	407.94	1.4473	105	281.86	<.0001	0.1	405.53	410.34
EGSTMNUM*LEG_SORT	3	201	416.70	1.4421	105	288.95	<.0001	0.1	414.31	419.10
EGSTMNUM*LEG_SORT	3	202	421.00	1.4469	105	290.97	<.0001	0.1	418.60	423.40
EGSTMNUM*LEG_SORT	3	203	408.43	1.4473	105	282.20	<.0001	0.1	406.03	410.83
EGSTMNUM*LEG_SORT	4	201	418.83	1.4421	105	290.42	<.0001	0.1	416.44	421.22
EGSTMNUM*LEG_SORT	4	202	422.34	1.4469	105	291.90	<.0001	0.1	419.94	424.74
EGSTMNUM*LEG_SORT	4	203	408.63	1.4473	105	282.34	<.0001	0.1	406.23	411.04
EGSTMNUM*LEG_SORT	5	201	411.56	1.4421	105	285.38	<.0001	0.1	409.17	413.95
EGSTMNUM*LEG_SORT	5	202	414.75	1.4469	105	286.66	<.0001	0.1	412.35	417.15
EGSTMNUM*LEG_SORT	5	203	403.03	1.4473	105	278.46	<.0001	0.1	400.63	405.43
EGSTMNUM*LEG_SORT	6	201	409.16	1.4421	105	283.72	<.0001	0.1	406.77	411.56

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	6	202	412.25	1.4469	105	284.93	<.0001	0.1	409.85	414.65
EGSTMNUM*LEG_SORT	6	203	401.76	1.4473	105	277.59	<.0001	0.1	399.36	404.16
EGSTMNUM*LEG_SORT	8	201	408.63	1.4421	105	283.35	<.0001	0.1	406.24	411.03
EGSTMNUM*LEG_SORT	8	202	411.26	1.4469	105	284.25	<.0001	0.1	408.86	413.66
EGSTMNUM*LEG_SORT	8	203	402.26	1.4473	105	277.93	<.0001	0.1	399.86	404.66
EGSTMNUM*LEG_SORT	12	201	411.16	1.4421	105	285.10	<.0001	0.1	408.77	413.55
EGSTMNUM*LEG_SORT	12	202	411.92	1.4469	105	284.70	<.0001	0.1	409.52	414.32
EGSTMNUM*LEG_SORT	12	203	404.48	1.4473	105	279.47	<.0001	0.1	402.08	406.88
EGSTMNUM*LEG_SORT	24	201	414.43	1.4341	103	288.98	<.0001	0.1	412.05	416.81
EGSTMNUM*LEG_SORT	24	202	413.87	1.4469	105	286.05	<.0001	0.1	411.47	416.27
EGSTMNUM*LEG_SORT	24	203	406.66	1.4473	105	280.98	<.0001	0.1	404.26	409.07

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-5.3841	1.5073	354	-3.57	0.0004	0.1	-7.8699	-2.8984
EGSTMNUM*LEG_SORT	1	201	1	203	7.6064	1.5033	354	5.06	<.0001	0.1	5.1273	10.0856
EGSTMNUM*LEG_SORT	1	201	2	201	-1.4296	1.2113	1176	-1.18	0.2382	0.1	-3.4235	0.5644
EGSTMNUM*LEG_SORT	1	201	2	202	-5.8855	1.5073	354	-3.90	0.0001	0.1	-8.3712	-3.3997
EGSTMNUM*LEG_SORT	1	201	2	203	6.7625	1.5033	354	4.50	<.0001	0.1	4.2834	9.2417
EGSTMNUM*LEG_SORT	1	201	3	201	-2.0033	1.2113	1176	-1.65	0.0984	0.1	-3.9972	-0.00932
EGSTMNUM*LEG_SORT	1	201	3	202	-6.3016	1.5073	354	-4.18	<.0001	0.1	-8.7874	-3.8159
EGSTMNUM*LEG_SORT	1	201	3	203	6.2670	1.5033	354	4.17	<.0001	0.1	3.7879	8.7462
EGSTMNUM*LEG_SORT	1	201	4	201	-4.1324	1.2113	1176	-3.41	0.0007	0.1	-6.1264	-2.1385
EGSTMNUM*LEG_SORT	1	201	4	202	-7.6380	1.5073	354	-5.07	<.0001	0.1	-10.1237	-5.1522
EGSTMNUM*LEG_SORT	1	201	4	203	6.0636	1.5033	354	4.03	<.0001	0.1	3.5844	8.5427
EGSTMNUM*LEG_SORT	1	201	5	201	3.1381	1.2113	1176	2.59	0.0097	0.1	1.1441	5.1320
EGSTMNUM*LEG_SORT	1	201	5	202	-0.05196	1.5073	354	-0.03	0.9725	0.1	-2.5377	2.4338
EGSTMNUM*LEG_SORT	1	201	5	203	11.6698	1.5033	354	7.76	<.0001	0.1	9.1906	14.1489
EGSTMNUM*LEG_SORT	1	201	6	201	5.5362	1.2113	1176	4.57	<.0001	0.1	3.5423	7.5302

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	6	202	2.4478	1.5073	354	1.62	0.1053	0.1	-0.03789	4.9336
EGSTMNUM*LEG_SORT	1	201	6	203	12.9413	1.5033	354	8.61	<.0001	0.1	10.4622	15.4205
EGSTMNUM*LEG_SORT	1	201	8	201	6.0637	1.2113	1176	5.01	<.0001	0.1	4.0698	8.0577
EGSTMNUM*LEG_SORT	1	201	8	202	3.4355	1.5073	354	2.28	0.0232	0.1	0.9498	5.9212
EGSTMNUM*LEG_SORT	1	201	8	203	12.4390	1.5033	354	8.27	<.0001	0.1	9.9599	14.9182
EGSTMNUM*LEG_SORT	1	201	12	201	3.5396	1.2113	1176	2.92	0.0035	0.1	1.5456	5.5335
EGSTMNUM*LEG_SORT	1	201	12	202	2.7819	1.5073	354	1.85	0.0658	0.1	0.2962	5.2677
EGSTMNUM*LEG_SORT	1	201	12	203	10.2171	1.5033	354	6.80	<.0001	0.1	7.7380	12.6963
EGSTMNUM*LEG_SORT	1	201	24	201	0.2699	1.2095	1181	0.22	0.8235	0.1	-1.7211	2.2608
EGSTMNUM*LEG_SORT	1	201	24	202	0.8256	1.5073	354	0.55	0.5842	0.1	-1.6601	3.3113
EGSTMNUM*LEG_SORT	1	201	24	203	8.0336	1.5033	354	5.34	<.0001	0.1	5.5545	10.5128
EGSTMNUM*LEG_SORT	1	202	1	203	12.9906	1.5055	355	8.63	<.0001	0.1	10.5077	15.4735
EGSTMNUM*LEG_SORT	1	202	2	201	3.9546	1.5073	354	2.62	0.0091	0.1	1.4688	6.4403
EGSTMNUM*LEG_SORT	1	202	2	202	-0.5013	1.2113	1176	-0.41	0.6790	0.1	-2.4953	1.4926
EGSTMNUM*LEG_SORT	1	202	2	203	12.1466	1.5055	355	8.07	<.0001	0.1	9.6638	14.6295
EGSTMNUM*LEG_SORT	1	202	3	201	3.3809	1.5073	354	2.24	0.0255	0.1	0.8951	5.8666
EGSTMNUM*LEG_SORT	1	202	3	202	-0.9175	1.2113	1176	-0.76	0.4489	0.1	-2.9114	1.0765
EGSTMNUM*LEG_SORT	1	202	3	203	11.6512	1.5055	355	7.74	<.0001	0.1	9.1683	14.1340
EGSTMNUM*LEG_SORT	1	202	4	201	1.2517	1.5073	354	0.83	0.4068	0.1	-1.2340	3.7374
EGSTMNUM*LEG_SORT	1	202	4	202	-2.2538	1.2113	1176	-1.86	0.0630	0.1	-4.2478	-0.2599
EGSTMNUM*LEG_SORT	1	202	4	203	11.4477	1.5055	355	7.60	<.0001	0.1	8.9648	13.9306
EGSTMNUM*LEG_SORT	1	202	5	201	8.5222	1.5073	354	5.65	<.0001	0.1	6.0365	11.0080
EGSTMNUM*LEG_SORT	1	202	5	202	5.3322	1.2113	1176	4.40	<.0001	0.1	3.3382	7.3261
EGSTMNUM*LEG_SORT	1	202	5	203	17.0539	1.5055	355	11.33	<.0001	0.1	14.5710	19.5368
EGSTMNUM*LEG_SORT	1	202	6	201	10.9204	1.5073	354	7.25	<.0001	0.1	8.4346	13.4061
EGSTMNUM*LEG_SORT	1	202	6	202	7.8320	1.2113	1176	6.47	<.0001	0.1	5.8380	9.8259
EGSTMNUM*LEG_SORT	1	202	6	203	18.3254	1.5055	355	12.17	<.0001	0.1	15.8426	20.8083
EGSTMNUM*LEG_SORT	1	202	8	201	11.4479	1.5073	354	7.60	<.0001	0.1	8.9621	13.9336
EGSTMNUM*LEG_SORT	1	202	8	202	8.8196	1.2113	1176	7.28	<.0001	0.1	6.8257	10.8136
EGSTMNUM*LEG_SORT	1	202	8	203	17.8231	1.5055	355	11.84	<.0001	0.1	15.3403	20.3060
EGSTMNUM*LEG_SORT	1	202	12	201	8.9237	1.5073	354	5.92	<.0001	0.1	6.4380	11.4094
EGSTMNUM*LEG_SORT	1	202	12	202	8.1661	1.2113	1176	6.74	<.0001	0.1	6.1721	10.1600
EGSTMNUM*LEG_SORT	1	202	12	203	15.6012	1.5055	355	10.36	<.0001	0.1	13.1184	18.0841
EGSTMNUM*LEG_SORT	1	202	24	201	5.6540	1.5039	356	3.76	0.0002	0.1	3.1738	8.1342
EGSTMNUM*LEG_SORT	1	202	24	202	6.2097	1.2113	1176	5.13	<.0001	0.1	4.2158	8.2037

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	24	203	13.4177	1.5055	355	8.91	<.0001	0.1	10.9349	15.9006
EGSTMNUM*LEG_SORT	1	203	2	201	-9.0360	1.5033	354	-6.01	<.0001	0.1	-11.5152	-6.5569
EGSTMNUM*LEG_SORT	1	203	2	202	-13.4919	1.5055	355	-8.96	<.0001	0.1	-15.9748	-11.0090
EGSTMNUM*LEG_SORT	1	203	2	203	-0.8439	1.2113	1176	-0.70	0.4861	0.1	-2.8379	1.1500
EGSTMNUM*LEG_SORT	1	203	3	201	-9.6097	1.5033	354	-6.39	<.0001	0.1	-12.0889	-7.1306
EGSTMNUM*LEG_SORT	1	203	3	202	-13.9081	1.5055	355	-9.24	<.0001	0.1	-16.3909	-11.4252
EGSTMNUM*LEG_SORT	1	203	3	203	-1.3394	1.2113	1176	-1.11	0.2690	0.1	-3.3334	0.6545
EGSTMNUM*LEG_SORT	1	203	4	201	-11.7389	1.5033	354	-7.81	<.0001	0.1	-14.2180	-9.2597
EGSTMNUM*LEG_SORT	1	203	4	202	-15.2444	1.5055	355	-10.13	<.0001	0.1	-17.7273	-12.7615
EGSTMNUM*LEG_SORT	1	203	4	203	-1.5429	1.2113	1176	-1.27	0.2030	0.1	-3.5368	0.4511
EGSTMNUM*LEG_SORT	1	203	5	201	-4.4684	1.5033	354	-2.97	0.0032	0.1	-6.9475	-1.9892
EGSTMNUM*LEG_SORT	1	203	5	202	-7.6584	1.5055	355	-5.09	<.0001	0.1	-10.1413	-5.1755
EGSTMNUM*LEG_SORT	1	203	5	203	4.0633	1.2113	1176	3.35	0.0008	0.1	2.0694	6.0573
EGSTMNUM*LEG_SORT	1	203	6	201	-2.0702	1.5033	354	-1.38	0.1693	0.1	-4.5493	0.4090
EGSTMNUM*LEG_SORT	1	203	6	202	-5.1586	1.5055	355	-3.43	0.0007	0.1	-7.6415	-2.6757
EGSTMNUM*LEG_SORT	1	203	6	203	5.3349	1.2113	1176	4.40	<.0001	0.1	3.3409	7.3288
EGSTMNUM*LEG_SORT	1	203	8	201	-1.5427	1.5033	354	-1.03	0.3055	0.1	-4.0219	0.9364
EGSTMNUM*LEG_SORT	1	203	8	202	-4.1709	1.5055	355	-2.77	0.0059	0.1	-6.6538	-1.6881
EGSTMNUM*LEG_SORT	1	203	8	203	4.8326	1.2113	1176	3.99	<.0001	0.1	2.8386	6.8265
EGSTMNUM*LEG_SORT	1	203	12	201	-4.0669	1.5033	354	-2.71	0.0072	0.1	-6.5460	-1.5877
EGSTMNUM*LEG_SORT	1	203	12	202	-4.8245	1.5055	355	-3.20	0.0015	0.1	-7.3074	-2.3416
EGSTMNUM*LEG_SORT	1	203	12	203	2.6107	1.2113	1176	2.16	0.0313	0.1	0.6167	4.6046
EGSTMNUM*LEG_SORT	1	203	24	201	-7.3366	1.5004	357	-4.89	<.0001	0.1	-9.8109	-4.8623
EGSTMNUM*LEG_SORT	1	203	24	202	-6.7808	1.5055	355	-4.50	<.0001	0.1	-9.2637	-4.2980
EGSTMNUM*LEG_SORT	1	203	24	203	0.4272	1.2113	1176	0.35	0.7244	0.1	-1.5668	2.4211
EGSTMNUM*LEG_SORT	2	201	2	202	-4.4559	1.5073	354	-2.96	0.0033	0.1	-6.9416	-1.9701
EGSTMNUM*LEG_SORT	2	201	2	203	8.1921	1.5033	354	5.45	<.0001	0.1	5.7129	10.6712
EGSTMNUM*LEG_SORT	2	201	3	201	-0.5737	1.2113	1176	-0.47	0.6359	0.1	-2.5677	1.4203
EGSTMNUM*LEG_SORT	2	201	3	202	-4.8720	1.5073	354	-3.23	0.0013	0.1	-7.3578	-2.3863
EGSTMNUM*LEG_SORT	2	201	3	203	7.6966	1.5033	354	5.12	<.0001	0.1	5.2175	10.1758
EGSTMNUM*LEG_SORT	2	201	4	201	-2.7028	1.2113	1176	-2.23	0.0258	0.1	-4.6968	-0.7089
EGSTMNUM*LEG_SORT	2	201	4	202	-6.2084	1.5073	354	-4.12	<.0001	0.1	-8.6941	-3.7226
EGSTMNUM*LEG_SORT	2	201	4	203	7.4932	1.5033	354	4.98	<.0001	0.1	5.0140	9.9723
EGSTMNUM*LEG_SORT	2	201	5	201	4.5677	1.2113	1176	3.77	0.0002	0.1	2.5737	6.5616
EGSTMNUM*LEG_SORT	2	201	5	202	1.3776	1.5073	354	0.91	0.3613	0.1	-1.1081	3.8634

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	5	203	13.0994	1.5033	354	8.71	<.0001	0.1	10.6202	15.5785
EGSTMNUM*LEG_SORT	2	201	6	201	6.9658	1.2113	1176	5.75	<.0001	0.1	4.9719	8.9598
EGSTMNUM*LEG_SORT	2	201	6	202	3.8774	1.5073	354	2.57	0.0105	0.1	1.3917	6.3632
EGSTMNUM*LEG_SORT	2	201	6	203	14.3709	1.5033	354	9.56	<.0001	0.1	11.8917	16.8500
EGSTMNUM*LEG_SORT	2	201	8	201	7.4933	1.2113	1176	6.19	<.0001	0.1	5.4993	9.4873
EGSTMNUM*LEG_SORT	2	201	8	202	4.8651	1.5073	354	3.23	0.0014	0.1	2.3793	7.3508
EGSTMNUM*LEG_SORT	2	201	8	203	13.8686	1.5033	354	9.23	<.0001	0.1	11.3894	16.3477
EGSTMNUM*LEG_SORT	2	201	12	201	4.9691	1.2113	1176	4.10	<.0001	0.1	2.9752	6.9631
EGSTMNUM*LEG_SORT	2	201	12	202	4.2115	1.5073	354	2.79	0.0055	0.1	1.7258	6.6972
EGSTMNUM*LEG_SORT	2	201	12	203	11.6467	1.5033	354	7.75	<.0001	0.1	9.1675	14.1258
EGSTMNUM*LEG_SORT	2	201	24	201	1.6994	1.2095	1181	1.41	0.1603	0.1	-0.2915	3.6904
EGSTMNUM*LEG_SORT	2	201	24	202	2.2552	1.5073	354	1.50	0.1355	0.1	-0.2306	4.7409
EGSTMNUM*LEG_SORT	2	201	24	203	9.4632	1.5033	354	6.30	<.0001	0.1	6.9840	11.9423
EGSTMNUM*LEG_SORT	2	202	2	203	12.6480	1.5055	355	8.40	<.0001	0.1	10.1651	15.1308
EGSTMNUM*LEG_SORT	2	202	3	201	3.8822	1.5073	354	2.58	0.0104	0.1	1.3964	6.3679
EGSTMNUM*LEG_SORT	2	202	3	202	-0.4162	1.2113	1176	-0.34	0.7312	0.1	-2.4101	1.5778
EGSTMNUM*LEG_SORT	2	202	3	203	12.1525	1.5055	355	8.07	<.0001	0.1	9.6696	14.6354
EGSTMNUM*LEG_SORT	2	202	4	201	1.7530	1.5073	354	1.16	0.2456	0.1	-0.7327	4.2388
EGSTMNUM*LEG_SORT	2	202	4	202	-1.7525	1.2113	1176	-1.45	0.1482	0.1	-3.7465	0.2414
EGSTMNUM*LEG_SORT	2	202	4	203	11.9490	1.5055	355	7.94	<.0001	0.1	9.4661	14.4319
EGSTMNUM*LEG_SORT	2	202	5	201	9.0235	1.5073	354	5.99	<.0001	0.1	6.5378	11.5093
EGSTMNUM*LEG_SORT	2	202	5	202	5.8335	1.2113	1176	4.82	<.0001	0.1	3.8395	7.8274
EGSTMNUM*LEG_SORT	2	202	5	203	17.5552	1.5055	355	11.66	<.0001	0.1	15.0724	20.0381
EGSTMNUM*LEG_SORT	2	202	6	201	11.4217	1.5073	354	7.58	<.0001	0.1	8.9360	13.9074
EGSTMNUM*LEG_SORT	2	202	6	202	8.3333	1.2113	1176	6.88	<.0001	0.1	6.3393	10.3273
EGSTMNUM*LEG_SORT	2	202	6	203	18.8268	1.5055	355	12.50	<.0001	0.1	16.3439	21.3096
EGSTMNUM*LEG_SORT	2	202	8	201	11.9492	1.5073	354	7.93	<.0001	0.1	9.4634	14.4349
EGSTMNUM*LEG_SORT	2	202	8	202	9.3209	1.2113	1176	7.70	<.0001	0.1	7.3270	11.3149
EGSTMNUM*LEG_SORT	2	202	8	203	18.3245	1.5055	355	12.17	<.0001	0.1	15.8416	20.8073
EGSTMNUM*LEG_SORT	2	202	12	201	9.4250	1.5073	354	6.25	<.0001	0.1	6.9393	11.9107
EGSTMNUM*LEG_SORT	2	202	12	202	8.6674	1.2113	1176	7.16	<.0001	0.1	6.6734	10.6613
EGSTMNUM*LEG_SORT	2	202	12	203	16.1026	1.5055	355	10.70	<.0001	0.1	13.6197	18.5854
EGSTMNUM*LEG_SORT	2	202	24	201	6.1553	1.5039	356	4.09	<.0001	0.1	3.6751	8.6355
EGSTMNUM*LEG_SORT	2	202	24	202	6.7110	1.2113	1176	5.54	<.0001	0.1	4.7171	8.7050
EGSTMNUM*LEG_SORT	2	202	24	203	13.9191	1.5055	355	9.25	<.0001	0.1	11.4362	16.4019

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	203	3	201	-8.7658	1.5033	354	-5.83	<.0001	0.1	-11.2449	-6.2866
EGSTMNUM*LEG_SORT	2	203	3	202	-13.0641	1.5055	355	-8.68	<.0001	0.1	-15.5470	-10.5812
EGSTMNUM*LEG_SORT	2	203	3	203	-0.4955	1.2113	1176	-0.41	0.6826	0.1	-2.4894	1.4985
EGSTMNUM*LEG_SORT	2	203	4	201	-10.8949	1.5033	354	-7.25	<.0001	0.1	-13.3741	-8.4158
EGSTMNUM*LEG_SORT	2	203	4	202	-14.4005	1.5055	355	-9.56	<.0001	0.1	-16.8834	-11.9176
EGSTMNUM*LEG_SORT	2	203	4	203	-0.6989	1.2113	1176	-0.58	0.5640	0.1	-2.6929	1.2950
EGSTMNUM*LEG_SORT	2	203	5	201	-3.6244	1.5033	354	-2.41	0.0164	0.1	-6.1036	-1.1453
EGSTMNUM*LEG_SORT	2	203	5	202	-6.8145	1.5055	355	-4.53	<.0001	0.1	-9.2974	-4.3316
EGSTMNUM*LEG_SORT	2	203	5	203	4.9073	1.2113	1176	4.05	<.0001	0.1	2.9133	6.9012
EGSTMNUM*LEG_SORT	2	203	6	201	-1.2263	1.5033	354	-0.82	0.4152	0.1	-3.7054	1.2529
EGSTMNUM*LEG_SORT	2	203	6	202	-4.3147	1.5055	355	-2.87	0.0044	0.1	-6.7975	-1.8318
EGSTMNUM*LEG_SORT	2	203	6	203	6.1788	1.2113	1176	5.10	<.0001	0.1	4.1848	8.1728
EGSTMNUM*LEG_SORT	2	203	8	201	-0.6988	1.5033	354	-0.46	0.6423	0.1	-3.1779	1.7804
EGSTMNUM*LEG_SORT	2	203	8	202	-3.3270	1.5055	355	-2.21	0.0278	0.1	-5.8099	-0.8441
EGSTMNUM*LEG_SORT	2	203	8	203	5.6765	1.2113	1176	4.69	<.0001	0.1	3.6825	7.6705
EGSTMNUM*LEG_SORT	2	203	12	201	-3.2230	1.5033	354	-2.14	0.0327	0.1	-5.7021	-0.7438
EGSTMNUM*LEG_SORT	2	203	12	202	-3.9806	1.5055	355	-2.64	0.0086	0.1	-6.4635	-1.4977
EGSTMNUM*LEG_SORT	2	203	12	203	3.4546	1.2113	1176	2.85	0.0044	0.1	1.4606	5.4486
EGSTMNUM*LEG_SORT	2	203	24	201	-6.4927	1.5004	357	-4.33	<.0001	0.1	-8.9670	-4.0183
EGSTMNUM*LEG_SORT	2	203	24	202	-5.9369	1.5055	355	-3.94	<.0001	0.1	-8.4198	-3.4540
EGSTMNUM*LEG_SORT	2	203	24	203	1.2711	1.2113	1176	1.05	0.2942	0.1	-0.7229	3.2651
EGSTMNUM*LEG_SORT	3	201	3	202	-4.2983	1.5073	354	-2.85	0.0046	0.1	-6.7841	-1.8126
EGSTMNUM*LEG_SORT	3	201	3	203	8.2703	1.5033	354	5.50	<.0001	0.1	5.7911	10.7494
EGSTMNUM*LEG_SORT	3	201	4	201	-2.1291	1.2113	1176	-1.76	0.0790	0.1	-4.1231	-0.1352
EGSTMNUM*LEG_SORT	3	201	4	202	-5.6347	1.5073	354	-3.74	0.0002	0.1	-8.1204	-3.1490
EGSTMNUM*LEG_SORT	3	201	4	203	8.0668	1.5033	354	5.37	<.0001	0.1	5.5877	10.5460
EGSTMNUM*LEG_SORT	3	201	5	201	5.1414	1.2113	1176	4.24	<.0001	0.1	3.1474	7.1353
EGSTMNUM*LEG_SORT	3	201	5	202	1.9513	1.5073	354	1.29	0.1963	0.1	-0.5344	4.4371
EGSTMNUM*LEG_SORT	3	201	5	203	13.6731	1.5033	354	9.10	<.0001	0.1	11.1939	16.1522
EGSTMNUM*LEG_SORT	3	201	6	201	7.5395	1.2113	1176	6.22	<.0001	0.1	5.5456	9.5335
EGSTMNUM*LEG_SORT	3	201	6	202	4.4511	1.5073	354	2.95	0.0034	0.1	1.9654	6.9369
EGSTMNUM*LEG_SORT	3	201	6	203	14.9446	1.5033	354	9.94	<.0001	0.1	12.4654	17.4237
EGSTMNUM*LEG_SORT	3	201	8	201	8.0670	1.2113	1176	6.66	<.0001	0.1	6.0730	10.0610
EGSTMNUM*LEG_SORT	3	201	8	202	5.4388	1.5073	354	3.61	0.0004	0.1	2.9530	7.9245
EGSTMNUM*LEG_SORT	3	201	8	203	14.4423	1.5033	354	9.61	<.0001	0.1	11.9631	16.9214

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	12	201	5.5428	1.2113	1176	4.58	<.0001	0.1	3.5489	7.5368
EGSTMNUM*LEG_SORT	3	201	12	202	4.7852	1.5073	354	3.17	0.0016	0.1	2.2995	7.2709
EGSTMNUM*LEG_SORT	3	201	12	203	12.2204	1.5033	354	8.13	<.0001	0.1	9.7412	14.6995
EGSTMNUM*LEG_SORT	3	201	24	201	2.2731	1.2095	1181	1.88	0.0604	0.1	0.2822	4.2641
EGSTMNUM*LEG_SORT	3	201	24	202	2.8289	1.5073	354	1.88	0.0614	0.1	0.3431	5.3146
EGSTMNUM*LEG_SORT	3	201	24	203	10.0369	1.5033	354	6.68	<.0001	0.1	7.5577	12.5160
EGSTMNUM*LEG_SORT	3	202	3	203	12.5686	1.5055	355	8.35	<.0001	0.1	10.0857	15.0515
EGSTMNUM*LEG_SORT	3	202	4	201	2.1692	1.5073	354	1.44	0.1510	0.1	-0.3166	4.6549
EGSTMNUM*LEG_SORT	3	202	4	202	-1.3364	1.2113	1176	-1.10	0.2701	0.1	-3.3303	0.6576
EGSTMNUM*LEG_SORT	3	202	4	203	12.3652	1.5055	355	8.21	<.0001	0.1	9.8823	14.8481
EGSTMNUM*LEG_SORT	3	202	5	201	9.4397	1.5073	354	6.26	<.0001	0.1	6.9540	11.9254
EGSTMNUM*LEG_SORT	3	202	5	202	6.2497	1.2113	1176	5.16	<.0001	0.1	4.2557	8.2436
EGSTMNUM*LEG_SORT	3	202	5	203	17.9714	1.5055	355	11.94	<.0001	0.1	15.4885	20.4543
EGSTMNUM*LEG_SORT	3	202	6	201	11.8379	1.5073	354	7.85	<.0001	0.1	9.3521	14.3236
EGSTMNUM*LEG_SORT	3	202	6	202	8.7495	1.2113	1176	7.22	<.0001	0.1	6.7555	10.7434
EGSTMNUM*LEG_SORT	3	202	6	203	19.2429	1.5055	355	12.78	<.0001	0.1	16.7600	21.7258
EGSTMNUM*LEG_SORT	3	202	8	201	12.3653	1.5073	354	8.20	<.0001	0.1	9.8796	14.8511
EGSTMNUM*LEG_SORT	3	202	8	202	9.7371	1.2113	1176	8.04	<.0001	0.1	7.7431	11.7311
EGSTMNUM*LEG_SORT	3	202	8	203	18.7406	1.5055	355	12.45	<.0001	0.1	16.2577	21.2235
EGSTMNUM*LEG_SORT	3	202	12	201	9.8412	1.5073	354	6.53	<.0001	0.1	7.3554	12.3269
EGSTMNUM*LEG_SORT	3	202	12	202	9.0835	1.2113	1176	7.50	<.0001	0.1	7.0896	11.0775
EGSTMNUM*LEG_SORT	3	202	12	203	16.5187	1.5055	355	10.97	<.0001	0.1	14.0358	19.0016
EGSTMNUM*LEG_SORT	3	202	24	201	6.5715	1.5039	356	4.37	<.0001	0.1	4.0912	9.0517
EGSTMNUM*LEG_SORT	3	202	24	202	7.1272	1.2113	1176	5.88	<.0001	0.1	5.1332	9.1212
EGSTMNUM*LEG_SORT	3	202	24	203	14.3352	1.5055	355	9.52	<.0001	0.1	11.8523	16.8181
EGSTMNUM*LEG_SORT	3	203	4	201	-10.3994	1.5033	354	-6.92	<.0001	0.1	-12.8786	-7.9203
EGSTMNUM*LEG_SORT	3	203	4	202	-13.9050	1.5055	355	-9.24	<.0001	0.1	-16.3879	-11.4221
EGSTMNUM*LEG_SORT	3	203	4	203	-0.2034	1.2113	1176	-0.17	0.8666	0.1	-2.1974	1.7905
EGSTMNUM*LEG_SORT	3	203	5	201	-3.1289	1.5033	354	-2.08	0.0381	0.1	-5.6081	-0.6498
EGSTMNUM*LEG_SORT	3	203	5	202	-6.3190	1.5055	355	-4.20	<.0001	0.1	-8.8019	-3.8361
EGSTMNUM*LEG_SORT	3	203	5	203	5.4028	1.2113	1176	4.46	<.0001	0.1	3.4088	7.3967
EGSTMNUM*LEG_SORT	3	203	6	201	-0.7308	1.5033	354	-0.49	0.6272	0.1	-3.2099	1.7484
EGSTMNUM*LEG_SORT	3	203	6	202	-3.8192	1.5055	355	-2.54	0.0116	0.1	-6.3021	-1.3363
EGSTMNUM*LEG_SORT	3	203	6	203	6.6743	1.2113	1176	5.51	<.0001	0.1	4.6803	8.6682
EGSTMNUM*LEG_SORT	3	203	8	201	-0.2033	1.5033	354	-0.14	0.8925	0.1	-2.6824	2.2759

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	8	202	-2.8315	1.5055	355	-1.88	0.0608	0.1	-5.3144	-0.3486
EGSTMNUM*LEG_SORT	3	203	8	203	6.1720	1.2113	1176	5.10	<.0001	0.1	4.1780	8.1659
EGSTMNUM*LEG_SORT	3	203	12	201	-2.7275	1.5033	354	-1.81	0.0705	0.1	-5.2066	-0.2483
EGSTMNUM*LEG_SORT	3	203	12	202	-3.4851	1.5055	355	-2.31	0.0212	0.1	-5.9680	-1.0022
EGSTMNUM*LEG_SORT	3	203	12	203	3.9501	1.2113	1176	3.26	0.0011	0.1	1.9561	5.9440
EGSTMNUM*LEG_SORT	3	203	24	201	-5.9972	1.5004	357	-4.00	<.0001	0.1	-8.4715	-3.5228
EGSTMNUM*LEG_SORT	3	203	24	202	-5.4414	1.5055	355	-3.61	0.0003	0.1	-7.9243	-2.9585
EGSTMNUM*LEG_SORT	3	203	24	203	1.7666	1.2113	1176	1.46	0.1450	0.1	-0.2274	3.7606
EGSTMNUM*LEG_SORT	4	201	4	202	-3.5055	1.5073	354	-2.33	0.0206	0.1	-5.9913	-1.0198
EGSTMNUM*LEG_SORT	4	201	4	203	10.1960	1.5033	354	6.78	<.0001	0.1	7.7168	12.6751
EGSTMNUM*LEG_SORT	4	201	5	201	7.2705	1.2113	1176	6.00	<.0001	0.1	5.2765	9.2645
EGSTMNUM*LEG_SORT	4	201	5	202	4.0805	1.5073	354	2.71	0.0071	0.1	1.5947	6.5662
EGSTMNUM*LEG_SORT	4	201	5	203	15.8022	1.5033	354	10.51	<.0001	0.1	13.3231	18.2814
EGSTMNUM*LEG_SORT	4	201	6	201	9.6687	1.2113	1176	7.98	<.0001	0.1	7.6747	11.6626
EGSTMNUM*LEG_SORT	4	201	6	202	6.5803	1.5073	354	4.37	<.0001	0.1	4.0945	9.0660
EGSTMNUM*LEG_SORT	4	201	6	203	17.0737	1.5033	354	11.36	<.0001	0.1	14.5946	19.5529
EGSTMNUM*LEG_SORT	4	201	8	201	10.1961	1.2113	1176	8.42	<.0001	0.1	8.2022	12.1901
EGSTMNUM*LEG_SORT	4	201	8	202	7.5679	1.5073	354	5.02	<.0001	0.1	5.0822	10.0537
EGSTMNUM*LEG_SORT	4	201	8	203	16.5714	1.5033	354	11.02	<.0001	0.1	14.0923	19.0506
EGSTMNUM*LEG_SORT	4	201	12	201	7.6720	1.2113	1176	6.33	<.0001	0.1	5.6780	9.6659
EGSTMNUM*LEG_SORT	4	201	12	202	6.9143	1.5073	354	4.59	<.0001	0.1	4.4286	9.4001
EGSTMNUM*LEG_SORT	4	201	12	203	14.3495	1.5033	354	9.55	<.0001	0.1	11.8704	16.8287
EGSTMNUM*LEG_SORT	4	201	24	201	4.4023	1.2095	1181	3.64	0.0003	0.1	2.4113	6.3932
EGSTMNUM*LEG_SORT	4	201	24	202	4.9580	1.5073	354	3.29	0.0011	0.1	2.4723	7.4438
EGSTMNUM*LEG_SORT	4	201	24	203	12.1660	1.5033	354	8.09	<.0001	0.1	9.6869	14.6452
EGSTMNUM*LEG_SORT	4	202	4	203	13.7015	1.5055	355	9.10	<.0001	0.1	11.2187	16.1844
EGSTMNUM*LEG_SORT	4	202	5	201	10.7760	1.5073	354	7.15	<.0001	0.1	8.2903	13.2618
EGSTMNUM*LEG_SORT	4	202	5	202	7.5860	1.2113	1176	6.26	<.0001	0.1	5.5921	9.5800
EGSTMNUM*LEG_SORT	4	202	5	203	19.3078	1.5055	355	12.82	<.0001	0.1	16.8249	21.7906
EGSTMNUM*LEG_SORT	4	202	6	201	13.1742	1.5073	354	8.74	<.0001	0.1	10.6885	15.6599
EGSTMNUM*LEG_SORT	4	202	6	202	10.0858	1.2113	1176	8.33	<.0001	0.1	8.0919	12.0798
EGSTMNUM*LEG_SORT	4	202	6	203	20.5793	1.5055	355	13.67	<.0001	0.1	18.0964	23.0622
EGSTMNUM*LEG_SORT	4	202	8	201	13.7017	1.5073	354	9.09	<.0001	0.1	11.2159	16.1874
EGSTMNUM*LEG_SORT	4	202	8	202	11.0735	1.2113	1176	9.14	<.0001	0.1	9.0795	13.0674
EGSTMNUM*LEG_SORT	4	202	8	203	20.0770	1.5055	355	13.34	<.0001	0.1	17.5941	22.5599

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	12	201	11.1775	1.5073	354	7.42	<.0001	0.1	8.6918	13.6633
EGSTMNUM*LEG_SORT	4	202	12	202	10.4199	1.2113	1176	8.60	<.0001	0.1	8.4259	12.4138
EGSTMNUM*LEG_SORT	4	202	12	203	17.8551	1.5055	355	11.86	<.0001	0.1	15.3722	20.3380
EGSTMNUM*LEG_SORT	4	202	24	201	7.9078	1.5039	356	5.26	<.0001	0.1	5.4276	10.3880
EGSTMNUM*LEG_SORT	4	202	24	202	8.4636	1.2113	1176	6.99	<.0001	0.1	6.4696	10.4575
EGSTMNUM*LEG_SORT	4	202	24	203	15.6716	1.5055	355	10.41	<.0001	0.1	13.1887	18.1545
EGSTMNUM*LEG_SORT	4	203	5	201	-2.9255	1.5033	354	-1.95	0.0524	0.1	-5.4046	-0.4463
EGSTMNUM*LEG_SORT	4	203	5	202	-6.1155	1.5055	355	-4.06	<.0001	0.1	-8.5984	-3.6326
EGSTMNUM*LEG_SORT	4	203	5	203	5.6062	1.2113	1176	4.63	<.0001	0.1	3.6123	7.6002
EGSTMNUM*LEG_SORT	4	203	6	201	-0.5273	1.5033	354	-0.35	0.7260	0.1	-3.0065	1.9518
EGSTMNUM*LEG_SORT	4	203	6	202	-3.6157	1.5055	355	-2.40	0.0168	0.1	-6.0986	-1.1328
EGSTMNUM*LEG_SORT	4	203	6	203	6.8777	1.2113	1176	5.68	<.0001	0.1	4.8838	8.8717
EGSTMNUM*LEG_SORT	4	203	8	201	0.000148	1.5033	354	0.00	0.9999	0.1	-2.4790	2.4793
EGSTMNUM*LEG_SORT	4	203	8	202	-2.6281	1.5055	355	-1.75	0.0817	0.1	-5.1110	-0.1452
EGSTMNUM*LEG_SORT	4	203	8	203	6.3754	1.2113	1176	5.26	<.0001	0.1	4.3815	8.3694
EGSTMNUM*LEG_SORT	4	203	12	201	-2.5240	1.5033	354	-1.68	0.0940	0.1	-5.0032	-0.0486
EGSTMNUM*LEG_SORT	4	203	12	202	-3.2816	1.5055	355	-2.18	0.0299	0.1	-5.7645	-0.7988
EGSTMNUM*LEG_SORT	4	203	12	203	4.1535	1.2113	1176	3.43	0.0006	0.1	2.1596	6.1475
EGSTMNUM*LEG_SORT	4	203	24	201	-5.7937	1.5004	357	-3.86	0.0001	0.1	-8.2680	-3.3194
EGSTMNUM*LEG_SORT	4	203	24	202	-5.2380	1.5055	355	-3.48	0.0006	0.1	-7.7209	-2.7551
EGSTMNUM*LEG_SORT	4	203	24	203	1.9700	1.2113	1176	1.63	0.1041	0.1	-0.02392	3.9640
EGSTMNUM*LEG_SORT	5	201	5	202	-3.1900	1.5073	354	-2.12	0.0350	0.1	-5.6758	-0.7043
EGSTMNUM*LEG_SORT	5	201	5	203	8.5317	1.5033	354	5.68	<.0001	0.1	6.0526	11.0109
EGSTMNUM*LEG_SORT	5	201	6	201	2.3982	1.2113	1176	1.98	0.0480	0.1	0.4042	4.3921
EGSTMNUM*LEG_SORT	5	201	6	202	-0.6902	1.5073	354	-0.46	0.6473	0.1	-3.1760	1.7955
EGSTMNUM*LEG_SORT	5	201	6	203	9.8032	1.5033	354	6.52	<.0001	0.1	7.3241	12.2824
EGSTMNUM*LEG_SORT	5	201	8	201	2.9256	1.2113	1176	2.42	0.0159	0.1	0.9317	4.9196
EGSTMNUM*LEG_SORT	5	201	8	202	0.2974	1.5073	354	0.20	0.8437	0.1	-2.1883	2.7832
EGSTMNUM*LEG_SORT	5	201	8	203	9.3009	1.5033	354	6.19	<.0001	0.1	6.8218	11.7801
EGSTMNUM*LEG_SORT	5	201	12	201	0.4015	1.2113	1176	0.33	0.7404	0.1	-1.5925	2.3954
EGSTMNUM*LEG_SORT	5	201	12	202	-0.3562	1.5073	354	-0.24	0.8133	0.1	-2.8419	2.1296
EGSTMNUM*LEG_SORT	5	201	12	203	7.0790	1.5033	354	4.71	<.0001	0.1	4.5999	9.5582
EGSTMNUM*LEG_SORT	5	201	24	201	-2.8682	1.2095	1181	-2.37	0.0179	0.1	-4.8592	-0.8773
EGSTMNUM*LEG_SORT	5	201	24	202	-2.3125	1.5073	354	-1.53	0.1259	0.1	-4.7982	0.1733
EGSTMNUM*LEG_SORT	5	201	24	203	4.8955	1.5033	354	3.26	0.0012	0.1	2.4164	7.3747

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	202	5	203	11.7217	1.5055	355	7.79	<.0001	0.1	9.2389	14.2046
EGSTMNUM*LEG_SORT	5	202	6	201	5.5882	1.5073	354	3.71	0.0002	0.1	3.1025	8.0739
EGSTMNUM*LEG_SORT	5	202	6	202	2.4998	1.2113	1176	2.06	0.0393	0.1	0.5059	4.4938
EGSTMNUM*LEG_SORT	5	202	6	203	12.9933	1.5055	355	8.63	<.0001	0.1	10.5104	15.4762
EGSTMNUM*LEG_SORT	5	202	8	201	6.1157	1.5073	354	4.06	<.0001	0.1	3.6299	8.6014
EGSTMNUM*LEG_SORT	5	202	8	202	3.4875	1.2113	1176	2.88	0.0041	0.1	1.4935	5.4814
EGSTMNUM*LEG_SORT	5	202	8	203	12.4910	1.5055	355	8.30	<.0001	0.1	10.0081	14.9739
EGSTMNUM*LEG_SORT	5	202	12	201	3.5915	1.5073	354	2.38	0.0177	0.1	1.1058	6.0773
EGSTMNUM*LEG_SORT	5	202	12	202	2.8339	1.2113	1176	2.34	0.0195	0.1	0.8399	4.8278
EGSTMNUM*LEG_SORT	5	202	12	203	10.2691	1.5055	355	6.82	<.0001	0.1	7.7862	12.7519
EGSTMNUM*LEG_SORT	5	202	24	201	0.3218	1.5039	356	0.21	0.8307	0.1	-2.1584	2.8020
EGSTMNUM*LEG_SORT	5	202	24	202	0.8776	1.2113	1176	0.72	0.4689	0.1	-1.1164	2.8715
EGSTMNUM*LEG_SORT	5	202	24	203	8.0856	1.5055	355	5.37	<.0001	0.1	5.6027	10.5685
EGSTMNUM*LEG_SORT	5	203	6	201	-6.1335	1.5033	354	-4.08	<.0001	0.1	-8.6127	-3.6544
EGSTMNUM*LEG_SORT	5	203	6	202	-9.2219	1.5055	355	-6.13	<.0001	0.1	-11.7048	-6.7391
EGSTMNUM*LEG_SORT	5	203	6	203	1.2715	1.2113	1176	1.05	0.2941	0.1	-0.7224	3.2655
EGSTMNUM*LEG_SORT	5	203	8	201	-5.6061	1.5033	354	-3.73	0.0002	0.1	-8.0852	-3.1269
EGSTMNUM*LEG_SORT	5	203	8	202	-8.2343	1.5055	355	-5.47	<.0001	0.1	-10.7172	-5.7514
EGSTMNUM*LEG_SORT	5	203	8	203	0.7692	1.2113	1176	0.64	0.5255	0.1	-1.2247	2.7632
EGSTMNUM*LEG_SORT	5	203	12	201	-8.1302	1.5033	354	-5.41	<.0001	0.1	-10.6094	-5.6511
EGSTMNUM*LEG_SORT	5	203	12	202	-8.8879	1.5055	355	-5.90	<.0001	0.1	-11.3707	-6.4050
EGSTMNUM*LEG_SORT	5	203	12	203	-1.4527	1.2113	1176	-1.20	0.2307	0.1	-3.4466	0.5413
EGSTMNUM*LEG_SORT	5	203	24	201	-11.3999	1.5004	357	-7.60	<.0001	0.1	-13.8743	-8.9256
EGSTMNUM*LEG_SORT	5	203	24	202	-10.8442	1.5055	355	-7.20	<.0001	0.1	-13.3271	-8.3613
EGSTMNUM*LEG_SORT	5	203	24	203	-3.6362	1.2113	1176	-3.00	0.0027	0.1	-5.6301	-1.6422
EGSTMNUM*LEG_SORT	6	201	6	202	-3.0884	1.5073	354	-2.05	0.0412	0.1	-5.5741	-0.6026
EGSTMNUM*LEG_SORT	6	201	6	203	7.4051	1.5033	354	4.93	<.0001	0.1	4.9259	9.8842
EGSTMNUM*LEG_SORT	6	201	8	201	0.5275	1.2113	1176	0.44	0.6633	0.1	-1.4665	2.5214
EGSTMNUM*LEG_SORT	6	201	8	202	-2.1007	1.5073	354	-1.39	0.1643	0.1	-4.5865	0.3850
EGSTMNUM*LEG_SORT	6	201	8	203	6.9028	1.5033	354	4.59	<.0001	0.1	4.4236	9.3819
EGSTMNUM*LEG_SORT	6	201	12	201	-1.9967	1.2113	1176	-1.65	0.0995	0.1	-3.9906	-0.00273
EGSTMNUM*LEG_SORT	6	201	12	202	-2.7543	1.5073	354	-1.83	0.0685	0.1	-5.2401	-0.2686
EGSTMNUM*LEG_SORT	6	201	12	203	4.6809	1.5033	354	3.11	0.0020	0.1	2.2017	7.1600
EGSTMNUM*LEG_SORT	6	201	24	201	-5.2664	1.2095	1181	-4.35	<.0001	0.1	-7.2574	-3.2754
EGSTMNUM*LEG_SORT	6	201	24	202	-4.7106	1.5073	354	-3.13	0.0019	0.1	-7.1964	-2.2249

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	6	201	24	203	2.4974	1.5033	354	1.66	0.0975	0.1	0.01822	4.9765
EGSTMNUM*LEG_SORT	6	202	6	203	10.4935	1.5055	355	6.97	<.0001	0.1	8.0106	12.9763
EGSTMNUM*LEG_SORT	6	202	8	201	3.6159	1.5073	354	2.40	0.0170	0.1	1.1301	6.1016
EGSTMNUM*LEG_SORT	6	202	8	202	0.9876	1.2113	1176	0.82	0.4150	0.1	-1.0063	2.9816
EGSTMNUM*LEG_SORT	6	202	8	203	9.9912	1.5055	355	6.64	<.0001	0.1	7.5083	12.4740
EGSTMNUM*LEG_SORT	6	202	12	201	1.0917	1.5073	354	0.72	0.4694	0.1	-1.3940	3.5774
EGSTMNUM*LEG_SORT	6	202	12	202	0.3341	1.2113	1176	0.28	0.7827	0.1	-1.6599	2.3280
EGSTMNUM*LEG_SORT	6	202	12	203	7.7693	1.5055	355	5.16	<.0001	0.1	5.2864	10.2521
EGSTMNUM*LEG_SORT	6	202	24	201	-2.1780	1.5039	356	-1.45	0.1484	0.1	-4.6582	0.3022
EGSTMNUM*LEG_SORT	6	202	24	202	-1.6223	1.2113	1176	-1.34	0.1807	0.1	-3.6162	0.3717
EGSTMNUM*LEG_SORT	6	202	24	203	5.5858	1.5055	355	3.71	0.0002	0.1	3.1029	8.0686
EGSTMNUM*LEG_SORT	6	203	8	201	-6.8776	1.5033	354	-4.58	<.0001	0.1	-9.3567	-4.3984
EGSTMNUM*LEG_SORT	6	203	8	202	-9.5058	1.5055	355	-6.31	<.0001	0.1	-11.9887	-7.0229
EGSTMNUM*LEG_SORT	6	203	8	203	-0.5023	1.2113	1176	-0.41	0.6784	0.1	-2.4963	1.4917
EGSTMNUM*LEG_SORT	6	203	12	201	-9.4018	1.5033	354	-6.25	<.0001	0.1	-11.8809	-6.9226
EGSTMNUM*LEG_SORT	6	203	12	202	-10.1594	1.5055	355	-6.75	<.0001	0.1	-12.6423	-7.6765
EGSTMNUM*LEG_SORT	6	203	12	203	-2.7242	1.2113	1176	-2.25	0.0247	0.1	-4.7182	-0.7302
EGSTMNUM*LEG_SORT	6	203	24	201	-12.6715	1.5004	357	-8.45	<.0001	0.1	-15.1458	-10.1971
EGSTMNUM*LEG_SORT	6	203	24	202	-12.1157	1.5055	355	-8.05	<.0001	0.1	-14.5986	-9.6328
EGSTMNUM*LEG_SORT	6	203	24	203	-4.9077	1.2113	1176	-4.05	<.0001	0.1	-6.9017	-2.9137
EGSTMNUM*LEG_SORT	8	201	8	202	-2.6282	1.5073	354	-1.74	0.0821	0.1	-5.1140	-0.1425
EGSTMNUM*LEG_SORT	8	201	8	203	6.3753	1.5033	354	4.24	<.0001	0.1	3.8961	8.8544
EGSTMNUM*LEG_SORT	8	201	12	201	-2.5242	1.2113	1176	-2.08	0.0374	0.1	-4.5181	-0.5302
EGSTMNUM*LEG_SORT	8	201	12	202	-3.2818	1.5073	354	-2.18	0.0301	0.1	-5.7675	-0.7961
EGSTMNUM*LEG_SORT	8	201	12	203	4.1534	1.5033	354	2.76	0.0060	0.1	1.6742	6.6325
EGSTMNUM*LEG_SORT	8	201	24	201	-5.7939	1.2095	1181	-4.79	<.0001	0.1	-7.7848	-3.8029
EGSTMNUM*LEG_SORT	8	201	24	202	-5.2381	1.5073	354	-3.48	0.0006	0.1	-7.7239	-2.7524
EGSTMNUM*LEG_SORT	8	201	24	203	1.9699	1.5033	354	1.31	0.1909	0.1	-0.5093	4.4490
EGSTMNUM*LEG_SORT	8	202	8	203	9.0035	1.5055	355	5.98	<.0001	0.1	6.5206	11.4864
EGSTMNUM*LEG_SORT	8	202	12	201	0.1041	1.5073	354	0.07	0.9450	0.1	-2.3817	2.5898
EGSTMNUM*LEG_SORT	8	202	12	202	-0.6536	1.2113	1176	-0.54	0.5896	0.1	-2.6475	1.3404
EGSTMNUM*LEG_SORT	8	202	12	203	6.7816	1.5055	355	4.50	<.0001	0.1	4.2987	9.2645
EGSTMNUM*LEG_SORT	8	202	24	201	-3.1656	1.5039	356	-2.10	0.0360	0.1	-5.6459	-0.6854
EGSTMNUM*LEG_SORT	8	202	24	202	-2.6099	1.2113	1176	-2.15	0.0314	0.1	-4.6039	-0.6159
EGSTMNUM*LEG_SORT	8	202	24	203	4.5981	1.5055	355	3.05	0.0024	0.1	2.1152	7.0810

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

The Mixed Procedure

Differences of Least Squares Means												
Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	203	12	201	-8.8995	1.5033	354	-5.92	<.0001	0.1	-11.3786	-6.4203
EGSTMNUM*LEG_SORT	8	203	12	202	-9.6571	1.5055	355	-6.41	<.0001	0.1	-12.1400	-7.1742
EGSTMNUM*LEG_SORT	8	203	12	203	-2.2219	1.2113	1176	-1.83	0.0669	0.1	-4.2159	-0.2279
EGSTMNUM*LEG_SORT	8	203	24	201	-12.1692	1.5004	357	-8.11	<.0001	0.1	-14.6435	-9.6948
EGSTMNUM*LEG_SORT	8	203	24	202	-11.6134	1.5055	355	-7.71	<.0001	0.1	-14.0963	-9.1305
EGSTMNUM*LEG_SORT	8	203	24	203	-4.4054	1.2113	1176	-3.64	0.0003	0.1	-6.3994	-2.4114
EGSTMNUM*LEG_SORT	12	201	12	202	-0.7576	1.5073	354	-0.50	0.6155	0.1	-3.2434	1.7281
EGSTMNUM*LEG_SORT	12	201	12	203	6.6775	1.5033	354	4.44	<.0001	0.1	4.1984	9.1567
EGSTMNUM*LEG_SORT	12	201	24	201	-3.2697	1.2095	1181	-2.70	0.0070	0.1	-5.2607	-1.2787
EGSTMNUM*LEG_SORT	12	201	24	202	-2.7140	1.5073	354	-1.80	0.0726	0.1	-5.1997	-0.2282
EGSTMNUM*LEG_SORT	12	201	24	203	4.4941	1.5033	354	2.99	0.0030	0.1	2.0149	6.9732
EGSTMNUM*LEG_SORT	12	202	12	203	7.4352	1.5055	355	4.94	<.0001	0.1	4.9523	9.9181
EGSTMNUM*LEG_SORT	12	202	24	201	-2.5121	1.5039	356	-1.67	0.0957	0.1	-4.9923	-0.03184
EGSTMNUM*LEG_SORT	12	202	24	202	-1.9563	1.2113	1176	-1.62	0.1066	0.1	-3.9503	0.03763
EGSTMNUM*LEG_SORT	12	202	24	203	5.2517	1.5055	355	3.49	0.0005	0.1	2.7688	7.7346
EGSTMNUM*LEG_SORT	12	203	24	201	-9.9473	1.5004	357	-6.63	<.0001	0.1	-12.4216	-7.4729
EGSTMNUM*LEG_SORT	12	203	24	202	-9.3915	1.5055	355	-6.24	<.0001	0.1	-11.8744	-6.9086
EGSTMNUM*LEG_SORT	12	203	24	203	-2.1835	1.2113	1176	-1.80	0.0717	0.1	-4.1774	-0.1895
EGSTMNUM*LEG_SORT	24	201	24	202	0.5557	1.5039	356	0.37	0.7120	0.1	-1.9245	3.0360
EGSTMNUM*LEG_SORT	24	201	24	203	7.7638	1.5004	357	5.17	<.0001	0.1	5.2894	10.2381
EGSTMNUM*LEG_SORT	24	202	24	203	7.2080	1.5055	355	4.79	<.0001	0.1	4.7251	9.6909

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:59)

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drggroup period egstmmum leg_sort;
model QTcI = drggroup period leg_sort egbase_QTcI egstmmum egstmmum*leg_sort/ddfm=kr;
random subjid(drggroup);
repeated / subject = period*subjid(drggroup) type=cs;
lsmeans egstmmum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (00:58)

SERTRALINE Protocol A0501104

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Model Information

```
Data Set                WORK.ECG3
Dependent Variable      QTcI
Covariance Structures  Variance Components,
                        Compound Symmetry
Subject Effect          SUBJI*PERIOD(DRGGRO)
Estimation Method       REML
Residual Variance Method Profile
Fixed Effects SE Method Kenward-Roger
Degrees of Freedom Method Kenward-Roger
```

Class Level Information

Class	Levels	Values		
SUBJID	46	10011001 10011002 10011003		
		10011004 10011005 10011006		
		10011008 10011009 10011010		
		10011011 10011012 10011013		
		10011014 10011015 10011016		
		10011017 10011018 10011019		
		10011020 10011021 10011023		
		10011024 10011025 10011026		
		10011027 10011028 10011029		
		10011031 10011032 10011033		
		10011034 10011035 10011037		
		10011038 10011039 10011040		
		10011041 10011042 10011043		
		10011046 10011047 10011049		
		10011051 10011052 10011053		
		10011054		
		DRGGROUP	6	ABC ACB BAC BCA CAB CBA
		PERIOD	3	Period 1 Period 2 Period 3
		EGSTMNUM	9	1 2 3 4 5 6 8 12 24
		LEG_SORT	3	201 202 203

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1      Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (00:58)

Supporting SAS Output for Statistical Summary (1) of QTcI between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	46
Subjects	1
Max Obs Per Subject	1242

Number of Observations

Number of Observations Read	1242
Number of Observations Used	1242
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	9019.87842298	
1	2	8238.94050052	0.00010797
2	1	8238.58867126	0.00000214
3	1	8238.58213623	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		54.8988
CS	SUBJI*PERIOD(DRGGRO)	16.5892
Residual		37.4048

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	8238.6
AIC (smaller is better)	8244.6
AICC (smaller is better)	8244.6
BIC (smaller is better)	8250.1

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	23.4	0.44	0.8171
PERIOD	2	68.6	0.78	0.4616
LEG_SORT	2	68.1	74.56	<.0001
EGBASE_QTCI	1	56.2	114.28	<.0001
EGSTMNUM	8	1080	45.38	<.0001
EGSTMNUM*LEG_SORT	16	1080	2.68	0.0004

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	415.37	1.5404	76.4	269.65	<.0001	0.1	412.81	417.93
EGSTMNUM*LEG_SORT	1	202	420.90	1.5414	76.4	273.06	<.0001	0.1	418.33	423.46
EGSTMNUM*LEG_SORT	1	203	407.63	1.5420	76.4	264.36	<.0001	0.1	405.07	410.20
EGSTMNUM*LEG_SORT	2	201	417.12	1.5404	76.4	270.79	<.0001	0.1	414.56	419.69
EGSTMNUM*LEG_SORT	2	202	421.81	1.5414	76.4	273.65	<.0001	0.1	419.25	424.38
EGSTMNUM*LEG_SORT	2	203	408.40	1.5420	76.4	264.86	<.0001	0.1	405.83	410.97
EGSTMNUM*LEG_SORT	3	201	417.07	1.5404	76.4	270.75	<.0001	0.1	414.50	419.63
EGSTMNUM*LEG_SORT	3	202	422.42	1.5414	76.4	274.05	<.0001	0.1	419.86	424.99
EGSTMNUM*LEG_SORT	3	203	409.13	1.5420	76.4	265.33	<.0001	0.1	406.57	411.70
EGSTMNUM*LEG_SORT	4	201	419.76	1.5404	76.4	272.50	<.0001	0.1	417.20	422.33
EGSTMNUM*LEG_SORT	4	202	423.44	1.5414	76.4	274.71	<.0001	0.1	420.87	426.01
EGSTMNUM*LEG_SORT	4	203	409.32	1.5420	76.4	265.45	<.0001	0.1	406.75	411.88
EGSTMNUM*LEG_SORT	5	201	412.34	1.5404	76.4	267.69	<.0001	0.1	409.78	414.90

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	202	415.89	1.5414	76.4	269.81	<.0001	0.1	413.32	418.46
EGSTMNUM*LEG_SORT	5	203	403.48	1.5420	76.4	261.67	<.0001	0.1	400.92	406.05
EGSTMNUM*LEG_SORT	6	201	410.04	1.5404	76.4	266.19	<.0001	0.1	407.48	412.61
EGSTMNUM*LEG_SORT	6	202	413.07	1.5414	76.4	267.98	<.0001	0.1	410.50	415.63
EGSTMNUM*LEG_SORT	6	203	402.04	1.5420	76.4	260.74	<.0001	0.1	399.48	404.61
EGSTMNUM*LEG_SORT	8	201	409.71	1.5404	76.4	265.98	<.0001	0.1	407.15	412.28
EGSTMNUM*LEG_SORT	8	202	412.51	1.5414	76.4	267.61	<.0001	0.1	409.94	415.07
EGSTMNUM*LEG_SORT	8	203	402.87	1.5420	76.4	261.27	<.0001	0.1	400.30	405.44
EGSTMNUM*LEG_SORT	12	201	412.25	1.5404	76.4	267.63	<.0001	0.1	409.68	414.81
EGSTMNUM*LEG_SORT	12	202	412.53	1.5414	76.4	267.63	<.0001	0.1	409.96	415.10
EGSTMNUM*LEG_SORT	12	203	404.98	1.5420	76.4	262.64	<.0001	0.1	402.42	407.55
EGSTMNUM*LEG_SORT	24	201	415.48	1.5404	76.4	269.72	<.0001	0.1	412.91	418.04
EGSTMNUM*LEG_SORT	24	202	414.36	1.5414	76.4	268.82	<.0001	0.1	411.79	416.93
EGSTMNUM*LEG_SORT	24	203	407.24	1.5420	76.4	264.10	<.0001	0.1	404.67	409.81

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-5.5285	1.5338	392	-3.60	0.0004	0.1	-8.0573	-2.9997
EGSTMNUM*LEG_SORT	1	201	1	203	7.7373	1.5335	392	5.05	<.0001	0.1	5.2090	10.2657
EGSTMNUM*LEG_SORT	1	201	2	201	-1.7509	1.2753	1080	-1.37	0.1700	0.1	-3.8503	0.3485
EGSTMNUM*LEG_SORT	1	201	2	202	-6.4416	1.5338	392	-4.20	<.0001	0.1	-8.9704	-3.9128
EGSTMNUM*LEG_SORT	1	201	2	203	6.9698	1.5335	392	4.55	<.0001	0.1	4.4414	9.4982
EGSTMNUM*LEG_SORT	1	201	3	201	-1.6965	1.2753	1080	-1.33	0.1837	0.1	-3.7959	0.4030
EGSTMNUM*LEG_SORT	1	201	3	202	-7.0528	1.5338	392	-4.60	<.0001	0.1	-9.5816	-4.5240
EGSTMNUM*LEG_SORT	1	201	3	203	6.2356	1.5335	392	4.07	<.0001	0.1	3.7073	8.7640
EGSTMNUM*LEG_SORT	1	201	4	201	-4.3925	1.2753	1080	-3.44	0.0006	0.1	-6.4920	-2.2931
EGSTMNUM*LEG_SORT	1	201	4	202	-8.0690	1.5338	392	-5.26	<.0001	0.1	-10.5978	-5.5402
EGSTMNUM*LEG_SORT	1	201	4	203	6.0527	1.5335	392	3.95	<.0001	0.1	3.5243	8.5810

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	5	201	3.0301	1.2753	1080	2.38	0.0177	0.1	0.9306	5.1295
EGSTMNUM*LEG_SORT	1	201	5	202	-0.5193	1.5338	392	-0.34	0.7351	0.1	-3.0481	2.0095
EGSTMNUM*LEG_SORT	1	201	5	203	11.8864	1.5335	392	7.75	<.0001	0.1	9.3580	14.4148
EGSTMNUM*LEG_SORT	1	201	6	201	5.3283	1.2753	1080	4.18	<.0001	0.1	3.2289	7.4277
EGSTMNUM*LEG_SORT	1	201	6	202	2.3045	1.5338	392	1.50	0.1338	0.1	-0.2243	4.8333
EGSTMNUM*LEG_SORT	1	201	6	203	13.3255	1.5335	392	8.69	<.0001	0.1	10.7971	15.8539
EGSTMNUM*LEG_SORT	1	201	8	201	5.6582	1.2753	1080	4.44	<.0001	0.1	3.5588	7.7576
EGSTMNUM*LEG_SORT	1	201	8	202	2.8649	1.5338	392	1.87	0.0625	0.1	0.3361	5.3937
EGSTMNUM*LEG_SORT	1	201	8	203	12.4994	1.5335	392	8.15	<.0001	0.1	9.9710	15.0278
EGSTMNUM*LEG_SORT	1	201	12	201	3.1213	1.2753	1080	2.45	0.0145	0.1	1.0219	5.2207
EGSTMNUM*LEG_SORT	1	201	12	202	2.8387	1.5338	392	1.85	0.0649	0.1	0.3099	5.3675
EGSTMNUM*LEG_SORT	1	201	12	203	10.3856	1.5335	392	6.77	<.0001	0.1	7.8572	12.9140
EGSTMNUM*LEG_SORT	1	201	24	201	-0.1096	1.2753	1080	-0.09	0.9316	0.1	-2.2090	1.9899
EGSTMNUM*LEG_SORT	1	201	24	202	1.0089	1.5338	392	0.66	0.5110	0.1	-1.5199	3.5377
EGSTMNUM*LEG_SORT	1	201	24	203	8.1307	1.5335	392	5.30	<.0001	0.1	5.6023	10.6591
EGSTMNUM*LEG_SORT	1	202	1	203	13.2658	1.5376	396	8.63	<.0001	0.1	10.7308	15.8009
EGSTMNUM*LEG_SORT	1	202	2	201	3.7776	1.5338	392	2.46	0.0142	0.1	1.2488	6.3064
EGSTMNUM*LEG_SORT	1	202	2	202	-0.9132	1.2753	1080	-0.72	0.4741	0.1	-3.0126	1.1863
EGSTMNUM*LEG_SORT	1	202	2	203	12.4983	1.5376	396	8.13	<.0001	0.1	9.9632	15.0334
EGSTMNUM*LEG_SORT	1	202	3	201	3.8320	1.5338	392	2.50	0.0129	0.1	1.3032	6.3608
EGSTMNUM*LEG_SORT	1	202	3	202	-1.5243	1.2753	1080	-1.20	0.2322	0.1	-3.6237	0.5751
EGSTMNUM*LEG_SORT	1	202	3	203	11.7641	1.5376	396	7.65	<.0001	0.1	9.2291	14.2992
EGSTMNUM*LEG_SORT	1	202	4	201	1.1359	1.5338	392	0.74	0.4594	0.1	-1.3929	3.6647
EGSTMNUM*LEG_SORT	1	202	4	202	-2.5405	1.2753	1080	-1.99	0.0466	0.1	-4.6399	-0.4411
EGSTMNUM*LEG_SORT	1	202	4	203	11.5811	1.5376	396	7.53	<.0001	0.1	9.0461	14.1162
EGSTMNUM*LEG_SORT	1	202	5	201	8.5585	1.5338	392	5.58	<.0001	0.1	6.0297	11.0873
EGSTMNUM*LEG_SORT	1	202	5	202	5.0092	1.2753	1080	3.93	<.0001	0.1	2.9097	7.1086
EGSTMNUM*LEG_SORT	1	202	5	203	17.4149	1.5376	396	11.33	<.0001	0.1	14.8798	19.9499
EGSTMNUM*LEG_SORT	1	202	6	201	10.8568	1.5338	392	7.08	<.0001	0.1	8.3280	13.3856
EGSTMNUM*LEG_SORT	1	202	6	202	7.8330	1.2753	1080	6.14	<.0001	0.1	5.7336	9.9324
EGSTMNUM*LEG_SORT	1	202	6	203	18.8540	1.5376	396	12.26	<.0001	0.1	16.3189	21.3891
EGSTMNUM*LEG_SORT	1	202	8	201	11.1867	1.5338	392	7.29	<.0001	0.1	8.6579	13.7155
EGSTMNUM*LEG_SORT	1	202	8	202	8.3934	1.2753	1080	6.58	<.0001	0.1	6.2940	10.4928
EGSTMNUM*LEG_SORT	1	202	8	203	18.0279	1.5376	396	11.72	<.0001	0.1	15.4928	20.5629

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	12	201	8.6498	1.5338	392	5.64	<.0001	0.1	6.1210	11.1786
EGSTMNUM*LEG_SORT	1	202	12	202	8.3672	1.2753	1080	6.56	<.0001	0.1	6.2678	10.4666
EGSTMNUM*LEG_SORT	1	202	12	203	15.9141	1.5376	396	10.35	<.0001	0.1	13.3790	18.4491
EGSTMNUM*LEG_SORT	1	202	24	201	5.4189	1.5338	392	3.53	0.0005	0.1	2.8901	7.9477
EGSTMNUM*LEG_SORT	1	202	24	202	6.5374	1.2753	1080	5.13	<.0001	0.1	4.4380	8.6368
EGSTMNUM*LEG_SORT	1	202	24	203	13.6592	1.5376	396	8.88	<.0001	0.1	11.1241	16.1942
EGSTMNUM*LEG_SORT	1	203	2	201	-9.4883	1.5335	392	-6.19	<.0001	0.1	-12.0167	-6.9599
EGSTMNUM*LEG_SORT	1	203	2	202	-14.1790	1.5376	396	-9.22	<.0001	0.1	-16.7140	-11.6439
EGSTMNUM*LEG_SORT	1	203	2	203	-0.7675	1.2753	1080	-0.60	0.5474	0.1	-2.8669	1.3319
EGSTMNUM*LEG_SORT	1	203	3	201	-9.4338	1.5335	392	-6.15	<.0001	0.1	-11.9622	-6.9054
EGSTMNUM*LEG_SORT	1	203	3	202	-14.7901	1.5376	396	-9.62	<.0001	0.1	-17.3252	-12.2551
EGSTMNUM*LEG_SORT	1	203	3	203	-1.5017	1.2753	1080	-1.18	0.2392	0.1	-3.6011	0.5977
EGSTMNUM*LEG_SORT	1	203	4	201	-12.1299	1.5335	392	-7.91	<.0001	0.1	-14.6583	-9.6015
EGSTMNUM*LEG_SORT	1	203	4	202	-15.8063	1.5376	396	-10.28	<.0001	0.1	-18.3414	-13.2713
EGSTMNUM*LEG_SORT	1	203	4	203	-1.6847	1.2753	1080	-1.32	0.1868	0.1	-3.7841	0.4147
EGSTMNUM*LEG_SORT	1	203	5	201	-4.7073	1.5335	392	-3.07	0.0023	0.1	-7.2357	-2.1789
EGSTMNUM*LEG_SORT	1	203	5	202	-8.2567	1.5376	396	-5.37	<.0001	0.1	-10.7917	-5.7216
EGSTMNUM*LEG_SORT	1	203	5	203	4.1491	1.2753	1080	3.25	0.0012	0.1	2.0496	6.2485
EGSTMNUM*LEG_SORT	1	203	6	201	-2.4090	1.5335	392	-1.57	0.1170	0.1	-4.9374	0.1193
EGSTMNUM*LEG_SORT	1	203	6	202	-5.4328	1.5376	396	-3.53	0.0005	0.1	-7.9679	-2.8978
EGSTMNUM*LEG_SORT	1	203	6	203	5.5882	1.2753	1080	4.38	<.0001	0.1	3.4887	7.6876
EGSTMNUM*LEG_SORT	1	203	8	201	-2.0791	1.5335	392	-1.36	0.1759	0.1	-4.6075	0.4493
EGSTMNUM*LEG_SORT	1	203	8	202	-4.8724	1.5376	396	-3.17	0.0016	0.1	-7.4075	-2.3374
EGSTMNUM*LEG_SORT	1	203	8	203	4.7620	1.2753	1080	3.73	0.0002	0.1	2.6626	6.8615
EGSTMNUM*LEG_SORT	1	203	12	201	-4.6161	1.5335	392	-3.01	0.0028	0.1	-7.1445	-2.0877
EGSTMNUM*LEG_SORT	1	203	12	202	-4.8986	1.5376	396	-3.19	0.0016	0.1	-7.4337	-2.3636
EGSTMNUM*LEG_SORT	1	203	12	203	2.6482	1.2753	1080	2.08	0.0381	0.1	0.5488	4.7477
EGSTMNUM*LEG_SORT	1	203	24	201	-7.8469	1.5335	392	-5.12	<.0001	0.1	-10.3753	-5.3185
EGSTMNUM*LEG_SORT	1	203	24	202	-6.7284	1.5376	396	-4.38	<.0001	0.1	-9.2635	-4.1933
EGSTMNUM*LEG_SORT	1	203	24	203	0.3933	1.2753	1080	0.31	0.7578	0.1	-1.7061	2.4927
EGSTMNUM*LEG_SORT	2	201	2	202	-4.6907	1.5338	392	-3.06	0.0024	0.1	-7.2195	-2.1619
EGSTMNUM*LEG_SORT	2	201	2	203	8.7207	1.5335	392	5.69	<.0001	0.1	6.1924	11.2491
EGSTMNUM*LEG_SORT	2	201	3	201	0.05446	1.2753	1080	0.04	0.9659	0.1	-2.0450	2.1539
EGSTMNUM*LEG_SORT	2	201	3	202	-5.3019	1.5338	392	-3.46	0.0006	0.1	-7.8307	-2.7731

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

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Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	3	203	7.9866	1.5335	392	5.21	<.0001	0.1	5.4582	10.5149
EGSTMNUM*LEG_SORT	2	201	4	201	-2.6416	1.2753	1080	-2.07	0.0386	0.1	-4.7410	-0.5422
EGSTMNUM*LEG_SORT	2	201	4	202	-6.3180	1.5338	392	-4.12	<.0001	0.1	-8.8468	-3.7893
EGSTMNUM*LEG_SORT	2	201	4	203	7.8036	1.5335	392	5.09	<.0001	0.1	5.2752	10.3320
EGSTMNUM*LEG_SORT	2	201	5	201	4.7810	1.2753	1080	3.75	0.0002	0.1	2.6816	6.8804
EGSTMNUM*LEG_SORT	2	201	5	202	1.2316	1.5338	392	0.80	0.4225	0.1	-1.2972	3.7604
EGSTMNUM*LEG_SORT	2	201	5	203	13.6373	1.5335	392	8.89	<.0001	0.1	11.1089	16.1657
EGSTMNUM*LEG_SORT	2	201	6	201	7.0792	1.2753	1080	5.55	<.0001	0.1	4.9798	9.1787
EGSTMNUM*LEG_SORT	2	201	6	202	4.0554	1.5338	392	2.64	0.0085	0.1	1.5266	6.5842
EGSTMNUM*LEG_SORT	2	201	6	203	15.0764	1.5335	392	9.83	<.0001	0.1	12.5481	17.6048
EGSTMNUM*LEG_SORT	2	201	8	201	7.4092	1.2753	1080	5.81	<.0001	0.1	5.3097	9.5086
EGSTMNUM*LEG_SORT	2	201	8	202	4.6158	1.5338	392	3.01	0.0028	0.1	2.0870	7.1446
EGSTMNUM*LEG_SORT	2	201	8	203	14.2503	1.5335	392	9.29	<.0001	0.1	11.7219	16.7787
EGSTMNUM*LEG_SORT	2	201	12	201	4.8722	1.2753	1080	3.82	0.0001	0.1	2.7728	6.9716
EGSTMNUM*LEG_SORT	2	201	12	202	4.5896	1.5338	392	2.99	0.0029	0.1	2.0608	7.1184
EGSTMNUM*LEG_SORT	2	201	12	203	12.1365	1.5335	392	7.91	<.0001	0.1	9.6081	14.6649
EGSTMNUM*LEG_SORT	2	201	24	201	1.6414	1.2753	1080	1.29	0.1983	0.1	-0.4581	3.7408
EGSTMNUM*LEG_SORT	2	201	24	202	2.7599	1.5338	392	1.80	0.0727	0.1	0.2311	5.2887
EGSTMNUM*LEG_SORT	2	201	24	203	9.8816	1.5335	392	6.44	<.0001	0.1	7.3532	12.4100
EGSTMNUM*LEG_SORT	2	202	2	203	13.4115	1.5376	396	8.72	<.0001	0.1	10.8764	15.9465
EGSTMNUM*LEG_SORT	2	202	3	201	4.7452	1.5338	392	3.09	0.0021	0.1	2.2164	7.2740
EGSTMNUM*LEG_SORT	2	202	3	202	-0.6112	1.2753	1080	-0.48	0.6319	0.1	-2.7106	1.4883
EGSTMNUM*LEG_SORT	2	202	3	203	12.6773	1.5376	396	8.24	<.0001	0.1	10.1422	15.2123
EGSTMNUM*LEG_SORT	2	202	4	201	2.0491	1.5338	392	1.34	0.1823	0.1	-0.4797	4.5779
EGSTMNUM*LEG_SORT	2	202	4	202	-1.6273	1.2753	1080	-1.28	0.2022	0.1	-3.7268	0.4721
EGSTMNUM*LEG_SORT	2	202	4	203	12.4943	1.5376	396	8.13	<.0001	0.1	9.9592	15.0294
EGSTMNUM*LEG_SORT	2	202	5	201	9.4717	1.5338	392	6.18	<.0001	0.1	6.9429	12.0005
EGSTMNUM*LEG_SORT	2	202	5	202	5.9223	1.2753	1080	4.64	<.0001	0.1	3.8229	8.0217
EGSTMNUM*LEG_SORT	2	202	5	203	18.3280	1.5376	396	11.92	<.0001	0.1	15.7930	20.8631
EGSTMNUM*LEG_SORT	2	202	6	201	11.7700	1.5338	392	7.67	<.0001	0.1	9.2412	14.2988
EGSTMNUM*LEG_SORT	2	202	6	202	8.7462	1.2753	1080	6.86	<.0001	0.1	6.6467	10.8456
EGSTMNUM*LEG_SORT	2	202	6	203	19.7671	1.5376	396	12.86	<.0001	0.1	17.2321	22.3022
EGSTMNUM*LEG_SORT	2	202	8	201	12.0999	1.5338	392	7.89	<.0001	0.1	9.5711	14.6287
EGSTMNUM*LEG_SORT	2	202	8	202	9.3065	1.2753	1080	7.30	<.0001	0.1	7.2071	11.4060

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	202	8	203	18.9410	1.5376	396	12.32	<.0001	0.1	16.4060	21.4761
EGSTMNUM*LEG_SORT	2	202	12	201	9.5629	1.5338	392	6.23	<.0001	0.1	7.0341	12.0917
EGSTMNUM*LEG_SORT	2	202	12	202	9.2804	1.2753	1080	7.28	<.0001	0.1	7.1809	11.3798
EGSTMNUM*LEG_SORT	2	202	12	203	16.8272	1.5376	396	10.94	<.0001	0.1	14.2922	19.3623
EGSTMNUM*LEG_SORT	2	202	24	201	6.3321	1.5338	392	4.13	<.0001	0.1	3.8033	8.8609
EGSTMNUM*LEG_SORT	2	202	24	202	7.4506	1.2753	1080	5.84	<.0001	0.1	5.3512	9.5500
EGSTMNUM*LEG_SORT	2	202	24	203	14.5723	1.5376	396	9.48	<.0001	0.1	12.0372	17.1074
EGSTMNUM*LEG_SORT	2	203	3	201	-8.6663	1.5335	392	-5.65	<.0001	0.1	-11.1947	-6.1379
EGSTMNUM*LEG_SORT	2	203	3	202	-14.0226	1.5376	396	-9.12	<.0001	0.1	-16.5577	-11.4876
EGSTMNUM*LEG_SORT	2	203	3	203	-0.7342	1.2753	1080	-0.58	0.5649	0.1	-2.8336	1.3652
EGSTMNUM*LEG_SORT	2	203	4	201	-11.3624	1.5335	392	-7.41	<.0001	0.1	-13.8907	-8.8340
EGSTMNUM*LEG_SORT	2	203	4	202	-15.0388	1.5376	396	-9.78	<.0001	0.1	-17.5739	-12.5037
EGSTMNUM*LEG_SORT	2	203	4	203	-0.9172	1.2753	1080	-0.72	0.4722	0.1	-3.0166	1.1823
EGSTMNUM*LEG_SORT	2	203	5	201	-3.9398	1.5335	392	-2.57	0.0106	0.1	-6.4681	-1.4114
EGSTMNUM*LEG_SORT	2	203	5	202	-7.4892	1.5376	396	-4.87	<.0001	0.1	-10.0242	-4.9541
EGSTMNUM*LEG_SORT	2	203	5	203	4.9166	1.2753	1080	3.86	0.0001	0.1	2.8172	7.0160
EGSTMNUM*LEG_SORT	2	203	6	201	-1.6415	1.5335	392	-1.07	0.2851	0.1	-4.1699	0.8869
EGSTMNUM*LEG_SORT	2	203	6	202	-4.6653	1.5376	396	-3.03	0.0026	0.1	-7.2004	-2.1302
EGSTMNUM*LEG_SORT	2	203	6	203	6.3557	1.2753	1080	4.98	<.0001	0.1	4.2563	8.4551
EGSTMNUM*LEG_SORT	2	203	8	201	-1.3116	1.5335	392	-0.86	0.3929	0.1	-3.8400	1.2168
EGSTMNUM*LEG_SORT	2	203	8	202	-4.1049	1.5376	396	-2.67	0.0079	0.1	-6.6400	-1.5699
EGSTMNUM*LEG_SORT	2	203	8	203	5.5296	1.2753	1080	4.34	<.0001	0.1	3.4301	7.6290
EGSTMNUM*LEG_SORT	2	203	12	201	-3.8486	1.5335	392	-2.51	0.0125	0.1	-6.3769	-1.3202
EGSTMNUM*LEG_SORT	2	203	12	202	-4.1311	1.5376	396	-2.69	0.0075	0.1	-6.6662	-1.5960
EGSTMNUM*LEG_SORT	2	203	12	203	3.4158	1.2753	1080	2.68	0.0075	0.1	1.3163	5.5152
EGSTMNUM*LEG_SORT	2	203	24	201	-7.0794	1.5335	392	-4.62	<.0001	0.1	-9.6078	-4.5510
EGSTMNUM*LEG_SORT	2	203	24	202	-5.9609	1.5376	396	-3.88	0.0001	0.1	-8.4959	-3.4258
EGSTMNUM*LEG_SORT	2	203	24	203	1.1608	1.2753	1080	0.91	0.3629	0.1	-0.9386	3.2603
EGSTMNUM*LEG_SORT	3	201	3	202	-5.3563	1.5338	392	-3.49	0.0005	0.1	-7.8851	-2.8275
EGSTMNUM*LEG_SORT	3	201	3	203	7.9321	1.5335	392	5.17	<.0001	0.1	5.4037	10.4605
EGSTMNUM*LEG_SORT	3	201	4	201	-2.6961	1.2753	1080	-2.11	0.0347	0.1	-4.7955	-0.5967
EGSTMNUM*LEG_SORT	3	201	4	202	-6.3725	1.5338	392	-4.15	<.0001	0.1	-8.9013	-3.8437
EGSTMNUM*LEG_SORT	3	201	4	203	7.7491	1.5335	392	5.05	<.0001	0.1	5.2207	10.2775
EGSTMNUM*LEG_SORT	3	201	5	201	4.7265	1.2753	1080	3.71	0.0002	0.1	2.6271	6.8259

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	5	202	1.1771	1.5338	392	0.77	0.4433	0.1	-1.3517	3.7059
EGSTMNUM*LEG_SORT	3	201	5	203	13.5829	1.5335	392	8.86	<.0001	0.1	11.0545	16.1112
EGSTMNUM*LEG_SORT	3	201	6	201	7.0248	1.2753	1080	5.51	<.0001	0.1	4.9254	9.1242
EGSTMNUM*LEG_SORT	3	201	6	202	4.0010	1.5338	392	2.61	0.0094	0.1	1.4722	6.5298
EGSTMNUM*LEG_SORT	3	201	6	203	15.0220	1.5335	392	9.80	<.0001	0.1	12.4936	17.5504
EGSTMNUM*LEG_SORT	3	201	8	201	7.3547	1.2753	1080	5.77	<.0001	0.1	5.2553	9.4541
EGSTMNUM*LEG_SORT	3	201	8	202	4.5614	1.5338	392	2.97	0.0031	0.1	2.0326	7.0902
EGSTMNUM*LEG_SORT	3	201	8	203	14.1958	1.5335	392	9.26	<.0001	0.1	11.6675	16.7242
EGSTMNUM*LEG_SORT	3	201	12	201	4.8177	1.2753	1080	3.78	0.0002	0.1	2.7183	6.9172
EGSTMNUM*LEG_SORT	3	201	12	202	4.5352	1.5338	392	2.96	0.0033	0.1	2.0064	7.0640
EGSTMNUM*LEG_SORT	3	201	12	203	12.0820	1.5335	392	7.88	<.0001	0.1	9.5537	14.6104
EGSTMNUM*LEG_SORT	3	201	24	201	1.5869	1.2753	1080	1.24	0.2136	0.1	-0.5125	3.6863
EGSTMNUM*LEG_SORT	3	201	24	202	2.7054	1.5338	392	1.76	0.0785	0.1	0.1766	5.2342
EGSTMNUM*LEG_SORT	3	201	24	203	9.8271	1.5335	392	6.41	<.0001	0.1	7.2988	12.3555
EGSTMNUM*LEG_SORT	3	202	3	203	13.2884	1.5376	396	8.64	<.0001	0.1	10.7534	15.8235
EGSTMNUM*LEG_SORT	3	202	4	201	2.6603	1.5338	392	1.73	0.0836	0.1	0.1315	5.1891
EGSTMNUM*LEG_SORT	3	202	4	202	-1.0162	1.2753	1080	-0.80	0.4257	0.1	-3.1156	1.0832
EGSTMNUM*LEG_SORT	3	202	4	203	13.1055	1.5376	396	8.52	<.0001	0.1	10.5704	15.6405
EGSTMNUM*LEG_SORT	3	202	5	201	10.0829	1.5338	392	6.57	<.0001	0.1	7.5541	12.6117
EGSTMNUM*LEG_SORT	3	202	5	202	6.5335	1.2753	1080	5.12	<.0001	0.1	4.4340	8.6329
EGSTMNUM*LEG_SORT	3	202	5	203	18.9392	1.5376	396	12.32	<.0001	0.1	16.4041	21.4743
EGSTMNUM*LEG_SORT	3	202	6	201	12.3811	1.5338	392	8.07	<.0001	0.1	9.8523	14.9099
EGSTMNUM*LEG_SORT	3	202	6	202	9.3573	1.2753	1080	7.34	<.0001	0.1	7.2579	11.4567
EGSTMNUM*LEG_SORT	3	202	6	203	20.3783	1.5376	396	13.25	<.0001	0.1	17.8432	22.9134
EGSTMNUM*LEG_SORT	3	202	8	201	12.7110	1.5338	392	8.29	<.0001	0.1	10.1822	15.2398
EGSTMNUM*LEG_SORT	3	202	8	202	9.9177	1.2753	1080	7.78	<.0001	0.1	7.8183	12.0171
EGSTMNUM*LEG_SORT	3	202	8	203	19.5522	1.5376	396	12.72	<.0001	0.1	17.0171	22.0872
EGSTMNUM*LEG_SORT	3	202	12	201	10.1741	1.5338	392	6.63	<.0001	0.1	7.6453	12.7029
EGSTMNUM*LEG_SORT	3	202	12	202	9.8915	1.2753	1080	7.76	<.0001	0.1	7.7921	11.9909
EGSTMNUM*LEG_SORT	3	202	12	203	17.4384	1.5376	396	11.34	<.0001	0.1	14.9033	19.9734
EGSTMNUM*LEG_SORT	3	202	24	201	6.9432	1.5338	392	4.53	<.0001	0.1	4.4144	9.4720
EGSTMNUM*LEG_SORT	3	202	24	202	8.0617	1.2753	1080	6.32	<.0001	0.1	5.9623	10.1612
EGSTMNUM*LEG_SORT	3	202	24	203	15.1835	1.5376	396	9.87	<.0001	0.1	12.6484	17.7185
EGSTMNUM*LEG_SORT	3	203	4	201	-10.6282	1.5335	392	-6.93	<.0001	0.1	-13.1566	-8.0998

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	4	202	-14.3046	1.5376	396	-9.30	<.0001	0.1	-16.8397	-11.7695
EGSTMNUM*LEG_SORT	3	203	4	203	-0.1830	1.2753	1080	-0.14	0.8859	0.1	-2.2824	1.9164
EGSTMNUM*LEG_SORT	3	203	5	201	-3.2056	1.5335	392	-2.09	0.0372	0.1	-5.7340	-0.6772
EGSTMNUM*LEG_SORT	3	203	5	202	-6.7550	1.5376	396	-4.39	<.0001	0.1	-9.2900	-4.2199
EGSTMNUM*LEG_SORT	3	203	5	203	5.6508	1.2753	1080	4.43	<.0001	0.1	3.5513	7.7502
EGSTMNUM*LEG_SORT	3	203	6	201	-0.9073	1.5335	392	-0.59	0.5544	0.1	-3.4357	1.6211
EGSTMNUM*LEG_SORT	3	203	6	202	-3.9311	1.5376	396	-2.56	0.0109	0.1	-6.4662	-1.3961
EGSTMNUM*LEG_SORT	3	203	6	203	7.0899	1.2753	1080	5.56	<.0001	0.1	4.9904	9.1893
EGSTMNUM*LEG_SORT	3	203	8	201	-0.5774	1.5335	392	-0.38	0.7067	0.1	-3.1058	1.9510
EGSTMNUM*LEG_SORT	3	203	8	202	-3.3707	1.5376	396	-2.19	0.0289	0.1	-5.9058	-0.8357
EGSTMNUM*LEG_SORT	3	203	8	203	6.2637	1.2753	1080	4.91	<.0001	0.1	4.1643	8.3632
EGSTMNUM*LEG_SORT	3	203	12	201	-3.1144	1.5335	392	-2.03	0.0429	0.1	-5.6427	-0.5860
EGSTMNUM*LEG_SORT	3	203	12	202	-3.3969	1.5376	396	-2.21	0.0277	0.1	-5.9320	-0.8619
EGSTMNUM*LEG_SORT	3	203	12	203	4.1499	1.2753	1080	3.25	0.0012	0.1	2.0505	6.2494
EGSTMNUM*LEG_SORT	3	203	24	201	-6.3452	1.5335	392	-4.14	<.0001	0.1	-8.8736	-3.8168
EGSTMNUM*LEG_SORT	3	203	24	202	-5.2267	1.5376	396	-3.40	0.0007	0.1	-7.7618	-2.6916
EGSTMNUM*LEG_SORT	3	203	24	203	1.8950	1.2753	1080	1.49	0.1376	0.1	-0.2044	3.9945
EGSTMNUM*LEG_SORT	4	201	4	202	-3.6764	1.5338	392	-2.40	0.0170	0.1	-6.2052	-1.1476
EGSTMNUM*LEG_SORT	4	201	4	203	10.4452	1.5335	392	6.81	<.0001	0.1	7.9168	12.9736
EGSTMNUM*LEG_SORT	4	201	5	201	7.4226	1.2753	1080	5.82	<.0001	0.1	5.3232	9.5220
EGSTMNUM*LEG_SORT	4	201	5	202	3.8732	1.5338	392	2.53	0.0120	0.1	1.3444	6.4020
EGSTMNUM*LEG_SORT	4	201	5	203	16.2789	1.5335	392	10.62	<.0001	0.1	13.7506	18.8073
EGSTMNUM*LEG_SORT	4	201	6	201	9.7209	1.2753	1080	7.62	<.0001	0.1	7.6214	11.8203
EGSTMNUM*LEG_SORT	4	201	6	202	6.6971	1.5338	392	4.37	<.0001	0.1	4.1683	9.2259
EGSTMNUM*LEG_SORT	4	201	6	203	17.7180	1.5335	392	11.55	<.0001	0.1	15.1897	20.2464
EGSTMNUM*LEG_SORT	4	201	8	201	10.0508	1.2753	1080	7.88	<.0001	0.1	7.9513	12.1502
EGSTMNUM*LEG_SORT	4	201	8	202	7.2574	1.5338	392	4.73	<.0001	0.1	4.7286	9.7862
EGSTMNUM*LEG_SORT	4	201	8	203	16.8919	1.5335	392	11.02	<.0001	0.1	14.3635	19.4203
EGSTMNUM*LEG_SORT	4	201	12	201	7.5138	1.2753	1080	5.89	<.0001	0.1	5.4144	9.6132
EGSTMNUM*LEG_SORT	4	201	12	202	7.2313	1.5338	392	4.71	<.0001	0.1	4.7025	9.7601
EGSTMNUM*LEG_SORT	4	201	12	203	14.7781	1.5335	392	9.64	<.0001	0.1	12.2497	17.3065
EGSTMNUM*LEG_SORT	4	201	24	201	4.2830	1.2753	1080	3.36	0.0008	0.1	2.1836	6.3824
EGSTMNUM*LEG_SORT	4	201	24	202	5.4015	1.5338	392	3.52	0.0005	0.1	2.8727	7.9303
EGSTMNUM*LEG_SORT	4	201	24	203	12.5232	1.5335	392	8.17	<.0001	0.1	9.9948	15.0516

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	4	203	14.1216	1.5376	396	9.18	<.0001	0.1	11.5866	16.6567
EGSTMNUM*LEG_SORT	4	202	5	201	11.0990	1.5338	392	7.24	<.0001	0.1	8.5702	13.6278
EGSTMNUM*LEG_SORT	4	202	5	202	7.5496	1.2753	1080	5.92	<.0001	0.1	5.4502	9.6491
EGSTMNUM*LEG_SORT	4	202	5	203	19.9554	1.5376	396	12.98	<.0001	0.1	17.4203	22.4904
EGSTMNUM*LEG_SORT	4	202	6	201	13.3973	1.5338	392	8.73	<.0001	0.1	10.8685	15.9261
EGSTMNUM*LEG_SORT	4	202	6	202	10.3735	1.2753	1080	8.13	<.0001	0.1	8.2741	12.4729
EGSTMNUM*LEG_SORT	4	202	6	203	21.3945	1.5376	396	13.91	<.0001	0.1	18.8594	23.9295
EGSTMNUM*LEG_SORT	4	202	8	201	13.7272	1.5338	392	8.95	<.0001	0.1	11.1984	16.2560
EGSTMNUM*LEG_SORT	4	202	8	202	10.9339	1.2753	1080	8.57	<.0001	0.1	8.8345	13.0333
EGSTMNUM*LEG_SORT	4	202	8	203	20.5684	1.5376	396	13.38	<.0001	0.1	18.0333	23.1034
EGSTMNUM*LEG_SORT	4	202	12	201	11.1902	1.5338	392	7.30	<.0001	0.1	8.6614	13.7190
EGSTMNUM*LEG_SORT	4	202	12	202	10.9077	1.2753	1080	8.55	<.0001	0.1	8.8083	13.0071
EGSTMNUM*LEG_SORT	4	202	12	203	18.4546	1.5376	396	12.00	<.0001	0.1	15.9195	20.9896
EGSTMNUM*LEG_SORT	4	202	24	201	7.9594	1.5338	392	5.19	<.0001	0.1	5.4306	10.4882
EGSTMNUM*LEG_SORT	4	202	24	202	9.0779	1.2753	1080	7.12	<.0001	0.1	6.9785	11.1773
EGSTMNUM*LEG_SORT	4	202	24	203	16.1996	1.5376	396	10.54	<.0001	0.1	13.6646	18.7347
EGSTMNUM*LEG_SORT	4	203	5	201	-3.0226	1.5335	392	-1.97	0.0494	0.1	-5.5510	-0.4942
EGSTMNUM*LEG_SORT	4	203	5	202	-6.5720	1.5376	396	-4.27	<.0001	0.1	-9.1071	-4.0369
EGSTMNUM*LEG_SORT	4	203	5	203	5.8337	1.2753	1080	4.57	<.0001	0.1	3.7343	7.9332
EGSTMNUM*LEG_SORT	4	203	6	201	-0.7243	1.5335	392	-0.47	0.6369	0.1	-3.2527	1.8040
EGSTMNUM*LEG_SORT	4	203	6	202	-3.7481	1.5376	396	-2.44	0.0152	0.1	-6.2832	-1.2131
EGSTMNUM*LEG_SORT	4	203	6	203	7.2728	1.2753	1080	5.70	<.0001	0.1	5.1734	9.3723
EGSTMNUM*LEG_SORT	4	203	8	201	-0.3944	1.5335	392	-0.26	0.7972	0.1	-2.9228	2.1339
EGSTMNUM*LEG_SORT	4	203	8	202	-3.1877	1.5376	396	-2.07	0.0388	0.1	-5.7228	-0.6527
EGSTMNUM*LEG_SORT	4	203	8	203	6.4467	1.2753	1080	5.06	<.0001	0.1	4.3473	8.5461
EGSTMNUM*LEG_SORT	4	203	12	201	-2.9314	1.5335	392	-1.91	0.0567	0.1	-5.4598	-0.4030
EGSTMNUM*LEG_SORT	4	203	12	202	-3.2139	1.5376	396	-2.09	0.0372	0.1	-5.7490	-0.6789
EGSTMNUM*LEG_SORT	4	203	12	203	4.3329	1.2753	1080	3.40	0.0007	0.1	2.2335	6.4323
EGSTMNUM*LEG_SORT	4	203	24	201	-6.1622	1.5335	392	-4.02	<.0001	0.1	-8.6906	-3.6338
EGSTMNUM*LEG_SORT	4	203	24	202	-5.0437	1.5376	396	-3.28	0.0011	0.1	-7.5788	-2.5087
EGSTMNUM*LEG_SORT	4	203	24	203	2.0780	1.2753	1080	1.63	0.1035	0.1	-0.02141	4.1774
EGSTMNUM*LEG_SORT	5	201	5	202	-3.5494	1.5338	392	-2.31	0.0212	0.1	-6.0782	-1.0206
EGSTMNUM*LEG_SORT	5	201	5	203	8.8563	1.5335	392	5.78	<.0001	0.1	6.3280	11.3847
EGSTMNUM*LEG_SORT	5	201	6	201	2.2983	1.2753	1080	1.80	0.0718	0.1	0.1988	4.3977

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	201	6	202	-0.7255	1.5338	392	-0.47	0.6364	0.1	-3.2543	1.8033
EGSTMNUM*LEG_SORT	5	201	6	203	10.2954	1.5335	392	6.71	<.0001	0.1	7.7671	12.8238
EGSTMNUM*LEG_SORT	5	201	8	201	2.6282	1.2753	1080	2.06	0.0396	0.1	0.5287	4.7276
EGSTMNUM*LEG_SORT	5	201	8	202	-0.1652	1.5338	392	-0.11	0.9143	0.1	-2.6940	2.3636
EGSTMNUM*LEG_SORT	5	201	8	203	9.4693	1.5335	392	6.17	<.0001	0.1	6.9409	11.9977
EGSTMNUM*LEG_SORT	5	201	12	201	0.09121	1.2753	1080	0.07	0.9430	0.1	-2.0082	2.1906
EGSTMNUM*LEG_SORT	5	201	12	202	-0.1913	1.5338	392	-0.12	0.9008	0.1	-2.7201	2.3375
EGSTMNUM*LEG_SORT	5	201	12	203	7.3555	1.5335	392	4.80	<.0001	0.1	4.8271	9.8839
EGSTMNUM*LEG_SORT	5	201	24	201	-3.1396	1.2753	1080	-2.46	0.0140	0.1	-5.2390	-1.0402
EGSTMNUM*LEG_SORT	5	201	24	202	-2.0211	1.5338	392	-1.32	0.1884	0.1	-4.5499	0.5077
EGSTMNUM*LEG_SORT	5	201	24	203	5.1006	1.5335	392	3.33	0.0010	0.1	2.5722	7.6290
EGSTMNUM*LEG_SORT	5	202	5	203	12.4057	1.5376	396	8.07	<.0001	0.1	9.8707	14.9408
EGSTMNUM*LEG_SORT	5	202	6	201	5.8476	1.5338	392	3.81	0.0002	0.1	3.3188	8.3764
EGSTMNUM*LEG_SORT	5	202	6	202	2.8239	1.2753	1080	2.21	0.0270	0.1	0.7244	4.9233
EGSTMNUM*LEG_SORT	5	202	6	203	13.8448	1.5376	396	9.00	<.0001	0.1	11.3098	16.3799
EGSTMNUM*LEG_SORT	5	202	8	201	6.1776	1.5338	392	4.03	<.0001	0.1	3.6488	8.7064
EGSTMNUM*LEG_SORT	5	202	8	202	3.3842	1.2753	1080	2.65	0.0081	0.1	1.2848	5.4837
EGSTMNUM*LEG_SORT	5	202	8	203	13.0187	1.5376	396	8.47	<.0001	0.1	10.4836	15.5538
EGSTMNUM*LEG_SORT	5	202	12	201	3.6406	1.5338	392	2.37	0.0181	0.1	1.1118	6.1694
EGSTMNUM*LEG_SORT	5	202	12	202	3.3580	1.2753	1080	2.63	0.0086	0.1	1.2586	5.4575
EGSTMNUM*LEG_SORT	5	202	12	203	10.9049	1.5376	396	7.09	<.0001	0.1	8.3699	13.4400
EGSTMNUM*LEG_SORT	5	202	24	201	0.4098	1.5338	392	0.27	0.7895	0.1	-2.1190	2.9386
EGSTMNUM*LEG_SORT	5	202	24	202	1.5283	1.2753	1080	1.20	0.2310	0.1	-0.5712	3.6277
EGSTMNUM*LEG_SORT	5	202	24	203	8.6500	1.5376	396	5.63	<.0001	0.1	6.1149	11.1851
EGSTMNUM*LEG_SORT	5	203	6	201	-6.5581	1.5335	392	-4.28	<.0001	0.1	-9.0865	-4.0297
EGSTMNUM*LEG_SORT	5	203	6	202	-9.5819	1.5376	396	-6.23	<.0001	0.1	-12.1169	-7.0468
EGSTMNUM*LEG_SORT	5	203	6	203	1.4391	1.2753	1080	1.13	0.2594	0.1	-0.6603	3.5385
EGSTMNUM*LEG_SORT	5	203	8	201	-6.2282	1.5335	392	-4.06	<.0001	0.1	-8.7566	-3.6998
EGSTMNUM*LEG_SORT	5	203	8	202	-9.0215	1.5376	396	-5.87	<.0001	0.1	-11.5566	-6.4864
EGSTMNUM*LEG_SORT	5	203	8	203	0.6130	1.2753	1080	0.48	0.6309	0.1	-1.4864	2.7124
EGSTMNUM*LEG_SORT	5	203	12	201	-8.7651	1.5335	392	-5.72	<.0001	0.1	-11.2935	-6.2367
EGSTMNUM*LEG_SORT	5	203	12	202	-9.0477	1.5376	396	-5.88	<.0001	0.1	-11.5827	-6.5126
EGSTMNUM*LEG_SORT	5	203	12	203	-1.5008	1.2753	1080	-1.18	0.2395	0.1	-3.6002	0.5986
EGSTMNUM*LEG_SORT	5	203	24	201	-11.9960	1.5335	392	-7.82	<.0001	0.1	-14.5243	-9.4676

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.  
 Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.  
 Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.  
 Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	203	24	202	-10.8775	1.5376	396	-7.07	<.0001	0.1	-13.4125	-8.3424
EGSTMNUM*LEG_SORT	5	203	24	203	-3.7557	1.2753	1080	-2.95	0.0033	0.1	-5.8552	-1.6563
EGSTMNUM*LEG_SORT	6	201	6	202	-3.0238	1.5338	392	-1.97	0.0494	0.1	-5.5526	-0.4950
EGSTMNUM*LEG_SORT	6	201	6	203	7.9972	1.5335	392	5.21	<.0001	0.1	5.4688	10.5256
EGSTMNUM*LEG_SORT	6	201	8	201	0.3299	1.2753	1080	0.26	0.7959	0.1	-1.7695	2.4293
EGSTMNUM*LEG_SORT	6	201	8	202	-2.4634	1.5338	392	-1.61	0.1091	0.1	-4.9922	0.06539
EGSTMNUM*LEG_SORT	6	201	8	203	7.1711	1.5335	392	4.68	<.0001	0.1	4.6427	9.6994
EGSTMNUM*LEG_SORT	6	201	12	201	-2.2070	1.2753	1080	-1.73	0.0838	0.1	-4.3065	-0.1076
EGSTMNUM*LEG_SORT	6	201	12	202	-2.4896	1.5338	392	-1.62	0.1054	0.1	-5.0184	0.03920
EGSTMNUM*LEG_SORT	6	201	12	203	5.0573	1.5335	392	3.30	0.0011	0.1	2.5289	7.5856
EGSTMNUM*LEG_SORT	6	201	24	201	-5.4379	1.2753	1080	-4.26	<.0001	0.1	-7.5373	-3.3385
EGSTMNUM*LEG_SORT	6	201	24	202	-4.3194	1.5338	392	-2.82	0.0051	0.1	-6.8482	-1.7906
EGSTMNUM*LEG_SORT	6	201	24	203	2.8024	1.5335	392	1.83	0.0684	0.1	0.2740	5.3307
EGSTMNUM*LEG_SORT	6	202	6	203	11.0210	1.5376	396	7.17	<.0001	0.1	8.4859	13.5560
EGSTMNUM*LEG_SORT	6	202	8	201	3.3537	1.5338	392	2.19	0.0294	0.1	0.8249	5.8825
EGSTMNUM*LEG_SORT	6	202	8	202	0.5604	1.2753	1080	0.44	0.6604	0.1	-1.5390	2.6598
EGSTMNUM*LEG_SORT	6	202	8	203	10.1949	1.5376	396	6.63	<.0001	0.1	7.6598	12.7299
EGSTMNUM*LEG_SORT	6	202	12	201	0.8168	1.5338	392	0.53	0.5947	0.1	-1.7120	3.3455
EGSTMNUM*LEG_SORT	6	202	12	202	0.5342	1.2753	1080	0.42	0.6754	0.1	-1.5652	2.6336
EGSTMNUM*LEG_SORT	6	202	12	203	8.0811	1.5376	396	5.26	<.0001	0.1	5.5460	10.6161
EGSTMNUM*LEG_SORT	6	202	24	201	-2.4141	1.5338	392	-1.57	0.1163	0.1	-4.9429	0.1147
EGSTMNUM*LEG_SORT	6	202	24	202	-1.2956	1.2753	1080	-1.02	0.3099	0.1	-3.3950	0.8038
EGSTMNUM*LEG_SORT	6	202	24	203	5.8261	1.5376	396	3.79	0.0002	0.1	3.2911	8.3612
EGSTMNUM*LEG_SORT	6	203	8	201	-7.6673	1.5335	392	-5.00	<.0001	0.1	-10.1957	-5.1389
EGSTMNUM*LEG_SORT	6	203	8	202	-10.4606	1.5376	396	-6.80	<.0001	0.1	-12.9957	-7.9255
EGSTMNUM*LEG_SORT	6	203	8	203	-0.8261	1.2753	1080	-0.65	0.5172	0.1	-2.9256	1.2733
EGSTMNUM*LEG_SORT	6	203	12	201	-10.2042	1.5335	392	-6.65	<.0001	0.1	-12.7326	-7.6759
EGSTMNUM*LEG_SORT	6	203	12	202	-10.4868	1.5376	396	-6.82	<.0001	0.1	-13.0219	-7.9517
EGSTMNUM*LEG_SORT	6	203	12	203	-2.9399	1.2753	1080	-2.31	0.0213	0.1	-5.0393	-0.8405
EGSTMNUM*LEG_SORT	6	203	24	201	-13.4351	1.5335	392	-8.76	<.0001	0.1	-15.9634	-10.9067
EGSTMNUM*LEG_SORT	6	203	24	202	-12.3166	1.5376	396	-8.01	<.0001	0.1	-14.8516	-9.7815
EGSTMNUM*LEG_SORT	6	203	24	203	-5.1948	1.2753	1080	-4.07	<.0001	0.1	-7.2943	-3.0954
EGSTMNUM*LEG_SORT	8	201	8	202	-2.7933	1.5338	392	-1.82	0.0693	0.1	-5.3221	-0.2645
EGSTMNUM*LEG_SORT	8	201	8	203	6.8412	1.5335	392	4.46	<.0001	0.1	4.3128	9.3695

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	201	12	201	-2.5370	1.2753	1080	-1.99	0.0469	0.1	-4.6364	-0.4375
EGSTMNUM*LEG_SORT	8	201	12	202	-2.8195	1.5338	392	-1.84	0.0668	0.1	-5.3483	-0.2907
EGSTMNUM*LEG_SORT	8	201	12	203	4.7274	1.5335	392	3.08	0.0022	0.1	2.1990	7.2557
EGSTMNUM*LEG_SORT	8	201	24	201	-5.7678	1.2753	1080	-4.52	<.0001	0.1	-7.8672	-3.6684
EGSTMNUM*LEG_SORT	8	201	24	202	-4.6493	1.5338	392	-3.03	0.0026	0.1	-7.1781	-2.1205
EGSTMNUM*LEG_SORT	8	201	24	203	2.4724	1.5335	392	1.61	0.1077	0.1	-0.05593	5.0008
EGSTMNUM*LEG_SORT	8	202	8	203	9.6345	1.5376	396	6.27	<.0001	0.1	7.0994	12.1695
EGSTMNUM*LEG_SORT	8	202	12	201	0.2564	1.5338	392	0.17	0.8673	0.1	-2.2724	2.7852
EGSTMNUM*LEG_SORT	8	202	12	202	-0.02619	1.2753	1080	-0.02	0.9836	0.1	-2.1256	2.0732
EGSTMNUM*LEG_SORT	8	202	12	203	7.5207	1.5376	396	4.89	<.0001	0.1	4.9856	10.0557
EGSTMNUM*LEG_SORT	8	202	24	201	-2.9745	1.5338	392	-1.94	0.0532	0.1	-5.5033	-0.4457
EGSTMNUM*LEG_SORT	8	202	24	202	-1.8560	1.2753	1080	-1.46	0.1459	0.1	-3.9554	0.2435
EGSTMNUM*LEG_SORT	8	202	24	203	5.2658	1.5376	396	3.42	0.0007	0.1	2.7307	7.8008
EGSTMNUM*LEG_SORT	8	203	12	201	-9.3781	1.5335	392	-6.12	<.0001	0.1	-11.9065	-6.8497
EGSTMNUM*LEG_SORT	8	203	12	202	-9.6607	1.5376	396	-6.28	<.0001	0.1	-12.1957	-7.1256
EGSTMNUM*LEG_SORT	8	203	12	203	-2.1138	1.2753	1080	-1.66	0.0977	0.1	-4.2132	-0.01437
EGSTMNUM*LEG_SORT	8	203	24	201	-12.6089	1.5335	392	-8.22	<.0001	0.1	-15.1373	-10.0806
EGSTMNUM*LEG_SORT	8	203	24	202	-11.4904	1.5376	396	-7.47	<.0001	0.1	-14.0255	-8.9554
EGSTMNUM*LEG_SORT	8	203	24	203	-4.3687	1.2753	1080	-3.43	0.0006	0.1	-6.4681	-2.2693
EGSTMNUM*LEG_SORT	12	201	12	202	-0.2826	1.5338	392	-0.18	0.8539	0.1	-2.8114	2.2462
EGSTMNUM*LEG_SORT	12	201	12	203	7.2643	1.5335	392	4.74	<.0001	0.1	4.7359	9.7927
EGSTMNUM*LEG_SORT	12	201	24	201	-3.2308	1.2753	1080	-2.53	0.0114	0.1	-5.3302	-1.1314
EGSTMNUM*LEG_SORT	12	201	24	202	-2.1123	1.5338	392	-1.38	0.1692	0.1	-4.6411	0.4165
EGSTMNUM*LEG_SORT	12	201	24	203	5.0094	1.5335	392	3.27	0.0012	0.1	2.4810	7.5378
EGSTMNUM*LEG_SORT	12	202	12	203	7.5469	1.5376	396	4.91	<.0001	0.1	5.0118	10.0819
EGSTMNUM*LEG_SORT	12	202	24	201	-2.9483	1.5338	392	-1.92	0.0553	0.1	-5.4771	-0.4195
EGSTMNUM*LEG_SORT	12	202	24	202	-1.8298	1.2753	1080	-1.43	0.1516	0.1	-3.9292	0.2696
EGSTMNUM*LEG_SORT	12	202	24	203	5.2920	1.5376	396	3.44	0.0006	0.1	2.7569	7.8270
EGSTMNUM*LEG_SORT	12	203	24	201	-10.4951	1.5335	392	-6.84	<.0001	0.1	-13.0235	-7.9668
EGSTMNUM*LEG_SORT	12	203	24	202	-9.3766	1.5376	396	-6.10	<.0001	0.1	-11.9117	-6.8416
EGSTMNUM*LEG_SORT	12	203	24	203	-2.2549	1.2753	1080	-1.77	0.0773	0.1	-4.3543	-0.1555
EGSTMNUM*LEG_SORT	24	201	24	202	1.1185	1.5338	392	0.73	0.4663	0.1	-1.4103	3.6473
EGSTMNUM*LEG_SORT	24	201	24	203	8.2402	1.5335	392	5.37	<.0001	0.1	5.7118	10.7686
EGSTMNUM*LEG_SORT	24	202	24	203	7.1217	1.5376	396	4.63	<.0001	0.1	4.5867	9.6568

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcI as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (00:58)

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drgggroup period egstmnum leg_sort;
model QTcN = drgggroup period leg_sort egbase_QTcN egstmnum egstmnum*leg_sort/ddfm=kr;
random subjid(drgggroup);
repeated / subject = period*subjid(drgggroup) type=cs;
lsmeans egstmnum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:01)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Model Information

Data Set WORK.ECG3  
 Dependent Variable QTcN  
 Covariance Structures Variance Components,  
 Compound Symmetry  
 Subject Effect SUBJI\*PERIOD(DRGGRO)  
 Estimation Method REML  
 Residual Variance Method Profile  
 Fixed Effects SE Method Kenward-Roger  
 Degrees of Freedom Method Kenward-Roger

Class Level Information

Class	Levels	Values		
SUBJID	54	10011001 10011002 10011003		
		10011004 10011005 10011006		
		10011007 10011008 10011009		
		10011010 10011011 10011012		
		10011013 10011014 10011015		
		10011016 10011017 10011018		
		10011019 10011020 10011021		
		10011022 10011023 10011024		
		10011025 10011026 10011027		
		10011028 10011029 10011030		
		10011031 10011032 10011033		
		10011034 10011035 10011036		
		10011037 10011038 10011039		
		10011040 10011041 10011042		
		10011043 10011044 10011045		
		10011046 10011047 10011048		
		10011049 10011050 10011051		
		10011052 10011053 10011054		
		DRGGROUP	6	ABC ACB BAC BCA CAB CBA
		PERIOD	3	Period 1 Period 2 Period 3
		EGSTMNUM	9	1 2 3 4 5 6 8 12 24
LEG_SORT	3	201 202 203		

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

SERTRALINE Protocol A0501104

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

## The Mixed Procedure

## Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	54
Subjects	1
Max Obs Per Subject	1351

## Number of Observations

Number of Observations Read	1351
Number of Observations Used	1351
Number of Observations Not Used	0

## Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	9663.69465665	
1	3	8603.02758033	0.00151046
2	1	8596.81578544	0.00083072
3	1	8593.70056259	0.00020261
4	1	8592.97915247	0.00001643
5	1	8592.92553575	0.00000014
6	1	8592.92510609	0.00000000

Convergence criteria met.

## Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		138.11
CS	SUBJI*PERIOD(DRGGRO)	9.8471
Residual		27.0743

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:01)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	8592.9
AIC (smaller is better)	8598.9
AICC (smaller is better)	8598.9
BIC (smaller is better)	8604.9

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	26.2	0.32	0.8982
PERIOD	2	67.2	1.15	0.3235
LEG_SORT	2	65.8	96.76	<.0001
EGBASE_QTCN	1	130	28.15	<.0001
EGSTMNUM	8	1176	55.66	<.0001
EGSTMNUM*LEG_SORT	16	1176	4.16	<.0001

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	414.22	1.8194	41.8	227.67	<.0001	0.1	411.16	417.28
EGSTMNUM*LEG_SORT	1	202	418.85	1.8220	42	229.88	<.0001	0.1	415.78	421.91
EGSTMNUM*LEG_SORT	1	203	407.11	1.8221	42.1	223.43	<.0001	0.1	404.05	410.18
EGSTMNUM*LEG_SORT	2	201	415.47	1.8194	41.8	228.36	<.0001	0.1	412.41	418.54
EGSTMNUM*LEG_SORT	2	202	419.84	1.8220	42	230.43	<.0001	0.1	416.78	422.91
EGSTMNUM*LEG_SORT	2	203	407.49	1.8221	42.1	223.63	<.0001	0.1	404.43	410.55
EGSTMNUM*LEG_SORT	3	201	416.38	1.8194	41.8	228.86	<.0001	0.1	413.32	419.44
EGSTMNUM*LEG_SORT	3	202	420.32	1.8220	42	230.68	<.0001	0.1	417.25	423.38
EGSTMNUM*LEG_SORT	3	203	408.42	1.8221	42.1	224.15	<.0001	0.1	405.36	411.49
EGSTMNUM*LEG_SORT	4	201	418.13	1.8194	41.8	229.82	<.0001	0.1	415.07	421.19
EGSTMNUM*LEG_SORT	4	202	421.72	1.8220	42	231.46	<.0001	0.1	418.66	424.79
EGSTMNUM*LEG_SORT	4	203	408.39	1.8221	42.1	224.13	<.0001	0.1	405.33	411.45
EGSTMNUM*LEG_SORT	5	201	411.59	1.8194	41.8	226.23	<.0001	0.1	408.53	414.65
EGSTMNUM*LEG_SORT	5	202	413.61	1.8220	42	227.00	<.0001	0.1	410.55	416.67

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	203	404.04	1.8221	42.1	221.74	<.0001	0.1	400.98	407.10
EGSTMNUM*LEG_SORT	6	201	409.24	1.8194	41.8	224.93	<.0001	0.1	406.18	412.30
EGSTMNUM*LEG_SORT	6	202	411.70	1.8220	42	225.95	<.0001	0.1	408.63	414.76
EGSTMNUM*LEG_SORT	6	203	402.62	1.8221	42.1	220.96	<.0001	0.1	399.56	405.69
EGSTMNUM*LEG_SORT	8	201	408.82	1.8194	41.8	224.70	<.0001	0.1	405.75	411.88
EGSTMNUM*LEG_SORT	8	202	410.77	1.8220	42	225.44	<.0001	0.1	407.70	413.83
EGSTMNUM*LEG_SORT	8	203	403.15	1.8221	42.1	221.25	<.0001	0.1	400.09	406.22
EGSTMNUM*LEG_SORT	12	201	411.20	1.8194	41.8	226.01	<.0001	0.1	408.14	414.26
EGSTMNUM*LEG_SORT	12	202	411.76	1.8220	42	225.99	<.0001	0.1	408.70	414.83
EGSTMNUM*LEG_SORT	12	203	405.53	1.8221	42.1	222.55	<.0001	0.1	402.46	408.59
EGSTMNUM*LEG_SORT	24	201	414.32	1.8142	41.3	228.38	<.0001	0.1	411.27	417.37
EGSTMNUM*LEG_SORT	24	202	412.62	1.8220	42	226.46	<.0001	0.1	409.55	415.68
EGSTMNUM*LEG_SORT	24	203	406.95	1.8221	42.1	223.34	<.0001	0.1	403.89	410.02

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-4.6327	1.2243	436	-3.78	0.0002	0.1	-6.6507	-2.6146
EGSTMNUM*LEG_SORT	1	201	1	203	7.1018	1.2209	442	5.82	<.0001	0.1	5.0894	9.1142
EGSTMNUM*LEG_SORT	1	201	2	201	-1.2592	1.0407	1176	-1.21	0.2265	0.1	-2.9723	0.4538
EGSTMNUM*LEG_SORT	1	201	2	202	-5.6284	1.2243	436	-4.60	<.0001	0.1	-7.6464	-3.6103
EGSTMNUM*LEG_SORT	1	201	2	203	6.7254	1.2209	442	5.51	<.0001	0.1	4.7130	8.7379
EGSTMNUM*LEG_SORT	1	201	3	201	-2.1623	1.0407	1176	-2.08	0.0379	0.1	-3.8754	-0.4493
EGSTMNUM*LEG_SORT	1	201	3	202	-6.0997	1.2243	436	-4.98	<.0001	0.1	-8.1177	-4.0816
EGSTMNUM*LEG_SORT	1	201	3	203	5.7909	1.2209	442	4.74	<.0001	0.1	3.7784	7.8033
EGSTMNUM*LEG_SORT	1	201	4	201	-3.9109	1.0407	1176	-3.76	0.0002	0.1	-5.6240	-2.1978
EGSTMNUM*LEG_SORT	1	201	4	202	-7.5056	1.2243	436	-6.13	<.0001	0.1	-9.5236	-5.4875
EGSTMNUM*LEG_SORT	1	201	4	203	5.8256	1.2209	442	4.77	<.0001	0.1	3.8132	7.8380
EGSTMNUM*LEG_SORT	1	201	5	201	2.6237	1.0407	1176	2.52	0.0118	0.1	0.9106	4.3368
EGSTMNUM*LEG_SORT	1	201	5	202	0.6059	1.2243	436	0.49	0.6209	0.1	-1.4121	2.6240

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	5	203	10.1752	1.2209	442	8.33	<.0001	0.1	8.1628	12.1877
EGSTMNUM*LEG_SORT	1	201	6	201	4.9777	1.0407	1176	4.78	<.0001	0.1	3.2646	6.6907
EGSTMNUM*LEG_SORT	1	201	6	202	2.5178	1.2243	436	2.06	0.0403	0.1	0.4997	4.5358
EGSTMNUM*LEG_SORT	1	201	6	203	11.5910	1.2209	442	9.49	<.0001	0.1	9.5786	13.6034
EGSTMNUM*LEG_SORT	1	201	8	201	5.4003	1.0407	1176	5.19	<.0001	0.1	3.6872	7.1134
EGSTMNUM*LEG_SORT	1	201	8	202	3.4481	1.2243	436	2.82	0.0051	0.1	1.4300	5.4661
EGSTMNUM*LEG_SORT	1	201	8	203	11.0612	1.2209	442	9.06	<.0001	0.1	9.0487	13.0736
EGSTMNUM*LEG_SORT	1	201	12	201	3.0152	1.0407	1176	2.90	0.0038	0.1	1.3021	4.7283
EGSTMNUM*LEG_SORT	1	201	12	202	2.4506	1.2243	436	2.00	0.0459	0.1	0.4325	4.4687
EGSTMNUM*LEG_SORT	1	201	12	203	8.6895	1.2209	442	7.12	<.0001	0.1	6.6770	10.7019
EGSTMNUM*LEG_SORT	1	201	24	201	-0.1041	1.0400	1178	-0.10	0.9203	0.1	-1.8161	1.6079
EGSTMNUM*LEG_SORT	1	201	24	202	1.5996	1.2243	436	1.31	0.1920	0.1	-0.4184	3.6177
EGSTMNUM*LEG_SORT	1	201	24	203	7.2630	1.2209	442	5.95	<.0001	0.1	5.2506	9.2754
EGSTMNUM*LEG_SORT	1	202	1	203	11.7345	1.2223	440	9.60	<.0001	0.1	9.7197	13.7492
EGSTMNUM*LEG_SORT	1	202	2	201	3.3734	1.2243	436	2.76	0.0061	0.1	1.3554	5.3915
EGSTMNUM*LEG_SORT	1	202	2	202	-0.9957	1.0407	1176	-0.96	0.3389	0.1	-2.7088	0.7174
EGSTMNUM*LEG_SORT	1	202	2	203	11.3581	1.2223	440	9.29	<.0001	0.1	9.3434	13.3729
EGSTMNUM*LEG_SORT	1	202	3	201	2.4704	1.2243	436	2.02	0.0442	0.1	0.4523	4.4884
EGSTMNUM*LEG_SORT	1	202	3	202	-1.4670	1.0407	1176	-1.41	0.1589	0.1	-3.1800	0.2461
EGSTMNUM*LEG_SORT	1	202	3	203	10.4235	1.2223	440	8.53	<.0001	0.1	8.4088	12.4383
EGSTMNUM*LEG_SORT	1	202	4	201	0.7218	1.2243	436	0.59	0.5558	0.1	-1.2962	2.7399
EGSTMNUM*LEG_SORT	1	202	4	202	-2.8729	1.0407	1176	-2.76	0.0059	0.1	-4.5860	-1.1598
EGSTMNUM*LEG_SORT	1	202	4	203	10.4583	1.2223	440	8.56	<.0001	0.1	8.4436	12.4731
EGSTMNUM*LEG_SORT	1	202	5	201	7.2564	1.2243	436	5.93	<.0001	0.1	5.2384	9.2745
EGSTMNUM*LEG_SORT	1	202	5	202	5.2386	1.0407	1176	5.03	<.0001	0.1	3.5255	6.9517
EGSTMNUM*LEG_SORT	1	202	5	203	14.8079	1.2223	440	12.11	<.0001	0.1	12.7932	16.8227
EGSTMNUM*LEG_SORT	1	202	6	201	9.6103	1.2243	436	7.85	<.0001	0.1	7.5923	11.6284
EGSTMNUM*LEG_SORT	1	202	6	202	7.1504	1.0407	1176	6.87	<.0001	0.1	5.4374	8.8635
EGSTMNUM*LEG_SORT	1	202	6	203	16.2237	1.2223	440	13.27	<.0001	0.1	14.2089	18.2384
EGSTMNUM*LEG_SORT	1	202	8	201	10.0330	1.2243	436	8.19	<.0001	0.1	8.0150	12.0511
EGSTMNUM*LEG_SORT	1	202	8	202	8.0808	1.0407	1176	7.77	<.0001	0.1	6.3677	9.7938
EGSTMNUM*LEG_SORT	1	202	8	203	15.6938	1.2223	440	12.84	<.0001	0.1	13.6791	17.7086
EGSTMNUM*LEG_SORT	1	202	12	201	7.6479	1.2243	436	6.25	<.0001	0.1	5.6298	9.6660
EGSTMNUM*LEG_SORT	1	202	12	202	7.0833	1.0407	1176	6.81	<.0001	0.1	5.3702	8.7964
EGSTMNUM*LEG_SORT	1	202	12	203	13.3221	1.2223	440	10.90	<.0001	0.1	11.3074	15.3369

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	24	201	4.5286	1.2232	439	3.70	0.0002	0.1	2.5123	6.5449
EGSTMNUM*LEG_SORT	1	202	24	202	6.2323	1.0407	1176	5.99	<.0001	0.1	4.5192	7.9454
EGSTMNUM*LEG_SORT	1	202	24	203	11.8957	1.2223	440	9.73	<.0001	0.1	9.8809	13.9104
EGSTMNUM*LEG_SORT	1	203	2	201	-8.3610	1.2209	442	-6.85	<.0001	0.1	-10.3734	-6.3486
EGSTMNUM*LEG_SORT	1	203	2	202	-12.7302	1.2223	440	-10.41	<.0001	0.1	-14.7449	-10.7154
EGSTMNUM*LEG_SORT	1	203	2	203	-0.3763	1.0407	1176	-0.36	0.7177	0.1	-2.0894	1.3368
EGSTMNUM*LEG_SORT	1	203	3	201	-9.2641	1.2209	442	-7.59	<.0001	0.1	-11.2765	-7.2517
EGSTMNUM*LEG_SORT	1	203	3	202	-13.2014	1.2223	440	-10.80	<.0001	0.1	-15.2162	-11.1867
EGSTMNUM*LEG_SORT	1	203	3	203	-1.3109	1.0407	1176	-1.26	0.2080	0.1	-3.0240	0.4022
EGSTMNUM*LEG_SORT	1	203	4	201	-11.0127	1.2209	442	-9.02	<.0001	0.1	-13.0251	-9.0002
EGSTMNUM*LEG_SORT	1	203	4	202	-14.6073	1.2223	440	-11.95	<.0001	0.1	-16.6221	-12.5926
EGSTMNUM*LEG_SORT	1	203	4	203	-1.2761	1.0407	1176	-1.23	0.2203	0.1	-2.9892	0.4369
EGSTMNUM*LEG_SORT	1	203	5	201	-4.4781	1.2209	442	-3.67	0.0003	0.1	-6.4905	-2.4656
EGSTMNUM*LEG_SORT	1	203	5	202	-6.4959	1.2223	440	-5.31	<.0001	0.1	-8.5106	-4.4811
EGSTMNUM*LEG_SORT	1	203	5	203	3.0735	1.0407	1176	2.95	0.0032	0.1	1.3604	4.7866
EGSTMNUM*LEG_SORT	1	203	6	201	-2.1241	1.2209	442	-1.74	0.0826	0.1	-4.1365	-0.1117
EGSTMNUM*LEG_SORT	1	203	6	202	-4.5840	1.2223	440	-3.75	0.0002	0.1	-6.5988	-2.5692
EGSTMNUM*LEG_SORT	1	203	6	203	4.4892	1.0407	1176	4.31	<.0001	0.1	2.7761	6.2023
EGSTMNUM*LEG_SORT	1	203	8	201	-1.7014	1.2209	442	-1.39	0.1641	0.1	-3.7139	0.3110
EGSTMNUM*LEG_SORT	1	203	8	202	-3.6537	1.2223	440	-2.99	0.0030	0.1	-5.6685	-1.6389
EGSTMNUM*LEG_SORT	1	203	8	203	3.9594	1.0407	1176	3.80	0.0001	0.1	2.2463	5.6725
EGSTMNUM*LEG_SORT	1	203	12	201	-4.0866	1.2209	442	-3.35	0.0009	0.1	-6.0990	-2.0742
EGSTMNUM*LEG_SORT	1	203	12	202	-4.6512	1.2223	440	-3.81	0.0002	0.1	-6.6659	-2.6364
EGSTMNUM*LEG_SORT	1	203	12	203	1.5877	1.0407	1176	1.53	0.1274	0.1	-0.1254	3.3008
EGSTMNUM*LEG_SORT	1	203	24	201	-7.2058	1.2200	444	-5.91	<.0001	0.1	-9.2167	-5.1950
EGSTMNUM*LEG_SORT	1	203	24	202	-5.5022	1.2223	440	-4.50	<.0001	0.1	-7.5169	-3.4874
EGSTMNUM*LEG_SORT	1	203	24	203	0.1612	1.0407	1176	0.15	0.8769	0.1	-1.5519	1.8743
EGSTMNUM*LEG_SORT	2	201	2	202	-4.3691	1.2243	436	-3.57	0.0004	0.1	-6.3872	-2.3511
EGSTMNUM*LEG_SORT	2	201	2	203	7.9847	1.2209	442	6.54	<.0001	0.1	5.9723	9.9971
EGSTMNUM*LEG_SORT	2	201	3	201	-0.9031	1.0407	1176	-0.87	0.3857	0.1	-2.6162	0.8100
EGSTMNUM*LEG_SORT	2	201	3	202	-4.8404	1.2243	436	-3.95	<.0001	0.1	-6.8585	-2.8223
EGSTMNUM*LEG_SORT	2	201	3	203	7.0501	1.2209	442	5.77	<.0001	0.1	5.0377	9.0625
EGSTMNUM*LEG_SORT	2	201	4	201	-2.6516	1.0407	1176	-2.55	0.0110	0.1	-4.3647	-0.9385
EGSTMNUM*LEG_SORT	2	201	4	202	-6.2463	1.2243	436	-5.10	<.0001	0.1	-8.2644	-4.2283
EGSTMNUM*LEG_SORT	2	201	4	203	7.0849	1.2209	442	5.80	<.0001	0.1	5.0725	9.0973

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	5	201	3.8830	1.0407	1176	3.73	0.0002	0.1	2.1699	5.5961
EGSTMNUM*LEG_SORT	2	201	5	202	1.8652	1.2243	436	1.52	0.1284	0.1	-0.1529	3.8832
EGSTMNUM*LEG_SORT	2	201	5	203	11.4345	1.2209	442	9.37	<.0001	0.1	9.4221	13.4469
EGSTMNUM*LEG_SORT	2	201	6	201	6.2369	1.0407	1176	5.99	<.0001	0.1	4.5238	7.9500
EGSTMNUM*LEG_SORT	2	201	6	202	3.7770	1.2243	436	3.09	0.0022	0.1	1.7589	5.7951
EGSTMNUM*LEG_SORT	2	201	6	203	12.8502	1.2209	442	10.53	<.0001	0.1	10.8378	14.8626
EGSTMNUM*LEG_SORT	2	201	8	201	6.6596	1.0407	1176	6.40	<.0001	0.1	4.9465	8.3727
EGSTMNUM*LEG_SORT	2	201	8	202	4.7073	1.2243	436	3.84	0.0001	0.1	2.6893	6.7254
EGSTMNUM*LEG_SORT	2	201	8	203	12.3204	1.2209	442	10.09	<.0001	0.1	10.3080	14.3328
EGSTMNUM*LEG_SORT	2	201	12	201	4.2745	1.0407	1176	4.11	<.0001	0.1	2.5614	5.9875
EGSTMNUM*LEG_SORT	2	201	12	202	3.7099	1.2243	436	3.03	0.0026	0.1	1.6918	5.7279
EGSTMNUM*LEG_SORT	2	201	12	203	9.9487	1.2209	442	8.15	<.0001	0.1	7.9363	11.9611
EGSTMNUM*LEG_SORT	2	201	24	201	1.1552	1.0400	1178	1.11	0.2669	0.1	-0.5568	2.8672
EGSTMNUM*LEG_SORT	2	201	24	202	2.8589	1.2243	436	2.34	0.0200	0.1	0.8408	4.8769
EGSTMNUM*LEG_SORT	2	201	24	203	8.5222	1.2209	442	6.98	<.0001	0.1	6.5098	10.5346
EGSTMNUM*LEG_SORT	2	202	2	203	12.3538	1.2223	440	10.11	<.0001	0.1	10.3391	14.3686
EGSTMNUM*LEG_SORT	2	202	3	201	3.4660	1.2243	436	2.83	0.0049	0.1	1.4480	5.4841
EGSTMNUM*LEG_SORT	2	202	3	202	-0.4713	1.0407	1176	-0.45	0.6507	0.1	-2.1844	1.2418
EGSTMNUM*LEG_SORT	2	202	3	203	11.4192	1.2223	440	9.34	<.0001	0.1	9.4045	13.4340
EGSTMNUM*LEG_SORT	2	202	4	201	1.7175	1.2243	436	1.40	0.1614	0.1	-0.3006	3.7356
EGSTMNUM*LEG_SORT	2	202	4	202	-1.8772	1.0407	1176	-1.80	0.0715	0.1	-3.5903	-0.1641
EGSTMNUM*LEG_SORT	2	202	4	203	11.4540	1.2223	440	9.37	<.0001	0.1	9.4392	13.4688
EGSTMNUM*LEG_SORT	2	202	5	201	8.2521	1.2243	436	6.74	<.0001	0.1	6.2340	10.2702
EGSTMNUM*LEG_SORT	2	202	5	202	6.2343	1.0407	1176	5.99	<.0001	0.1	4.5212	7.9474
EGSTMNUM*LEG_SORT	2	202	5	203	15.8036	1.2223	440	12.93	<.0001	0.1	13.7889	17.8184
EGSTMNUM*LEG_SORT	2	202	6	201	10.6060	1.2243	436	8.66	<.0001	0.1	8.5880	12.6241
EGSTMNUM*LEG_SORT	2	202	6	202	8.1461	1.0407	1176	7.83	<.0001	0.1	6.4330	9.8592
EGSTMNUM*LEG_SORT	2	202	6	203	17.2194	1.2223	440	14.09	<.0001	0.1	15.2046	19.2341
EGSTMNUM*LEG_SORT	2	202	8	201	11.0287	1.2243	436	9.01	<.0001	0.1	9.0106	13.0468
EGSTMNUM*LEG_SORT	2	202	8	202	9.0765	1.0407	1176	8.72	<.0001	0.1	7.3634	10.7895
EGSTMNUM*LEG_SORT	2	202	8	203	16.6895	1.2223	440	13.65	<.0001	0.1	14.6748	18.7043
EGSTMNUM*LEG_SORT	2	202	12	201	8.6436	1.2243	436	7.06	<.0001	0.1	6.6255	10.6616
EGSTMNUM*LEG_SORT	2	202	12	202	8.0790	1.0407	1176	7.76	<.0001	0.1	6.3659	9.7921
EGSTMNUM*LEG_SORT	2	202	12	203	14.3178	1.2223	440	11.71	<.0001	0.1	12.3031	16.3326
EGSTMNUM*LEG_SORT	2	202	24	201	5.5243	1.2232	439	4.52	<.0001	0.1	3.5080	7.5406

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	202	24	202	7.2280	1.0407	1176	6.95	<.0001	0.1	5.5149	8.9411
EGSTMNUM*LEG_SORT	2	202	24	203	12.8914	1.2223	440	10.55	<.0001	0.1	10.8766	14.9061
EGSTMNUM*LEG_SORT	2	203	3	201	-8.8878	1.2209	442	-7.28	<.0001	0.1	-10.9002	-6.8754
EGSTMNUM*LEG_SORT	2	203	3	202	-12.8251	1.2223	440	-10.49	<.0001	0.1	-14.8399	-10.8103
EGSTMNUM*LEG_SORT	2	203	3	203	-0.9346	1.0407	1176	-0.90	0.3693	0.1	-2.6477	0.7785
EGSTMNUM*LEG_SORT	2	203	4	201	-10.6363	1.2209	442	-8.71	<.0001	0.1	-12.6487	-8.6239
EGSTMNUM*LEG_SORT	2	203	4	202	-14.2310	1.2223	440	-11.64	<.0001	0.1	-16.2458	-12.2162
EGSTMNUM*LEG_SORT	2	203	4	203	-0.8998	1.0407	1176	-0.86	0.3874	0.1	-2.6129	0.8133
EGSTMNUM*LEG_SORT	2	203	5	201	-4.1017	1.2209	442	-3.36	0.0008	0.1	-6.1141	-2.0893
EGSTMNUM*LEG_SORT	2	203	5	202	-6.1195	1.2223	440	-5.01	<.0001	0.1	-8.1343	-4.1048
EGSTMNUM*LEG_SORT	2	203	5	203	3.4498	1.0407	1176	3.32	0.0009	0.1	1.7367	5.1629
EGSTMNUM*LEG_SORT	2	203	6	201	-1.7478	1.2209	442	-1.43	0.1530	0.1	-3.7602	0.2646
EGSTMNUM*LEG_SORT	2	203	6	202	-4.2077	1.2223	440	-3.44	0.0006	0.1	-6.2225	-2.1929
EGSTMNUM*LEG_SORT	2	203	6	203	4.8655	1.0407	1176	4.68	<.0001	0.1	3.1525	6.5786
EGSTMNUM*LEG_SORT	2	203	8	201	-1.3251	1.2209	442	-1.09	0.2783	0.1	-3.3375	0.6873
EGSTMNUM*LEG_SORT	2	203	8	202	-3.2774	1.2223	440	-2.68	0.0076	0.1	-5.2921	-1.2626
EGSTMNUM*LEG_SORT	2	203	8	203	4.3357	1.0407	1176	4.17	<.0001	0.1	2.6226	6.0488
EGSTMNUM*LEG_SORT	2	203	12	201	-3.7102	1.2209	442	-3.04	0.0025	0.1	-5.7226	-1.6978
EGSTMNUM*LEG_SORT	2	203	12	202	-4.2748	1.2223	440	-3.50	0.0005	0.1	-6.2896	-2.2601
EGSTMNUM*LEG_SORT	2	203	12	203	1.9640	1.0407	1176	1.89	0.0594	0.1	0.2509	3.6771
EGSTMNUM*LEG_SORT	2	203	24	201	-6.8295	1.2200	444	-5.60	<.0001	0.1	-8.8404	-4.8186
EGSTMNUM*LEG_SORT	2	203	24	202	-5.1258	1.2223	440	-4.19	<.0001	0.1	-7.1406	-3.1111
EGSTMNUM*LEG_SORT	2	203	24	203	0.5375	1.0407	1176	0.52	0.6056	0.1	-1.1756	2.2506
EGSTMNUM*LEG_SORT	3	201	3	202	-3.9373	1.2243	436	-3.22	0.0014	0.1	-5.9554	-1.9193
EGSTMNUM*LEG_SORT	3	201	3	203	7.9532	1.2209	442	6.51	<.0001	0.1	5.9408	9.9656
EGSTMNUM*LEG_SORT	3	201	4	201	-1.7485	1.0407	1176	-1.68	0.0932	0.1	-3.4616	-0.03546
EGSTMNUM*LEG_SORT	3	201	4	202	-5.3432	1.2243	436	-4.36	<.0001	0.1	-7.3613	-3.3252
EGSTMNUM*LEG_SORT	3	201	4	203	7.9880	1.2209	442	6.54	<.0001	0.1	5.9756	10.0004
EGSTMNUM*LEG_SORT	3	201	5	201	4.7861	1.0407	1176	4.60	<.0001	0.1	3.0730	6.4991
EGSTMNUM*LEG_SORT	3	201	5	202	2.7682	1.2243	436	2.26	0.0242	0.1	0.7502	4.7863
EGSTMNUM*LEG_SORT	3	201	5	203	12.3376	1.2209	442	10.11	<.0001	0.1	10.3252	14.3500
EGSTMNUM*LEG_SORT	3	201	6	201	7.1400	1.0407	1176	6.86	<.0001	0.1	5.4269	8.8531
EGSTMNUM*LEG_SORT	3	201	6	202	4.6801	1.2243	436	3.82	0.0002	0.1	2.6620	6.6981
EGSTMNUM*LEG_SORT	3	201	6	203	13.7533	1.2209	442	11.27	<.0001	0.1	11.7409	15.7657
EGSTMNUM*LEG_SORT	3	201	8	201	7.5627	1.0407	1176	7.27	<.0001	0.1	5.8496	9.2757

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	8	202	5.6104	1.2243	436	4.58	<.0001	0.1	3.5923	7.6285
EGSTMNUM*LEG_SORT	3	201	8	203	13.2235	1.2209	442	10.83	<.0001	0.1	11.2111	15.2359
EGSTMNUM*LEG_SORT	3	201	12	201	5.1775	1.0407	1176	4.98	<.0001	0.1	3.4645	6.8906
EGSTMNUM*LEG_SORT	3	201	12	202	4.6129	1.2243	436	3.77	0.0002	0.1	2.5949	6.6310
EGSTMNUM*LEG_SORT	3	201	12	203	10.8518	1.2209	442	8.89	<.0001	0.1	8.8394	12.8642
EGSTMNUM*LEG_SORT	3	201	24	201	2.0583	1.0400	1178	1.98	0.0480	0.1	0.3462	3.7703
EGSTMNUM*LEG_SORT	3	201	24	202	3.7619	1.2243	436	3.07	0.0023	0.1	1.7439	5.7800
EGSTMNUM*LEG_SORT	3	201	24	203	9.4253	1.2209	442	7.72	<.0001	0.1	7.4129	11.4377
EGSTMNUM*LEG_SORT	3	202	3	203	11.8905	1.2223	440	9.73	<.0001	0.1	9.8757	13.9053
EGSTMNUM*LEG_SORT	3	202	4	201	2.1888	1.2243	436	1.79	0.0745	0.1	0.1707	4.2068
EGSTMNUM*LEG_SORT	3	202	4	202	-1.4059	1.0407	1176	-1.35	0.1770	0.1	-3.1190	0.3072
EGSTMNUM*LEG_SORT	3	202	4	203	11.9253	1.2223	440	9.76	<.0001	0.1	9.9105	13.9401
EGSTMNUM*LEG_SORT	3	202	5	201	8.7234	1.2243	436	7.13	<.0001	0.1	6.7053	10.7414
EGSTMNUM*LEG_SORT	3	202	5	202	6.7056	1.0407	1176	6.44	<.0001	0.1	4.9925	8.4186
EGSTMNUM*LEG_SORT	3	202	5	203	16.2749	1.2223	440	13.31	<.0001	0.1	14.2601	18.2897
EGSTMNUM*LEG_SORT	3	202	6	201	11.0773	1.2243	436	9.05	<.0001	0.1	9.0592	13.0954
EGSTMNUM*LEG_SORT	3	202	6	202	8.6174	1.0407	1176	8.28	<.0001	0.1	6.9043	10.3305
EGSTMNUM*LEG_SORT	3	202	6	203	17.6906	1.2223	440	14.47	<.0001	0.1	15.6759	19.7054
EGSTMNUM*LEG_SORT	3	202	8	201	11.5000	1.2243	436	9.39	<.0001	0.1	9.4819	13.5180
EGSTMNUM*LEG_SORT	3	202	8	202	9.5477	1.0407	1176	9.17	<.0001	0.1	7.8346	11.2608
EGSTMNUM*LEG_SORT	3	202	8	203	17.1608	1.2223	440	14.04	<.0001	0.1	15.1460	19.1756
EGSTMNUM*LEG_SORT	3	202	12	201	9.1149	1.2243	436	7.45	<.0001	0.1	7.0968	11.1329
EGSTMNUM*LEG_SORT	3	202	12	202	8.5503	1.0407	1176	8.22	<.0001	0.1	6.8372	10.2633
EGSTMNUM*LEG_SORT	3	202	12	203	14.7891	1.2223	440	12.10	<.0001	0.1	12.7743	16.8039
EGSTMNUM*LEG_SORT	3	202	24	201	5.9956	1.2232	439	4.90	<.0001	0.1	3.9793	8.0119
EGSTMNUM*LEG_SORT	3	202	24	202	7.6993	1.0407	1176	7.40	<.0001	0.1	5.9862	9.4123
EGSTMNUM*LEG_SORT	3	202	24	203	13.3626	1.2223	440	10.93	<.0001	0.1	11.3479	15.3774
EGSTMNUM*LEG_SORT	3	203	4	201	-9.7017	1.2209	442	-7.95	<.0001	0.1	-11.7141	-7.6893
EGSTMNUM*LEG_SORT	3	203	4	202	-13.2964	1.2223	440	-10.88	<.0001	0.1	-15.3112	-11.2817
EGSTMNUM*LEG_SORT	3	203	4	203	0.03478	1.0407	1176	0.03	0.9733	0.1	-1.6783	1.7479
EGSTMNUM*LEG_SORT	3	203	5	201	-3.1671	1.2209	442	-2.59	0.0098	0.1	-5.1795	-1.1547
EGSTMNUM*LEG_SORT	3	203	5	202	-5.1849	1.2223	440	-4.24	<.0001	0.1	-7.1997	-3.1702
EGSTMNUM*LEG_SORT	3	203	5	203	4.3844	1.0407	1176	4.21	<.0001	0.1	2.6713	6.0975
EGSTMNUM*LEG_SORT	3	203	6	201	-0.8132	1.2209	442	-0.67	0.5057	0.1	-2.8256	1.1992
EGSTMNUM*LEG_SORT	3	203	6	202	-3.2731	1.2223	440	-2.68	0.0077	0.1	-5.2879	-1.2583

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	6	203	5.8001	1.0407	1176	5.57	<.0001	0.1	4.0870	7.5132
EGSTMNUM*LEG_SORT	3	203	8	201	-0.3905	1.2209	442	-0.32	0.7492	0.1	-2.4029	1.6219
EGSTMNUM*LEG_SORT	3	203	8	202	-2.3428	1.2223	440	-1.92	0.0559	0.1	-4.3576	-0.3280
EGSTMNUM*LEG_SORT	3	203	8	203	5.2703	1.0407	1176	5.06	<.0001	0.1	3.5572	6.9834
EGSTMNUM*LEG_SORT	3	203	12	201	-2.7756	1.2209	442	-2.27	0.0235	0.1	-4.7880	-0.7632
EGSTMNUM*LEG_SORT	3	203	12	202	-3.3403	1.2223	440	-2.73	0.0065	0.1	-5.3550	-1.3255
EGSTMNUM*LEG_SORT	3	203	12	203	2.8986	1.0407	1176	2.79	0.0054	0.1	1.1855	4.6117
EGSTMNUM*LEG_SORT	3	203	24	201	-5.8949	1.2200	444	-4.83	<.0001	0.1	-7.9058	-3.8840
EGSTMNUM*LEG_SORT	3	203	24	202	-4.1912	1.2223	440	-3.43	0.0007	0.1	-6.2060	-2.1765
EGSTMNUM*LEG_SORT	3	203	24	203	1.4721	1.0407	1176	1.41	0.1575	0.1	-0.2410	3.1852
EGSTMNUM*LEG_SORT	4	201	4	202	-3.5947	1.2243	436	-2.94	0.0035	0.1	-5.6127	-1.5766
EGSTMNUM*LEG_SORT	4	201	4	203	9.7365	1.2209	442	7.97	<.0001	0.1	7.7241	11.7489
EGSTMNUM*LEG_SORT	4	201	5	201	6.5346	1.0407	1176	6.28	<.0001	0.1	4.8215	8.2477
EGSTMNUM*LEG_SORT	4	201	5	202	4.5168	1.2243	436	3.69	0.0003	0.1	2.4987	6.5348
EGSTMNUM*LEG_SORT	4	201	5	203	14.0861	1.2209	442	11.54	<.0001	0.1	12.0737	16.0985
EGSTMNUM*LEG_SORT	4	201	6	201	8.8885	1.0407	1176	8.54	<.0001	0.1	7.1754	10.6016
EGSTMNUM*LEG_SORT	4	201	6	202	6.4286	1.2243	436	5.25	<.0001	0.1	4.4106	8.4467
EGSTMNUM*LEG_SORT	4	201	6	203	15.5019	1.2209	442	12.70	<.0001	0.1	13.4895	17.5143
EGSTMNUM*LEG_SORT	4	201	8	201	9.3112	1.0407	1176	8.95	<.0001	0.1	7.5981	11.0243
EGSTMNUM*LEG_SORT	4	201	8	202	7.3589	1.2243	436	6.01	<.0001	0.1	5.3409	9.3770
EGSTMNUM*LEG_SORT	4	201	8	203	14.9720	1.2209	442	12.26	<.0001	0.1	12.9596	16.9844
EGSTMNUM*LEG_SORT	4	201	12	201	6.9261	1.0407	1176	6.66	<.0001	0.1	5.2130	8.6392
EGSTMNUM*LEG_SORT	4	201	12	202	6.3615	1.2243	436	5.20	<.0001	0.1	4.3434	8.3795
EGSTMNUM*LEG_SORT	4	201	12	203	12.6003	1.2209	442	10.32	<.0001	0.1	10.5879	14.6127
EGSTMNUM*LEG_SORT	4	201	24	201	3.8068	1.0400	1178	3.66	0.0003	0.1	2.0948	5.5188
EGSTMNUM*LEG_SORT	4	201	24	202	5.5105	1.2243	436	4.50	<.0001	0.1	3.4924	7.5285
EGSTMNUM*LEG_SORT	4	201	24	203	11.1738	1.2209	442	9.15	<.0001	0.1	9.1614	13.1863
EGSTMNUM*LEG_SORT	4	202	4	203	13.3312	1.2223	440	10.91	<.0001	0.1	11.3164	15.3460
EGSTMNUM*LEG_SORT	4	202	5	201	10.1293	1.2243	436	8.27	<.0001	0.1	8.1112	12.1473
EGSTMNUM*LEG_SORT	4	202	5	202	8.1115	1.0407	1176	7.79	<.0001	0.1	6.3984	9.8246
EGSTMNUM*LEG_SORT	4	202	5	203	17.6808	1.2223	440	14.47	<.0001	0.1	15.6660	19.6956
EGSTMNUM*LEG_SORT	4	202	6	201	12.4832	1.2243	436	10.20	<.0001	0.1	10.4652	14.5013
EGSTMNUM*LEG_SORT	4	202	6	202	10.0233	1.0407	1176	9.63	<.0001	0.1	8.3102	11.7364
EGSTMNUM*LEG_SORT	4	202	6	203	19.0966	1.2223	440	15.62	<.0001	0.1	17.0818	21.1113
EGSTMNUM*LEG_SORT	4	202	8	201	12.9059	1.2243	436	10.54	<.0001	0.1	10.8878	14.9239

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	8	202	10.9536	1.0407	1176	10.53	<.0001	0.1	9.2406	12.6667
EGSTMNUM*LEG_SORT	4	202	8	203	18.5667	1.2223	440	15.19	<.0001	0.1	16.5520	20.5815
EGSTMNUM*LEG_SORT	4	202	12	201	10.5208	1.2243	436	8.59	<.0001	0.1	8.5027	12.5388
EGSTMNUM*LEG_SORT	4	202	12	202	9.9562	1.0407	1176	9.57	<.0001	0.1	8.2431	11.6693
EGSTMNUM*LEG_SORT	4	202	12	203	16.1950	1.2223	440	13.25	<.0001	0.1	14.1802	18.2098
EGSTMNUM*LEG_SORT	4	202	24	201	7.4015	1.2232	439	6.05	<.0001	0.1	5.3852	9.4178
EGSTMNUM*LEG_SORT	4	202	24	202	9.1052	1.0407	1176	8.75	<.0001	0.1	7.3921	10.8183
EGSTMNUM*LEG_SORT	4	202	24	203	14.7685	1.2223	440	12.08	<.0001	0.1	12.7538	16.7833
EGSTMNUM*LEG_SORT	4	203	5	201	-3.2019	1.2209	442	-2.62	0.0090	0.1	-5.2143	-1.1895
EGSTMNUM*LEG_SORT	4	203	5	202	-5.2197	1.2223	440	-4.27	<.0001	0.1	-7.2345	-3.2049
EGSTMNUM*LEG_SORT	4	203	5	203	4.3496	1.0407	1176	4.18	<.0001	0.1	2.6365	6.0627
EGSTMNUM*LEG_SORT	4	203	6	201	-0.8480	1.2209	442	-0.69	0.4877	0.1	-2.8604	1.1644
EGSTMNUM*LEG_SORT	4	203	6	202	-3.3079	1.2223	440	-2.71	0.0071	0.1	-5.3227	-1.2931
EGSTMNUM*LEG_SORT	4	203	6	203	5.7653	1.0407	1176	5.54	<.0001	0.1	4.0523	7.4784
EGSTMNUM*LEG_SORT	4	203	8	201	-0.4253	1.2209	442	-0.35	0.7277	0.1	-2.4377	1.5871
EGSTMNUM*LEG_SORT	4	203	8	202	-2.3776	1.2223	440	-1.95	0.0524	0.1	-4.3923	-0.3628
EGSTMNUM*LEG_SORT	4	203	8	203	5.2355	1.0407	1176	5.03	<.0001	0.1	3.5224	6.9486
EGSTMNUM*LEG_SORT	4	203	12	201	-2.8104	1.2209	442	-2.30	0.0218	0.1	-4.8228	-0.7980
EGSTMNUM*LEG_SORT	4	203	12	202	-3.3750	1.2223	440	-2.76	0.0060	0.1	-5.3898	-1.3603
EGSTMNUM*LEG_SORT	4	203	12	203	2.8638	1.0407	1176	2.75	0.0060	0.1	1.1507	4.5769
EGSTMNUM*LEG_SORT	4	203	24	201	-5.9297	1.2200	444	-4.86	<.0001	0.1	-7.9406	-3.9188
EGSTMNUM*LEG_SORT	4	203	24	202	-4.2260	1.2223	440	-3.46	0.0006	0.1	-6.2408	-2.2113
EGSTMNUM*LEG_SORT	4	203	24	203	1.4373	1.0407	1176	1.38	0.1675	0.1	-0.2757	3.1504
EGSTMNUM*LEG_SORT	5	201	5	202	-2.0178	1.2243	436	-1.65	0.1000	0.1	-4.0359	0.000250
EGSTMNUM*LEG_SORT	5	201	5	203	7.5515	1.2209	442	6.19	<.0001	0.1	5.5391	9.5639
EGSTMNUM*LEG_SORT	5	201	6	201	2.3539	1.0407	1176	2.26	0.0239	0.1	0.6408	4.0670
EGSTMNUM*LEG_SORT	5	201	6	202	-0.1060	1.2243	436	-0.09	0.9311	0.1	-2.1240	1.9121
EGSTMNUM*LEG_SORT	5	201	6	203	8.9673	1.2209	442	7.34	<.0001	0.1	6.9549	10.9797
EGSTMNUM*LEG_SORT	5	201	8	201	2.7766	1.0407	1176	2.67	0.0077	0.1	1.0635	4.4897
EGSTMNUM*LEG_SORT	5	201	8	202	0.8244	1.2243	436	0.67	0.5011	0.1	-1.1937	2.8424
EGSTMNUM*LEG_SORT	5	201	8	203	8.4374	1.2209	442	6.91	<.0001	0.1	6.4250	10.4498
EGSTMNUM*LEG_SORT	5	201	12	201	0.3915	1.0407	1176	0.38	0.7068	0.1	-1.3216	2.1046
EGSTMNUM*LEG_SORT	5	201	12	202	-0.1731	1.2243	436	-0.14	0.8876	0.1	-2.1912	1.8449
EGSTMNUM*LEG_SORT	5	201	12	203	6.0657	1.2209	442	4.97	<.0001	0.1	4.0533	8.0781
EGSTMNUM*LEG_SORT	5	201	24	201	-2.7278	1.0400	1178	-2.62	0.0088	0.1	-4.4398	-1.0158

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	201	24	202	-1.0241	1.2243	436	-0.84	0.4033	0.1	-3.0422	0.9939
EGSTMNUM*LEG_SORT	5	201	24	203	4.6393	1.2209	442	3.80	0.0002	0.1	2.6268	6.6517
EGSTMNUM*LEG_SORT	5	202	5	203	9.5693	1.2223	440	7.83	<.0001	0.1	7.5546	11.5841
EGSTMNUM*LEG_SORT	5	202	6	201	4.3717	1.2243	436	3.57	0.0004	0.1	2.3537	6.3898
EGSTMNUM*LEG_SORT	5	202	6	202	1.9118	1.0407	1176	1.84	0.0664	0.1	0.1988	3.6249
EGSTMNUM*LEG_SORT	5	202	6	203	10.9851	1.2223	440	8.99	<.0001	0.1	8.9703	12.9998
EGSTMNUM*LEG_SORT	5	202	8	201	4.7944	1.2243	436	3.92	0.0001	0.1	2.7764	6.8125
EGSTMNUM*LEG_SORT	5	202	8	202	2.8422	1.0407	1176	2.73	0.0064	0.1	1.1291	4.5552
EGSTMNUM*LEG_SORT	5	202	8	203	10.4552	1.2223	440	8.55	<.0001	0.1	8.4405	12.4700
EGSTMNUM*LEG_SORT	5	202	12	201	2.4093	1.2243	436	1.97	0.0497	0.1	0.3912	4.4274
EGSTMNUM*LEG_SORT	5	202	12	202	1.8447	1.0407	1176	1.77	0.0766	0.1	0.1316	3.5578
EGSTMNUM*LEG_SORT	5	202	12	203	8.0835	1.2223	440	6.61	<.0001	0.1	6.0688	10.0983
EGSTMNUM*LEG_SORT	5	202	24	201	-0.7100	1.2232	439	-0.58	0.5619	0.1	-2.7263	1.3063
EGSTMNUM*LEG_SORT	5	202	24	202	0.9937	1.0407	1176	0.95	0.3398	0.1	-0.7194	2.7068
EGSTMNUM*LEG_SORT	5	202	24	203	6.6571	1.2223	440	5.45	<.0001	0.1	4.6423	8.6718
EGSTMNUM*LEG_SORT	5	203	6	201	-5.1976	1.2209	442	-4.26	<.0001	0.1	-7.2100	-3.1852
EGSTMNUM*LEG_SORT	5	203	6	202	-7.6575	1.2223	440	-6.26	<.0001	0.1	-9.6723	-5.6427
EGSTMNUM*LEG_SORT	5	203	6	203	1.4157	1.0407	1176	1.36	0.1740	0.1	-0.2973	3.1288
EGSTMNUM*LEG_SORT	5	203	8	201	-4.7749	1.2209	442	-3.91	0.0001	0.1	-6.7873	-2.7625
EGSTMNUM*LEG_SORT	5	203	8	202	-6.7272	1.2223	440	-5.50	<.0001	0.1	-8.7419	-4.7124
EGSTMNUM*LEG_SORT	5	203	8	203	0.8859	1.0407	1176	0.85	0.3948	0.1	-0.8272	2.5990
EGSTMNUM*LEG_SORT	5	203	12	201	-7.1600	1.2209	442	-5.86	<.0001	0.1	-9.1724	-5.1476
EGSTMNUM*LEG_SORT	5	203	12	202	-7.7246	1.2223	440	-6.32	<.0001	0.1	-9.7394	-5.7099
EGSTMNUM*LEG_SORT	5	203	12	203	-1.4858	1.0407	1176	-1.43	0.1536	0.1	-3.1989	0.2273
EGSTMNUM*LEG_SORT	5	203	24	201	-10.2793	1.2200	444	-8.43	<.0001	0.1	-12.2902	-8.2684
EGSTMNUM*LEG_SORT	5	203	24	202	-8.5756	1.2223	440	-7.02	<.0001	0.1	-10.5904	-6.5609
EGSTMNUM*LEG_SORT	5	203	24	203	-2.9123	1.0407	1176	-2.80	0.0052	0.1	-4.6254	-1.1992
EGSTMNUM*LEG_SORT	6	201	6	202	-2.4599	1.2243	436	-2.01	0.0451	0.1	-4.4780	-0.4418
EGSTMNUM*LEG_SORT	6	201	6	203	6.6133	1.2209	442	5.42	<.0001	0.1	4.6009	8.6257
EGSTMNUM*LEG_SORT	6	201	8	201	0.4227	1.0407	1176	0.41	0.6847	0.1	-1.2904	2.1358
EGSTMNUM*LEG_SORT	6	201	8	202	-1.5296	1.2243	436	-1.25	0.2122	0.1	-3.5476	0.4885
EGSTMNUM*LEG_SORT	6	201	8	203	6.0835	1.2209	442	4.98	<.0001	0.1	4.0711	8.0959
EGSTMNUM*LEG_SORT	6	201	12	201	-1.9624	1.0407	1176	-1.89	0.0596	0.1	-3.6755	-0.2494
EGSTMNUM*LEG_SORT	6	201	12	202	-2.5270	1.2243	436	-2.06	0.0396	0.1	-4.5451	-0.5090
EGSTMNUM*LEG_SORT	6	201	12	203	3.7118	1.2209	442	3.04	0.0025	0.1	1.6994	5.7242

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	6	201	24	201	-5.0817	1.0400	1178	-4.89	<.0001	0.1	-6.7937	-3.3697
EGSTMNUM*LEG_SORT	6	201	24	202	-3.3780	1.2243	436	-2.76	0.0060	0.1	-5.3961	-1.3600
EGSTMNUM*LEG_SORT	6	201	24	203	2.2853	1.2209	442	1.87	0.0619	0.1	0.2729	4.2977
EGSTMNUM*LEG_SORT	6	202	6	203	9.0732	1.2223	440	7.42	<.0001	0.1	7.0585	11.0880
EGSTMNUM*LEG_SORT	6	202	8	201	2.8826	1.2243	436	2.35	0.0190	0.1	0.8645	4.9006
EGSTMNUM*LEG_SORT	6	202	8	202	0.9303	1.0407	1176	0.89	0.3715	0.1	-0.7828	2.6434
EGSTMNUM*LEG_SORT	6	202	8	203	8.5434	1.2223	440	6.99	<.0001	0.1	6.5286	10.5582
EGSTMNUM*LEG_SORT	6	202	12	201	0.4975	1.2243	436	0.41	0.6847	0.1	-1.5206	2.5155
EGSTMNUM*LEG_SORT	6	202	12	202	-0.06715	1.0407	1176	-0.06	0.9486	0.1	-1.7802	1.6459
EGSTMNUM*LEG_SORT	6	202	12	203	6.1717	1.2223	440	5.05	<.0001	0.1	4.1569	8.1865
EGSTMNUM*LEG_SORT	6	202	24	201	-2.6218	1.2232	439	-2.14	0.0326	0.1	-4.6381	-0.6055
EGSTMNUM*LEG_SORT	6	202	24	202	-0.9181	1.0407	1176	-0.88	0.3778	0.1	-2.6312	0.7949
EGSTMNUM*LEG_SORT	6	202	24	203	4.7452	1.2223	440	3.88	0.0001	0.1	2.7304	6.7600
EGSTMNUM*LEG_SORT	6	203	8	201	-6.1907	1.2209	442	-5.07	<.0001	0.1	-8.2031	-4.1783
EGSTMNUM*LEG_SORT	6	203	8	202	-8.1429	1.2223	440	-6.66	<.0001	0.1	-10.1577	-6.1281
EGSTMNUM*LEG_SORT	6	203	8	203	-0.5298	1.0407	1176	-0.51	0.6108	0.1	-2.2429	1.1833
EGSTMNUM*LEG_SORT	6	203	12	201	-8.5758	1.2209	442	-7.02	<.0001	0.1	-10.5882	-6.5634
EGSTMNUM*LEG_SORT	6	203	12	202	-9.1404	1.2223	440	-7.48	<.0001	0.1	-11.1552	-7.1256
EGSTMNUM*LEG_SORT	6	203	12	203	-2.9015	1.0407	1176	-2.79	0.0054	0.1	-4.6146	-1.1884
EGSTMNUM*LEG_SORT	6	203	24	201	-11.6951	1.2200	444	-9.59	<.0001	0.1	-13.7059	-9.6842
EGSTMNUM*LEG_SORT	6	203	24	202	-9.9914	1.2223	440	-8.17	<.0001	0.1	-12.0061	-7.9766
EGSTMNUM*LEG_SORT	6	203	24	203	-4.3280	1.0407	1176	-4.16	<.0001	0.1	-6.0411	-2.6149
EGSTMNUM*LEG_SORT	8	201	8	202	-1.9523	1.2243	436	-1.59	0.1115	0.1	-3.9703	0.06580
EGSTMNUM*LEG_SORT	8	201	8	203	5.6608	1.2209	442	4.64	<.0001	0.1	3.6484	7.6732
EGSTMNUM*LEG_SORT	8	201	12	201	-2.3851	1.0407	1176	-2.29	0.0221	0.1	-4.0982	-0.6720
EGSTMNUM*LEG_SORT	8	201	12	202	-2.9497	1.2243	436	-2.41	0.0164	0.1	-4.9678	-0.9317
EGSTMNUM*LEG_SORT	8	201	12	203	3.2891	1.2209	442	2.69	0.0073	0.1	1.2767	5.3015
EGSTMNUM*LEG_SORT	8	201	24	201	-5.5044	1.0400	1178	-5.29	<.0001	0.1	-7.2164	-3.7924
EGSTMNUM*LEG_SORT	8	201	24	202	-3.8007	1.2243	436	-3.10	0.0020	0.1	-5.8188	-1.7827
EGSTMNUM*LEG_SORT	8	201	24	203	1.8626	1.2209	442	1.53	0.1278	0.1	-0.1498	3.8751
EGSTMNUM*LEG_SORT	8	202	8	203	7.6131	1.2223	440	6.23	<.0001	0.1	5.5983	9.6279
EGSTMNUM*LEG_SORT	8	202	12	201	-0.4329	1.2243	436	-0.35	0.7238	0.1	-2.4509	1.5852
EGSTMNUM*LEG_SORT	8	202	12	202	-0.9975	1.0407	1176	-0.96	0.3380	0.1	-2.7106	0.7156
EGSTMNUM*LEG_SORT	8	202	12	203	5.2414	1.2223	440	4.29	<.0001	0.1	3.2266	7.2562
EGSTMNUM*LEG_SORT	8	202	24	201	-3.5521	1.2232	439	-2.90	0.0039	0.1	-5.5684	-1.5358

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Primary ECG Analysis Population

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	202	24	202	-1.8485	1.0407	1176	-1.78	0.0760	0.1	-3.5615	-0.1354
EGSTMNUM*LEG_SORT	8	202	24	203	3.8149	1.2223	440	3.12	0.0019	0.1	1.8001	5.8297
EGSTMNUM*LEG_SORT	8	203	12	201	-8.0459	1.2209	442	-6.59	<.0001	0.1	-10.0583	-6.0335
EGSTMNUM*LEG_SORT	8	203	12	202	-8.6106	1.2223	440	-7.04	<.0001	0.1	-10.6253	-6.5958
EGSTMNUM*LEG_SORT	8	203	12	203	-2.3717	1.0407	1176	-2.28	0.0228	0.1	-4.0848	-0.6586
EGSTMNUM*LEG_SORT	8	203	24	201	-11.1652	1.2200	444	-9.15	<.0001	0.1	-13.1761	-9.1543
EGSTMNUM*LEG_SORT	8	203	24	202	-9.4615	1.2223	440	-7.74	<.0001	0.1	-11.4763	-7.4468
EGSTMNUM*LEG_SORT	8	203	24	203	-3.7982	1.0407	1176	-3.65	0.0003	0.1	-5.5113	-2.0851
EGSTMNUM*LEG_SORT	12	201	12	202	-0.5646	1.2243	436	-0.46	0.6449	0.1	-2.5827	1.4534
EGSTMNUM*LEG_SORT	12	201	12	203	5.6742	1.2209	442	4.65	<.0001	0.1	3.6618	7.6866
EGSTMNUM*LEG_SORT	12	201	24	201	-3.1193	1.0400	1178	-3.00	0.0028	0.1	-4.8313	-1.4073
EGSTMNUM*LEG_SORT	12	201	24	202	-1.4156	1.2243	436	-1.16	0.2482	0.1	-3.4337	0.6025
EGSTMNUM*LEG_SORT	12	201	24	203	4.2478	1.2209	442	3.48	0.0006	0.1	2.2354	6.2602
EGSTMNUM*LEG_SORT	12	202	12	203	6.2388	1.2223	440	5.10	<.0001	0.1	4.2241	8.2536
EGSTMNUM*LEG_SORT	12	202	24	201	-2.5547	1.2232	439	-2.09	0.0373	0.1	-4.5710	-0.5384
EGSTMNUM*LEG_SORT	12	202	24	202	-0.8510	1.0407	1176	-0.82	0.4137	0.1	-2.5641	0.8621
EGSTMNUM*LEG_SORT	12	202	24	203	4.8124	1.2223	440	3.94	<.0001	0.1	2.7976	6.8271
EGSTMNUM*LEG_SORT	12	203	24	201	-8.7935	1.2200	444	-7.21	<.0001	0.1	-10.8044	-6.7826
EGSTMNUM*LEG_SORT	12	203	24	202	-7.0898	1.2223	440	-5.80	<.0001	0.1	-9.1046	-5.0751
EGSTMNUM*LEG_SORT	12	203	24	203	-1.4265	1.0407	1176	-1.37	0.1707	0.1	-3.1396	0.2866
EGSTMNUM*LEG_SORT	24	201	24	202	1.7037	1.2232	439	1.39	0.1644	0.1	-0.3126	3.7200
EGSTMNUM*LEG_SORT	24	201	24	203	7.3670	1.2200	444	6.04	<.0001	0.1	5.3562	9.3779
EGSTMNUM*LEG_SORT	24	202	24	203	5.6634	1.2223	440	4.63	<.0001	0.1	3.6486	7.6781

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Primary ECG analysis population is defined as all subjects randomized and treated who have at least 1 post-dose ECG measurement in at least 1 period.

Unplanned readings have been excluded from the presentation.

For primary analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:01)

## SAS Code for Mixed Model

```
proc mixed data=ecg3 method=reml;
class subjid drggroup period egstmmnum leg_sort;
model QTcN = drggroup period leg_sort egbase_QTcN egstmmnum egstmmnum*leg_sort/ddfm=kr;
random subjid(drggroup);
repeated / subject = period*subjid(drggroup) type=cs;
lsmeans egstmmnum*leg_sort/cl diff alpha=0.1;
ods output lsmeans=lsmeans diffs=diffs tests3= tests3;
run;
```

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:19)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Model Information

Data Set WORK.ECG3  
 Dependent Variable QTcN  
 Covariance Structures Variance Components,  
 Compound Symmetry  
 Subject Effect SUBJI\*PERIOD(DRGGRO)  
 Estimation Method REML  
 Residual Variance Method Profile  
 Fixed Effects SE Method Kenward-Roger  
 Degrees of Freedom Method Kenward-Roger

Class Level Information

Class	Levels	Values		
SUBJID	46	10011001 10011002 10011003		
		10011004 10011005 10011006		
		10011008 10011009 10011010		
		10011011 10011012 10011013		
		10011014 10011015 10011016		
		10011017 10011018 10011019		
		10011020 10011021 10011023		
		10011024 10011025 10011026		
		10011027 10011028 10011029		
		10011031 10011032 10011033		
		10011034 10011035 10011037		
		10011038 10011039 10011040		
		10011041 10011042 10011043		
		10011046 10011047 10011049		
		10011051 10011052 10011053		
		10011054		
		DRGGROUP	6	ABC ACB BAC BCA CAB CBA
		PERIOD	3	Period 1 Period 2 Period 3
		EGSTMNUM	9	1 2 3 4 5 6 8 12 24
		LEG_SORT	3	201 202 203

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

Supporting SAS Output for Statistical Summary (1) of QTcN between Sertraline vs. Placebo and Moxifloxacin vs. Placebo on Day 14 - Completer ECG Analysis Population

The Mixed Procedure

Dimensions

Covariance Parameters	3
Columns in X	50
Columns in Z	46
Subjects	1
Max Obs Per Subject	1242

Number of Observations

Number of Observations Read	1242
Number of Observations Used	1242
Number of Observations Not Used	0

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	8806.55586565	
1	3	7865.56941802	0.00177412
2	1	7859.46393571	0.00075015
3	1	7856.86739581	0.00017065
4	1	7856.31421343	0.00001290
5	1	7856.27592030	0.00000009
6	1	7856.27565747	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
SUBJID(DRGGROUP)		118.87
CS	SUBJI*PERIOD(DRGGRO)	8.7160
Residual		26.8105

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1      Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Fit Statistics

-2 Res Log Likelihood	7856.3
AIC (smaller is better)	7862.3
AICC (smaller is better)	7862.3
BIC (smaller is better)	7867.8

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DRGGROUP	5	24.5	0.37	0.8612
PERIOD	2	69.6	1.68	0.1932
LEG_SORT	2	68.1	107.24	<.0001
EGBASE_QTCN	1	121	27.75	<.0001
EGSTMNUM	8	1080	53.36	<.0001
EGSTMNUM*LEG_SORT	16	1080	4.16	<.0001

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	415.34	1.8350	39.3	226.35	<.0001	0.1	412.25	418.43
EGSTMNUM*LEG_SORT	1	202	419.79	1.8353	39.3	228.73	<.0001	0.1	416.70	422.88
EGSTMNUM*LEG_SORT	1	203	408.06	1.8356	39.3	222.30	<.0001	0.1	404.96	411.15
EGSTMNUM*LEG_SORT	2	201	416.85	1.8350	39.3	227.17	<.0001	0.1	413.76	419.94
EGSTMNUM*LEG_SORT	2	202	421.13	1.8353	39.3	229.45	<.0001	0.1	418.03	424.22
EGSTMNUM*LEG_SORT	2	203	408.34	1.8356	39.3	222.45	<.0001	0.1	405.24	411.43
EGSTMNUM*LEG_SORT	3	201	417.08	1.8350	39.3	227.30	<.0001	0.1	413.99	420.17
EGSTMNUM*LEG_SORT	3	202	421.72	1.8353	39.3	229.77	<.0001	0.1	418.62	424.81
EGSTMNUM*LEG_SORT	3	203	409.49	1.8356	39.3	223.08	<.0001	0.1	406.40	412.58
EGSTMNUM*LEG_SORT	4	201	419.32	1.8350	39.3	228.52	<.0001	0.1	416.23	422.41
EGSTMNUM*LEG_SORT	4	202	423.05	1.8353	39.3	230.50	<.0001	0.1	419.95	426.14
EGSTMNUM*LEG_SORT	4	203	409.41	1.8356	39.3	223.03	<.0001	0.1	406.32	412.50
EGSTMNUM*LEG_SORT	5	201	412.36	1.8350	39.3	224.72	<.0001	0.1	409.27	415.45

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	202	414.95	1.8353	39.3	226.09	<.0001	0.1	411.85	418.04
EGSTMNUM*LEG_SORT	5	203	404.57	1.8356	39.3	220.40	<.0001	0.1	401.47	407.66
EGSTMNUM*LEG_SORT	6	201	410.20	1.8350	39.3	223.55	<.0001	0.1	407.11	413.29
EGSTMNUM*LEG_SORT	6	202	413.03	1.8353	39.3	225.04	<.0001	0.1	409.94	416.12
EGSTMNUM*LEG_SORT	6	203	403.05	1.8356	39.3	219.57	<.0001	0.1	399.96	406.14
EGSTMNUM*LEG_SORT	8	201	410.02	1.8350	39.3	223.45	<.0001	0.1	406.93	413.11
EGSTMNUM*LEG_SORT	8	202	412.47	1.8353	39.3	224.74	<.0001	0.1	409.38	415.56
EGSTMNUM*LEG_SORT	8	203	404.10	1.8356	39.3	220.14	<.0001	0.1	401.01	407.19
EGSTMNUM*LEG_SORT	12	201	412.43	1.8350	39.3	224.76	<.0001	0.1	409.34	415.52
EGSTMNUM*LEG_SORT	12	202	412.42	1.8353	39.3	224.71	<.0001	0.1	409.32	415.51
EGSTMNUM*LEG_SORT	12	203	406.17	1.8356	39.3	221.27	<.0001	0.1	403.07	409.26
EGSTMNUM*LEG_SORT	24	201	415.58	1.8350	39.3	226.48	<.0001	0.1	412.49	418.68
EGSTMNUM*LEG_SORT	24	202	413.52	1.8353	39.3	225.31	<.0001	0.1	410.43	416.61
EGSTMNUM*LEG_SORT	24	203	407.91	1.8356	39.3	222.22	<.0001	0.1	404.82	411.00

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	1	202	-4.4488	1.2437	495	-3.58	0.0004	0.1	-6.4982	-2.3993
EGSTMNUM*LEG_SORT	1	201	1	203	7.2859	1.2437	495	5.86	<.0001	0.1	5.2364	9.3355
EGSTMNUM*LEG_SORT	1	201	2	201	-1.5059	1.0797	1080	-1.39	0.1634	0.1	-3.2834	0.2715
EGSTMNUM*LEG_SORT	1	201	2	202	-5.7849	1.2437	495	-4.65	<.0001	0.1	-7.8344	-3.7355
EGSTMNUM*LEG_SORT	1	201	2	203	7.0061	1.2437	495	5.63	<.0001	0.1	4.9565	9.0557
EGSTMNUM*LEG_SORT	1	201	3	201	-1.7419	1.0797	1080	-1.61	0.1069	0.1	-3.5193	0.03548
EGSTMNUM*LEG_SORT	1	201	3	202	-6.3748	1.2437	495	-5.13	<.0001	0.1	-8.4242	-4.3253
EGSTMNUM*LEG_SORT	1	201	3	203	5.8543	1.2437	495	4.71	<.0001	0.1	3.8047	7.9039
EGSTMNUM*LEG_SORT	1	201	4	201	-3.9771	1.0797	1080	-3.68	0.0002	0.1	-5.7545	-2.1997
EGSTMNUM*LEG_SORT	1	201	4	202	-7.7050	1.2437	495	-6.20	<.0001	0.1	-9.7544	-5.6555
EGSTMNUM*LEG_SORT	1	201	4	203	5.9340	1.2437	495	4.77	<.0001	0.1	3.8844	7.9835

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	201	5	201	2.9828	1.0797	1080	2.76	0.0058	0.1	1.2054	4.7603
EGSTMNUM*LEG_SORT	1	201	5	202	0.3954	1.2437	495	0.32	0.7507	0.1	-1.6541	2.4448
EGSTMNUM*LEG_SORT	1	201	5	203	10.7754	1.2437	495	8.66	<.0001	0.1	8.7258	12.8250
EGSTMNUM*LEG_SORT	1	201	6	201	5.1431	1.0797	1080	4.76	<.0001	0.1	3.3657	6.9205
EGSTMNUM*LEG_SORT	1	201	6	202	2.3118	1.2437	495	1.86	0.0636	0.1	0.2623	4.3612
EGSTMNUM*LEG_SORT	1	201	6	203	12.2937	1.2437	495	9.88	<.0001	0.1	10.2441	14.3432
EGSTMNUM*LEG_SORT	1	201	8	201	5.3194	1.0797	1080	4.93	<.0001	0.1	3.5420	7.0968
EGSTMNUM*LEG_SORT	1	201	8	202	2.8734	1.2437	495	2.31	0.0213	0.1	0.8240	4.9229
EGSTMNUM*LEG_SORT	1	201	8	203	11.2414	1.2437	495	9.04	<.0001	0.1	9.9191	13.2910
EGSTMNUM*LEG_SORT	1	201	12	201	2.9121	1.0797	1080	2.70	0.0071	0.1	1.1346	4.6895
EGSTMNUM*LEG_SORT	1	201	12	202	2.9258	1.2437	495	2.35	0.0190	0.1	0.8763	4.9752
EGSTMNUM*LEG_SORT	1	201	12	203	9.1761	1.2437	495	7.38	<.0001	0.1	7.1266	11.2257
EGSTMNUM*LEG_SORT	1	201	24	201	-0.2429	1.0797	1080	-0.23	0.8220	0.1	-2.0203	1.5345
EGSTMNUM*LEG_SORT	1	201	24	202	1.8220	1.2437	495	1.47	0.1435	0.1	-0.2275	3.8715
EGSTMNUM*LEG_SORT	1	201	24	203	7.4310	1.2437	495	5.97	<.0001	0.1	5.3815	9.4806
EGSTMNUM*LEG_SORT	1	202	1	203	11.7347	1.2460	493	9.42	<.0001	0.1	9.6814	13.7880
EGSTMNUM*LEG_SORT	1	202	2	201	2.9428	1.2437	495	2.37	0.0184	0.1	0.8933	4.9923
EGSTMNUM*LEG_SORT	1	202	2	202	-1.3362	1.0797	1080	-1.24	0.2161	0.1	-3.1136	0.4412
EGSTMNUM*LEG_SORT	1	202	2	203	11.4549	1.2460	493	9.19	<.0001	0.1	9.4016	13.5082
EGSTMNUM*LEG_SORT	1	202	3	201	2.7068	1.2437	495	2.18	0.0300	0.1	0.6574	4.7563
EGSTMNUM*LEG_SORT	1	202	3	202	-1.9260	1.0797	1080	-1.78	0.0747	0.1	-3.7034	-0.1486
EGSTMNUM*LEG_SORT	1	202	3	203	10.3031	1.2460	493	8.27	<.0001	0.1	8.2498	12.3564
EGSTMNUM*LEG_SORT	1	202	4	201	0.4717	1.2437	495	0.38	0.7047	0.1	-1.5778	2.5211
EGSTMNUM*LEG_SORT	1	202	4	202	-3.2562	1.0797	1080	-3.02	0.0026	0.1	-5.0336	-1.4788
EGSTMNUM*LEG_SORT	1	202	4	203	10.3827	1.2460	493	8.33	<.0001	0.1	8.3294	12.4360
EGSTMNUM*LEG_SORT	1	202	5	201	7.4316	1.2437	495	5.98	<.0001	0.1	5.3821	9.4811
EGSTMNUM*LEG_SORT	1	202	5	202	4.8441	1.0797	1080	4.49	<.0001	0.1	3.0667	6.6215
EGSTMNUM*LEG_SORT	1	202	5	203	15.2242	1.2460	493	12.22	<.0001	0.1	13.1709	17.2775
EGSTMNUM*LEG_SORT	1	202	6	201	9.5919	1.2437	495	7.71	<.0001	0.1	7.5424	11.6413
EGSTMNUM*LEG_SORT	1	202	6	202	6.7605	1.0797	1080	6.26	<.0001	0.1	4.9831	8.5379
EGSTMNUM*LEG_SORT	1	202	6	203	16.7424	1.2460	493	13.44	<.0001	0.1	14.6891	18.7957
EGSTMNUM*LEG_SORT	1	202	8	201	9.7681	1.2437	495	7.85	<.0001	0.1	7.7187	11.8176
EGSTMNUM*LEG_SORT	1	202	8	202	7.3222	1.0797	1080	6.78	<.0001	0.1	5.5448	9.0996
EGSTMNUM*LEG_SORT	1	202	8	203	15.6902	1.2460	493	12.59	<.0001	0.1	13.6369	17.7435

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	1	202	12	201	7.3608	1.2437	495	5.92	<.0001	0.1	5.3113	9.4103
EGSTMNUM*LEG_SORT	1	202	12	202	7.3745	1.0797	1080	6.83	<.0001	0.1	5.5971	9.1519
EGSTMNUM*LEG_SORT	1	202	12	203	13.6249	1.2460	493	10.94	<.0001	0.1	11.5716	15.6782
EGSTMNUM*LEG_SORT	1	202	24	201	4.2058	1.2437	495	3.38	0.0008	0.1	2.1564	6.2553
EGSTMNUM*LEG_SORT	1	202	24	202	6.2708	1.0797	1080	5.81	<.0001	0.1	4.4934	8.0482
EGSTMNUM*LEG_SORT	1	202	24	203	11.8798	1.2460	493	9.53	<.0001	0.1	9.8265	13.9331
EGSTMNUM*LEG_SORT	1	203	2	201	-8.7919	1.2437	495	-7.07	<.0001	0.1	-10.8414	-6.7423
EGSTMNUM*LEG_SORT	1	203	2	202	-13.0709	1.2460	493	-10.49	<.0001	0.1	-15.1241	-11.0176
EGSTMNUM*LEG_SORT	1	203	2	203	-0.2798	1.0797	1080	-0.26	0.7955	0.1	-2.0572	1.4976
EGSTMNUM*LEG_SORT	1	203	3	201	-9.0279	1.2437	495	-7.26	<.0001	0.1	-11.0774	-6.9783
EGSTMNUM*LEG_SORT	1	203	3	202	-13.6607	1.2460	493	-10.96	<.0001	0.1	-15.7140	-11.6074
EGSTMNUM*LEG_SORT	1	203	3	203	-1.4316	1.0797	1080	-1.33	0.1851	0.1	-3.2090	0.3458
EGSTMNUM*LEG_SORT	1	203	4	201	-11.2630	1.2437	495	-9.06	<.0001	0.1	-13.3126	-9.2134
EGSTMNUM*LEG_SORT	1	203	4	202	-14.9909	1.2460	493	-12.03	<.0001	0.1	-17.0442	-12.9376
EGSTMNUM*LEG_SORT	1	203	4	203	-1.3519	1.0797	1080	-1.25	0.2108	0.1	-3.1294	0.4255
EGSTMNUM*LEG_SORT	1	203	5	201	-4.3031	1.2437	495	-3.46	0.0006	0.1	-6.3527	-2.2535
EGSTMNUM*LEG_SORT	1	203	5	202	-6.8906	1.2460	493	-5.53	<.0001	0.1	-8.9439	-4.8373
EGSTMNUM*LEG_SORT	1	203	5	203	3.4895	1.0797	1080	3.23	0.0013	0.1	1.7121	5.2669
EGSTMNUM*LEG_SORT	1	203	6	201	-2.1428	1.2437	495	-1.72	0.0855	0.1	-4.1924	-0.09326
EGSTMNUM*LEG_SORT	1	203	6	202	-4.9742	1.2460	493	-3.99	<.0001	0.1	-7.0274	-2.9209
EGSTMNUM*LEG_SORT	1	203	6	203	5.0077	1.0797	1080	4.64	<.0001	0.1	3.2303	6.7852
EGSTMNUM*LEG_SORT	1	203	8	201	-1.9665	1.2437	495	-1.58	0.1145	0.1	-4.0161	0.08303
EGSTMNUM*LEG_SORT	1	203	8	202	-4.4125	1.2460	493	-3.54	0.0004	0.1	-6.4658	-2.3592
EGSTMNUM*LEG_SORT	1	203	8	203	3.9555	1.0797	1080	3.66	0.0003	0.1	2.1781	5.7329
EGSTMNUM*LEG_SORT	1	203	12	201	-4.3739	1.2437	495	-3.52	0.0005	0.1	-6.4234	-2.3243
EGSTMNUM*LEG_SORT	1	203	12	202	-4.3602	1.2460	493	-3.50	0.0005	0.1	-6.4134	-2.3069
EGSTMNUM*LEG_SORT	1	203	12	203	1.8902	1.0797	1080	1.75	0.0803	0.1	0.1128	3.6676
EGSTMNUM*LEG_SORT	1	203	24	201	-7.5288	1.2437	495	-6.05	<.0001	0.1	-9.5784	-5.4793
EGSTMNUM*LEG_SORT	1	203	24	202	-5.4639	1.2460	493	-4.39	<.0001	0.1	-7.5172	-3.4106
EGSTMNUM*LEG_SORT	1	203	24	203	0.1451	1.0797	1080	0.13	0.8931	0.1	-1.6323	1.9225
EGSTMNUM*LEG_SORT	2	201	2	202	-4.2790	1.2437	495	-3.44	0.0006	0.1	-6.3285	-2.2295
EGSTMNUM*LEG_SORT	2	201	2	203	8.5120	1.2437	495	6.84	<.0001	0.1	6.4625	10.5616
EGSTMNUM*LEG_SORT	2	201	3	201	-0.2360	1.0797	1080	-0.22	0.8270	0.1	-2.0134	1.5414
EGSTMNUM*LEG_SORT	2	201	3	202	-4.8688	1.2437	495	-3.91	0.0001	0.1	-6.9183	-2.8193

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	201	3	203	7.3602	1.2437	495	5.92	<.0001	0.1	5.3107	9.4098
EGSTMNUM*LEG_SORT	2	201	4	201	-2.4711	1.0797	1080	-2.29	0.0223	0.1	-4.2486	-0.6937
EGSTMNUM*LEG_SORT	2	201	4	202	-6.1990	1.2437	495	-4.98	<.0001	0.1	-8.2485	-4.1495
EGSTMNUM*LEG_SORT	2	201	4	203	7.4399	1.2437	495	5.98	<.0001	0.1	5.3904	9.4895
EGSTMNUM*LEG_SORT	2	201	5	201	4.4888	1.0797	1080	4.16	<.0001	0.1	2.7114	6.2662
EGSTMNUM*LEG_SORT	2	201	5	202	1.9013	1.2437	495	1.53	0.1270	0.1	-0.1482	3.9508
EGSTMNUM*LEG_SORT	2	201	5	203	12.2814	1.2437	495	9.87	<.0001	0.1	10.2318	14.3309
EGSTMNUM*LEG_SORT	2	201	6	201	6.6490	1.0797	1080	6.16	<.0001	0.1	4.8716	8.4265
EGSTMNUM*LEG_SORT	2	201	6	202	3.8177	1.2437	495	3.07	0.0023	0.1	1.7682	5.8672
EGSTMNUM*LEG_SORT	2	201	6	203	13.7996	1.2437	495	11.10	<.0001	0.1	11.7500	15.8492
EGSTMNUM*LEG_SORT	2	201	8	201	6.8253	1.0797	1080	6.32	<.0001	0.1	5.0479	8.6027
EGSTMNUM*LEG_SORT	2	201	8	202	4.3794	1.2437	495	3.52	0.0005	0.1	2.3299	6.4289
EGSTMNUM*LEG_SORT	2	201	8	203	12.7474	1.2437	495	10.25	<.0001	0.1	10.6978	14.7970
EGSTMNUM*LEG_SORT	2	201	12	201	4.4180	1.0797	1080	4.09	<.0001	0.1	2.6406	6.1954
EGSTMNUM*LEG_SORT	2	201	12	202	4.4317	1.2437	495	3.56	0.0004	0.1	2.3822	6.4812
EGSTMNUM*LEG_SORT	2	201	12	203	10.6821	1.2437	495	8.59	<.0001	0.1	8.6325	12.7317
EGSTMNUM*LEG_SORT	2	201	24	201	1.2630	1.0797	1080	1.17	0.2423	0.1	-0.5144	3.0404
EGSTMNUM*LEG_SORT	2	201	24	202	3.3280	1.2437	495	2.68	0.0077	0.1	1.2785	5.3774
EGSTMNUM*LEG_SORT	2	201	24	203	8.9370	1.2437	495	7.19	<.0001	0.1	6.8874	10.9866
EGSTMNUM*LEG_SORT	2	202	2	203	12.7910	1.2460	493	10.27	<.0001	0.1	10.7377	14.8443
EGSTMNUM*LEG_SORT	2	202	3	201	4.0430	1.2437	495	3.25	0.0012	0.1	1.9935	6.0925
EGSTMNUM*LEG_SORT	2	202	3	202	-0.5898	1.0797	1080	-0.55	0.5850	0.1	-2.3672	1.1876
EGSTMNUM*LEG_SORT	2	202	3	203	11.6392	1.2460	493	9.34	<.0001	0.1	9.5859	13.6925
EGSTMNUM*LEG_SORT	2	202	4	201	1.8078	1.2437	495	1.45	0.1467	0.1	-0.2416	3.8573
EGSTMNUM*LEG_SORT	2	202	4	202	-1.9200	1.0797	1080	-1.78	0.0756	0.1	-3.6974	-0.1426
EGSTMNUM*LEG_SORT	2	202	4	203	11.7189	1.2460	493	9.41	<.0001	0.1	9.6656	13.7722
EGSTMNUM*LEG_SORT	2	202	5	201	8.7678	1.2437	495	7.05	<.0001	0.1	6.7183	10.8172
EGSTMNUM*LEG_SORT	2	202	5	202	6.1803	1.0797	1080	5.72	<.0001	0.1	4.4029	7.9577
EGSTMNUM*LEG_SORT	2	202	5	203	16.5603	1.2460	493	13.29	<.0001	0.1	14.5071	18.6136
EGSTMNUM*LEG_SORT	2	202	6	201	10.9280	1.2437	495	8.79	<.0001	0.1	8.8786	12.9775
EGSTMNUM*LEG_SORT	2	202	6	202	8.0967	1.0797	1080	7.50	<.0001	0.1	6.3193	9.8741
EGSTMNUM*LEG_SORT	2	202	6	203	18.0786	1.2460	493	14.51	<.0001	0.1	16.0253	20.1319
EGSTMNUM*LEG_SORT	2	202	8	201	11.1043	1.2437	495	8.93	<.0001	0.1	9.0548	13.1538
EGSTMNUM*LEG_SORT	2	202	8	202	8.6584	1.0797	1080	8.02	<.0001	0.1	6.8809	10.4358

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	2	202	8	203	17.0264	1.2460	493	13.67	<.0001	0.1	14.9731	19.0797
EGSTMNUM*LEG_SORT	2	202	12	201	8.6970	1.2437	495	6.99	<.0001	0.1	6.6475	10.7465
EGSTMNUM*LEG_SORT	2	202	12	202	8.7107	1.0797	1080	8.07	<.0001	0.1	6.9333	10.4881
EGSTMNUM*LEG_SORT	2	202	12	203	14.9611	1.2460	493	12.01	<.0001	0.1	12.9078	17.0144
EGSTMNUM*LEG_SORT	2	202	24	201	5.5420	1.2437	495	4.46	<.0001	0.1	3.4925	7.5915
EGSTMNUM*LEG_SORT	2	202	24	202	7.6069	1.0797	1080	7.05	<.0001	0.1	5.8295	9.3844
EGSTMNUM*LEG_SORT	2	202	24	203	13.2160	1.2460	493	10.61	<.0001	0.1	11.1627	15.2693
EGSTMNUM*LEG_SORT	2	203	3	201	-8.7480	1.2437	495	-7.03	<.0001	0.1	-10.7976	-6.6985
EGSTMNUM*LEG_SORT	2	203	3	202	-13.3809	1.2460	493	-10.74	<.0001	0.1	-15.4342	-11.3276
EGSTMNUM*LEG_SORT	2	203	3	203	-1.1518	1.0797	1080	-1.07	0.2863	0.1	-2.9292	0.6256
EGSTMNUM*LEG_SORT	2	203	4	201	-10.9832	1.2437	495	-8.83	<.0001	0.1	-13.0328	-8.9336
EGSTMNUM*LEG_SORT	2	203	4	202	-14.7111	1.2460	493	-11.81	<.0001	0.1	-16.7643	-12.6578
EGSTMNUM*LEG_SORT	2	203	4	203	-1.0721	1.0797	1080	-0.99	0.3209	0.1	-2.8495	0.7053
EGSTMNUM*LEG_SORT	2	203	5	201	-4.0233	1.2437	495	-3.23	0.0013	0.1	-6.0728	-1.9737
EGSTMNUM*LEG_SORT	2	203	5	202	-6.6107	1.2460	493	-5.31	<.0001	0.1	-8.6640	-4.5574
EGSTMNUM*LEG_SORT	2	203	5	203	3.7693	1.0797	1080	3.49	0.0005	0.1	1.9919	5.5467
EGSTMNUM*LEG_SORT	2	203	6	201	-1.8630	1.2437	495	-1.50	0.1348	0.1	-3.9126	0.1866
EGSTMNUM*LEG_SORT	2	203	6	202	-4.6943	1.2460	493	-3.77	0.0002	0.1	-6.7476	-2.6410
EGSTMNUM*LEG_SORT	2	203	6	203	5.2876	1.0797	1080	4.90	<.0001	0.1	3.5102	7.0650
EGSTMNUM*LEG_SORT	2	203	8	201	-1.6867	1.2437	495	-1.36	0.1757	0.1	-3.7363	0.3629
EGSTMNUM*LEG_SORT	2	203	8	202	-4.1327	1.2460	493	-3.32	0.0010	0.1	-6.1860	-2.0794
EGSTMNUM*LEG_SORT	2	203	8	203	4.2353	1.0797	1080	3.92	<.0001	0.1	2.4579	6.0127
EGSTMNUM*LEG_SORT	2	203	12	201	-4.0940	1.2437	495	-3.29	0.0011	0.1	-6.1436	-2.0445
EGSTMNUM*LEG_SORT	2	203	12	202	-4.0803	1.2460	493	-3.27	0.0011	0.1	-6.1336	-2.0270
EGSTMNUM*LEG_SORT	2	203	12	203	2.1700	1.0797	1080	2.01	0.0447	0.1	0.3926	3.9475
EGSTMNUM*LEG_SORT	2	203	24	201	-7.2490	1.2437	495	-5.83	<.0001	0.1	-9.2986	-5.1995
EGSTMNUM*LEG_SORT	2	203	24	202	-5.1841	1.2460	493	-4.16	<.0001	0.1	-7.2374	-3.1308
EGSTMNUM*LEG_SORT	2	203	24	203	0.4249	1.0797	1080	0.39	0.6940	0.1	-1.3525	2.2023
EGSTMNUM*LEG_SORT	3	201	3	202	-4.6328	1.2437	495	-3.73	0.0002	0.1	-6.6823	-2.5834
EGSTMNUM*LEG_SORT	3	201	3	203	7.5962	1.2437	495	6.11	<.0001	0.1	5.5467	9.6458
EGSTMNUM*LEG_SORT	3	201	4	201	-2.2352	1.0797	1080	-2.07	0.0387	0.1	-4.0126	-0.4577
EGSTMNUM*LEG_SORT	3	201	4	202	-5.9630	1.2437	495	-4.79	<.0001	0.1	-8.0125	-3.9135
EGSTMNUM*LEG_SORT	3	201	4	203	7.6759	1.2437	495	6.17	<.0001	0.1	5.6263	9.7255
EGSTMNUM*LEG_SORT	3	201	5	201	4.7248	1.0797	1080	4.38	<.0001	0.1	2.9474	6.5022

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.  
 Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.  
 Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.  
 Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.  
 Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	201	5	202	2.1373	1.2437	495	1.72	0.0863	0.1	0.08782	4.1868
EGSTMNUM*LEG_SORT	3	201	5	203	12.5174	1.2437	495	10.06	<.0001	0.1	10.4678	14.5669
EGSTMNUM*LEG_SORT	3	201	6	201	6.8850	1.0797	1080	6.38	<.0001	0.1	5.1076	8.6624
EGSTMNUM*LEG_SORT	3	201	6	202	4.0537	1.2437	495	3.26	0.0012	0.1	2.0042	6.1032
EGSTMNUM*LEG_SORT	3	201	6	203	14.0356	1.2437	495	11.29	<.0001	0.1	11.9860	16.0852
EGSTMNUM*LEG_SORT	3	201	8	201	7.0613	1.0797	1080	6.54	<.0001	0.1	5.2839	8.8387
EGSTMNUM*LEG_SORT	3	201	8	202	4.6154	1.2437	495	3.71	0.0002	0.1	2.5659	6.6648
EGSTMNUM*LEG_SORT	3	201	8	203	12.9834	1.2437	495	10.44	<.0001	0.1	10.9338	15.0329
EGSTMNUM*LEG_SORT	3	201	12	201	4.6540	1.0797	1080	4.31	<.0001	0.1	2.8766	6.4314
EGSTMNUM*LEG_SORT	3	201	12	202	4.6677	1.2437	495	3.75	0.0002	0.1	2.6182	6.7172
EGSTMNUM*LEG_SORT	3	201	12	203	10.9181	1.2437	495	8.78	<.0001	0.1	8.8685	12.9677
EGSTMNUM*LEG_SORT	3	201	24	201	1.4990	1.0797	1080	1.39	0.1653	0.1	-0.2784	3.2764
EGSTMNUM*LEG_SORT	3	201	24	202	3.5639	1.2437	495	2.87	0.0043	0.1	1.5145	5.6134
EGSTMNUM*LEG_SORT	3	201	24	203	9.1730	1.2437	495	7.38	<.0001	0.1	7.1234	11.2225
EGSTMNUM*LEG_SORT	3	202	3	203	12.2291	1.2460	493	9.81	<.0001	0.1	10.1758	14.2823
EGSTMNUM*LEG_SORT	3	202	4	201	2.3977	1.2437	495	1.93	0.0544	0.1	0.3482	4.4471
EGSTMNUM*LEG_SORT	3	202	4	202	-1.3302	1.0797	1080	-1.23	0.2182	0.1	-3.1076	0.4472
EGSTMNUM*LEG_SORT	3	202	4	203	12.3087	1.2460	493	9.88	<.0001	0.1	10.2554	14.3620
EGSTMNUM*LEG_SORT	3	202	5	201	9.3576	1.2437	495	7.52	<.0001	0.1	7.3081	11.4071
EGSTMNUM*LEG_SORT	3	202	5	202	6.7701	1.0797	1080	6.27	<.0001	0.1	4.9927	8.5475
EGSTMNUM*LEG_SORT	3	202	5	203	17.1502	1.2460	493	13.76	<.0001	0.1	15.0969	19.2035
EGSTMNUM*LEG_SORT	3	202	6	201	11.5179	1.2437	495	9.26	<.0001	0.1	9.4684	13.5673
EGSTMNUM*LEG_SORT	3	202	6	202	8.6865	1.0797	1080	8.05	<.0001	0.1	6.9091	10.4639
EGSTMNUM*LEG_SORT	3	202	6	203	18.6684	1.2460	493	14.98	<.0001	0.1	16.6151	20.7217
EGSTMNUM*LEG_SORT	3	202	8	201	11.6941	1.2437	495	9.40	<.0001	0.1	9.6447	13.7436
EGSTMNUM*LEG_SORT	3	202	8	202	9.2482	1.0797	1080	8.57	<.0001	0.1	7.4708	11.0256
EGSTMNUM*LEG_SORT	3	202	8	203	17.6162	1.2460	493	14.14	<.0001	0.1	15.5629	19.6695
EGSTMNUM*LEG_SORT	3	202	12	201	9.2868	1.2437	495	7.47	<.0001	0.1	7.2373	11.3363
EGSTMNUM*LEG_SORT	3	202	12	202	9.3005	1.0797	1080	8.61	<.0001	0.1	7.5231	11.0779
EGSTMNUM*LEG_SORT	3	202	12	203	15.5509	1.2460	493	12.48	<.0001	0.1	13.4976	17.6042
EGSTMNUM*LEG_SORT	3	202	24	201	6.1318	1.2437	495	4.93	<.0001	0.1	4.0824	8.1813
EGSTMNUM*LEG_SORT	3	202	24	202	8.1968	1.0797	1080	7.59	<.0001	0.1	6.4194	9.9742
EGSTMNUM*LEG_SORT	3	202	24	203	13.8058	1.2460	493	11.08	<.0001	0.1	11.7525	15.8591
EGSTMNUM*LEG_SORT	3	203	4	201	-9.8314	1.2437	495	-7.90	<.0001	0.1	-11.8810	-7.7818

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	3	203	4	202	-13.5592	1.2460	493	-10.88	<.0001	0.1	-15.6125	-11.5060
EGSTMNUM*LEG_SORT	3	203	4	203	0.07968	1.0797	1080	0.07	0.9412	0.1	-1.6977	1.8571
EGSTMNUM*LEG_SORT	3	203	5	201	-2.8715	1.2437	495	-2.31	0.0214	0.1	-4.9210	-0.8219
EGSTMNUM*LEG_SORT	3	203	5	202	-5.4589	1.2460	493	-4.38	<.0001	0.1	-7.5122	-3.4056
EGSTMNUM*LEG_SORT	3	203	5	203	4.9211	1.0797	1080	4.56	<.0001	0.1	3.1437	6.6985
EGSTMNUM*LEG_SORT	3	203	6	201	-0.7112	1.2437	495	-0.57	0.5677	0.1	-2.7608	1.3384
EGSTMNUM*LEG_SORT	3	203	6	202	-3.5425	1.2460	493	-2.84	0.0047	0.1	-5.5958	-1.4892
EGSTMNUM*LEG_SORT	3	203	6	203	6.4394	1.0797	1080	5.96	<.0001	0.1	4.6620	8.2168
EGSTMNUM*LEG_SORT	3	203	8	201	-0.5349	1.2437	495	-0.43	0.6673	0.1	-2.5845	1.5147
EGSTMNUM*LEG_SORT	3	203	8	202	-2.9809	1.2460	493	-2.39	0.0171	0.1	-5.0342	-0.9276
EGSTMNUM*LEG_SORT	3	203	8	203	5.3871	1.0797	1080	4.99	<.0001	0.1	3.6097	7.1646
EGSTMNUM*LEG_SORT	3	203	12	201	-2.9422	1.2437	495	-2.37	0.0184	0.1	-4.9918	-0.8927
EGSTMNUM*LEG_SORT	3	203	12	202	-2.9285	1.2460	493	-2.35	0.0191	0.1	-4.9818	-0.8752
EGSTMNUM*LEG_SORT	3	203	12	203	3.3219	1.0797	1080	3.08	0.0021	0.1	1.5444	5.0993
EGSTMNUM*LEG_SORT	3	203	24	201	-6.0972	1.2437	495	-4.90	<.0001	0.1	-8.1468	-4.0476
EGSTMNUM*LEG_SORT	3	203	24	202	-4.0323	1.2460	493	-3.24	0.0013	0.1	-6.0856	-1.9790
EGSTMNUM*LEG_SORT	3	203	24	203	1.5767	1.0797	1080	1.46	0.1445	0.1	-0.2007	3.3542
EGSTMNUM*LEG_SORT	4	201	4	202	-3.7279	1.2437	495	-3.00	0.0029	0.1	-5.7773	-1.6784
EGSTMNUM*LEG_SORT	4	201	4	203	9.9111	1.2437	495	7.97	<.0001	0.1	7.8615	11.9606
EGSTMNUM*LEG_SORT	4	201	5	201	6.9599	1.0797	1080	6.45	<.0001	0.1	5.1825	8.7373
EGSTMNUM*LEG_SORT	4	201	5	202	4.3725	1.2437	495	3.52	0.0005	0.1	2.3230	6.4219
EGSTMNUM*LEG_SORT	4	201	5	203	14.7525	1.2437	495	11.86	<.0001	0.1	12.7029	16.8021
EGSTMNUM*LEG_SORT	4	201	6	201	9.1202	1.0797	1080	8.45	<.0001	0.1	7.3428	10.8976
EGSTMNUM*LEG_SORT	4	201	6	202	6.2889	1.2437	495	5.06	<.0001	0.1	4.2394	8.3383
EGSTMNUM*LEG_SORT	4	201	6	203	16.2708	1.2437	495	13.08	<.0001	0.1	14.2212	18.3203
EGSTMNUM*LEG_SORT	4	201	8	201	9.2965	1.0797	1080	8.61	<.0001	0.1	7.5191	11.0739
EGSTMNUM*LEG_SORT	4	201	8	202	6.8505	1.2437	495	5.51	<.0001	0.1	4.8011	8.9000
EGSTMNUM*LEG_SORT	4	201	8	203	15.2185	1.2437	495	12.24	<.0001	0.1	13.1690	17.2681
EGSTMNUM*LEG_SORT	4	201	12	201	6.8891	1.0797	1080	6.38	<.0001	0.1	5.1117	8.6666
EGSTMNUM*LEG_SORT	4	201	12	202	6.9029	1.2437	495	5.55	<.0001	0.1	4.8534	8.9523
EGSTMNUM*LEG_SORT	4	201	12	203	13.1532	1.2437	495	10.58	<.0001	0.1	11.1037	15.2028
EGSTMNUM*LEG_SORT	4	201	24	201	3.7342	1.0797	1080	3.46	0.0006	0.1	1.9568	5.5116
EGSTMNUM*LEG_SORT	4	201	24	202	5.7991	1.2437	495	4.66	<.0001	0.1	3.7496	7.8486
EGSTMNUM*LEG_SORT	4	201	24	203	11.4081	1.2437	495	9.17	<.0001	0.1	9.3586	13.4577

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	4	202	4	203	13.6389	1.2460	493	10.95	<.0001	0.1	11.5856	15.6922
EGSTMNUM*LEG_SORT	4	202	5	201	10.6878	1.2437	495	8.59	<.0001	0.1	8.6383	12.7373
EGSTMNUM*LEG_SORT	4	202	5	202	8.1003	1.0797	1080	7.50	<.0001	0.1	6.3229	9.8777
EGSTMNUM*LEG_SORT	4	202	5	203	18.4804	1.2460	493	14.83	<.0001	0.1	16.4271	20.5337
EGSTMNUM*LEG_SORT	4	202	6	201	12.8480	1.2437	495	10.33	<.0001	0.1	10.7986	14.8975
EGSTMNUM*LEG_SORT	4	202	6	202	10.0167	1.0797	1080	9.28	<.0001	0.1	8.2393	11.7941
EGSTMNUM*LEG_SORT	4	202	6	203	19.9986	1.2460	493	16.05	<.0001	0.1	17.9453	22.0519
EGSTMNUM*LEG_SORT	4	202	8	201	13.0243	1.2437	495	10.47	<.0001	0.1	10.9749	15.0738
EGSTMNUM*LEG_SORT	4	202	8	202	10.5784	1.0797	1080	9.80	<.0001	0.1	8.8010	12.3558
EGSTMNUM*LEG_SORT	4	202	8	203	18.9464	1.2460	493	15.21	<.0001	0.1	16.8931	20.9997
EGSTMNUM*LEG_SORT	4	202	12	201	10.6170	1.2437	495	8.54	<.0001	0.1	8.5675	12.6665
EGSTMNUM*LEG_SORT	4	202	12	202	10.6307	1.0797	1080	9.85	<.0001	0.1	8.8533	12.4081
EGSTMNUM*LEG_SORT	4	202	12	203	16.8811	1.2460	493	13.55	<.0001	0.1	14.8278	18.9344
EGSTMNUM*LEG_SORT	4	202	24	201	7.4620	1.2437	495	6.00	<.0001	0.1	5.4126	9.5115
EGSTMNUM*LEG_SORT	4	202	24	202	9.5270	1.0797	1080	8.82	<.0001	0.1	7.7496	11.3044
EGSTMNUM*LEG_SORT	4	202	24	203	15.1360	1.2460	493	12.15	<.0001	0.1	13.0827	17.1893
EGSTMNUM*LEG_SORT	4	203	5	201	-2.9511	1.2437	495	-2.37	0.0180	0.1	-5.0007	-0.9016
EGSTMNUM*LEG_SORT	4	203	5	202	-5.5386	1.2460	493	-4.45	<.0001	0.1	-7.5919	-3.4853
EGSTMNUM*LEG_SORT	4	203	5	203	4.8414	1.0797	1080	4.48	<.0001	0.1	3.0640	6.6189
EGSTMNUM*LEG_SORT	4	203	6	201	-0.7909	1.2437	495	-0.64	0.5251	0.1	-2.8405	1.2587
EGSTMNUM*LEG_SORT	4	203	6	202	-3.6222	1.2460	493	-2.91	0.0038	0.1	-5.6755	-1.5689
EGSTMNUM*LEG_SORT	4	203	6	203	6.3597	1.0797	1080	5.89	<.0001	0.1	4.5823	8.1371
EGSTMNUM*LEG_SORT	4	203	8	201	-0.6146	1.2437	495	-0.49	0.6214	0.1	-2.6642	1.4350
EGSTMNUM*LEG_SORT	4	203	8	202	-3.0605	1.2460	493	-2.46	0.0144	0.1	-5.1138	-1.0073
EGSTMNUM*LEG_SORT	4	203	8	203	5.3075	1.0797	1080	4.92	<.0001	0.1	3.5300	7.0849
EGSTMNUM*LEG_SORT	4	203	12	201	-3.0219	1.2437	495	-2.43	0.0155	0.1	-5.0715	-0.9724
EGSTMNUM*LEG_SORT	4	203	12	202	-3.0082	1.2460	493	-2.41	0.0161	0.1	-5.0615	-0.9549
EGSTMNUM*LEG_SORT	4	203	12	203	3.2422	1.0797	1080	3.00	0.0027	0.1	1.4648	5.0196
EGSTMNUM*LEG_SORT	4	203	24	201	-6.1769	1.2437	495	-4.97	<.0001	0.1	-8.2265	-4.1273
EGSTMNUM*LEG_SORT	4	203	24	202	-4.1120	1.2460	493	-3.30	0.0010	0.1	-6.1653	-2.0587
EGSTMNUM*LEG_SORT	4	203	24	203	1.4971	1.0797	1080	1.39	0.1659	0.1	-0.2804	3.2745
EGSTMNUM*LEG_SORT	5	201	5	202	-2.5875	1.2437	495	-2.08	0.0380	0.1	-4.6370	-0.5380
EGSTMNUM*LEG_SORT	5	201	5	203	7.7926	1.2437	495	6.27	<.0001	0.1	5.7430	9.8421
EGSTMNUM*LEG_SORT	5	201	6	201	2.1603	1.0797	1080	2.00	0.0457	0.1	0.3828	3.9377

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	201	6	202	-0.6711	1.2437	495	-0.54	0.5897	0.1	-2.7205	1.3784
EGSTMNUM*LEG_SORT	5	201	6	203	9.3108	1.2437	495	7.49	<.0001	0.1	7.2613	11.3604
EGSTMNUM*LEG_SORT	5	201	8	201	2.3365	1.0797	1080	2.16	0.0307	0.1	0.5591	4.1140
EGSTMNUM*LEG_SORT	5	201	8	202	-0.1094	1.2437	495	-0.09	0.9299	0.1	-2.1589	1.9401
EGSTMNUM*LEG_SORT	5	201	8	203	8.2586	1.2437	495	6.64	<.0001	0.1	6.2090	10.3082
EGSTMNUM*LEG_SORT	5	201	12	201	-0.07079	1.0797	1080	-0.07	0.9477	0.1	-1.8482	1.7066
EGSTMNUM*LEG_SORT	5	201	12	202	-0.05707	1.2437	495	-0.05	0.9634	0.1	-2.1065	1.9924
EGSTMNUM*LEG_SORT	5	201	12	203	6.1933	1.2437	495	4.98	<.0001	0.1	4.1437	8.2429
EGSTMNUM*LEG_SORT	5	201	24	201	-3.2258	1.0797	1080	-2.99	0.0029	0.1	-5.0032	-1.4484
EGSTMNUM*LEG_SORT	5	201	24	202	-1.1608	1.2437	495	-0.93	0.3511	0.1	-3.2103	0.8886
EGSTMNUM*LEG_SORT	5	201	24	203	4.4482	1.2437	495	3.58	0.0004	0.1	2.3986	6.4978
EGSTMNUM*LEG_SORT	5	202	5	203	10.3801	1.2460	493	8.33	<.0001	0.1	8.3268	12.4334
EGSTMNUM*LEG_SORT	5	202	6	201	4.7477	1.2437	495	3.82	0.0002	0.1	2.6983	6.7972
EGSTMNUM*LEG_SORT	5	202	6	202	1.9164	1.0797	1080	1.78	0.0762	0.1	0.1390	3.6938
EGSTMNUM*LEG_SORT	5	202	6	203	11.8983	1.2460	493	9.55	<.0001	0.1	9.8450	13.9516
EGSTMNUM*LEG_SORT	5	202	8	201	4.9240	1.2437	495	3.96	<.0001	0.1	2.8746	6.9735
EGSTMNUM*LEG_SORT	5	202	8	202	2.4781	1.0797	1080	2.30	0.0219	0.1	0.7007	4.2555
EGSTMNUM*LEG_SORT	5	202	8	203	10.8461	1.2460	493	8.70	<.0001	0.1	8.7928	12.8994
EGSTMNUM*LEG_SORT	5	202	12	201	2.5167	1.2437	495	2.02	0.0435	0.1	0.4672	4.5662
EGSTMNUM*LEG_SORT	5	202	12	202	2.5304	1.0797	1080	2.34	0.0193	0.1	0.7530	4.3078
EGSTMNUM*LEG_SORT	5	202	12	203	8.7808	1.2460	493	7.05	<.0001	0.1	6.7275	10.8341
EGSTMNUM*LEG_SORT	5	202	24	201	-0.6383	1.2437	495	-0.51	0.6080	0.1	-2.6878	1.4112
EGSTMNUM*LEG_SORT	5	202	24	202	1.4267	1.0797	1080	1.32	0.1867	0.1	-0.3508	3.2041
EGSTMNUM*LEG_SORT	5	202	24	203	7.0357	1.2460	493	5.65	<.0001	0.1	4.9824	9.0890
EGSTMNUM*LEG_SORT	5	203	6	201	-5.6323	1.2437	495	-4.53	<.0001	0.1	-7.6819	-3.5828
EGSTMNUM*LEG_SORT	5	203	6	202	-8.4637	1.2460	493	-6.79	<.0001	0.1	-10.5169	-6.4104
EGSTMNUM*LEG_SORT	5	203	6	203	1.5183	1.0797	1080	1.41	0.1599	0.1	-0.2592	3.2957
EGSTMNUM*LEG_SORT	5	203	8	201	-5.4560	1.2437	495	-4.39	<.0001	0.1	-7.5056	-3.4065
EGSTMNUM*LEG_SORT	5	203	8	202	-7.9020	1.2460	493	-6.34	<.0001	0.1	-9.9553	-5.8487
EGSTMNUM*LEG_SORT	5	203	8	203	0.4660	1.0797	1080	0.43	0.6661	0.1	-1.3114	2.2434
EGSTMNUM*LEG_SORT	5	203	12	201	-7.8634	1.2437	495	-6.32	<.0001	0.1	-9.9129	-5.8138
EGSTMNUM*LEG_SORT	5	203	12	202	-7.8497	1.2460	493	-6.30	<.0001	0.1	-9.9029	-5.7964
EGSTMNUM*LEG_SORT	5	203	12	203	-1.5993	1.0797	1080	-1.48	0.1388	0.1	-3.3767	0.1781
EGSTMNUM*LEG_SORT	5	203	24	201	-11.0183	1.2437	495	-8.86	<.0001	0.1	-13.0679	-8.9688

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	5	203	24	202	-8.9534	1.2460	493	-7.19	<.0001	0.1	-11.0067	-6.9001
EGSTMNUM*LEG_SORT	5	203	24	203	-3.3444	1.0797	1080	-3.10	0.0020	0.1	-5.1218	-1.5670
EGSTMNUM*LEG_SORT	6	201	6	202	-2.8313	1.2437	495	-2.28	0.0232	0.1	-4.8808	-0.7819
EGSTMNUM*LEG_SORT	6	201	6	203	7.1506	1.2437	495	5.75	<.0001	0.1	5.1010	9.2001
EGSTMNUM*LEG_SORT	6	201	8	201	0.1763	1.0797	1080	0.16	0.8703	0.1	-1.6011	1.9537
EGSTMNUM*LEG_SORT	6	201	8	202	-2.2697	1.2437	495	-1.82	0.0686	0.1	-4.3191	-0.2202
EGSTMNUM*LEG_SORT	6	201	8	203	6.0983	1.2437	495	4.90	<.0001	0.1	4.0488	8.1479
EGSTMNUM*LEG_SORT	6	201	12	201	-2.2310	1.0797	1080	-2.07	0.0390	0.1	-4.0085	-0.4536
EGSTMNUM*LEG_SORT	6	201	12	202	-2.2173	1.2437	495	-1.78	0.0752	0.1	-4.2668	-0.1679
EGSTMNUM*LEG_SORT	6	201	12	203	4.0331	1.2437	495	3.24	0.0013	0.1	1.9835	6.0826
EGSTMNUM*LEG_SORT	6	201	24	201	-5.3860	1.0797	1080	-4.99	<.0001	0.1	-7.1634	-3.6086
EGSTMNUM*LEG_SORT	6	201	24	202	-3.3211	1.2437	495	-2.67	0.0078	0.1	-5.3706	-1.2716
EGSTMNUM*LEG_SORT	6	201	24	203	2.2879	1.2437	495	1.84	0.0664	0.1	0.2384	4.3375
EGSTMNUM*LEG_SORT	6	202	6	203	9.9819	1.2460	493	8.01	<.0001	0.1	7.9286	12.0352
EGSTMNUM*LEG_SORT	6	202	8	201	3.0076	1.2437	495	2.42	0.0160	0.1	0.9581	5.0571
EGSTMNUM*LEG_SORT	6	202	8	202	0.5617	1.0797	1080	0.52	0.6030	0.1	-1.2157	2.3391
EGSTMNUM*LEG_SORT	6	202	8	203	8.9297	1.2460	493	7.17	<.0001	0.1	6.8764	10.9830
EGSTMNUM*LEG_SORT	6	202	12	201	0.6003	1.2437	495	0.48	0.6295	0.1	-1.4492	2.6498
EGSTMNUM*LEG_SORT	6	202	12	202	0.6140	1.0797	1080	0.57	0.5697	0.1	-1.1634	2.3914
EGSTMNUM*LEG_SORT	6	202	12	203	6.8644	1.2460	493	5.51	<.0001	0.1	4.8111	8.9177
EGSTMNUM*LEG_SORT	6	202	24	201	-2.5547	1.2437	495	-2.05	0.0405	0.1	-4.6042	-0.5052
EGSTMNUM*LEG_SORT	6	202	24	202	-0.4898	1.0797	1080	-0.45	0.6502	0.1	-2.2672	1.2877
EGSTMNUM*LEG_SORT	6	202	24	203	5.1193	1.2460	493	4.11	<.0001	0.1	3.0660	7.1726
EGSTMNUM*LEG_SORT	6	203	8	201	-6.9743	1.2437	495	-5.61	<.0001	0.1	-9.0239	-4.9247
EGSTMNUM*LEG_SORT	6	203	8	202	-9.4202	1.2460	493	-7.56	<.0001	0.1	-11.4735	-7.3669
EGSTMNUM*LEG_SORT	6	203	8	203	-1.0522	1.0797	1080	-0.97	0.3300	0.1	-2.8296	0.7252
EGSTMNUM*LEG_SORT	6	203	12	201	-9.3816	1.2437	495	-7.54	<.0001	0.1	-11.4312	-7.3320
EGSTMNUM*LEG_SORT	6	203	12	202	-9.3679	1.2460	493	-7.52	<.0001	0.1	-11.4212	-7.3146
EGSTMNUM*LEG_SORT	6	203	12	203	-3.1175	1.0797	1080	-2.89	0.0040	0.1	-4.8949	-1.3401
EGSTMNUM*LEG_SORT	6	203	24	201	-12.5366	1.2437	495	-10.08	<.0001	0.1	-14.5862	-10.4870
EGSTMNUM*LEG_SORT	6	203	24	202	-10.4717	1.2460	493	-8.40	<.0001	0.1	-12.5249	-8.4184
EGSTMNUM*LEG_SORT	6	203	24	203	-4.8626	1.0797	1080	-4.50	<.0001	0.1	-6.6400	-3.0852
EGSTMNUM*LEG_SORT	8	201	8	202	-2.4460	1.2437	495	-1.97	0.0498	0.1	-4.4954	-0.3965
EGSTMNUM*LEG_SORT	8	201	8	203	5.9221	1.2437	495	4.76	<.0001	0.1	3.8725	7.9716

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.

Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

The Mixed Procedure

Differences of Least Squares Means

Effect	Planned Timepoint	Treatment group sort order	Planned Timepoint	Treatment group sort order	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
EGSTMNUM*LEG_SORT	8	201	12	201	-2.4073	1.0797	1080	-2.23	0.0260	0.1	-4.1847	-0.6299
EGSTMNUM*LEG_SORT	8	201	12	202	-2.3936	1.2437	495	-1.92	0.0548	0.1	-4.4431	-0.3441
EGSTMNUM*LEG_SORT	8	201	12	203	3.8568	1.2437	495	3.10	0.0020	0.1	1.8072	5.9063
EGSTMNUM*LEG_SORT	8	201	24	201	-5.5623	1.0797	1080	-5.15	<.0001	0.1	-7.3397	-3.7849
EGSTMNUM*LEG_SORT	8	201	24	202	-3.4974	1.2437	495	-2.81	0.0051	0.1	-5.5468	-1.4479
EGSTMNUM*LEG_SORT	8	201	24	203	2.1117	1.2437	495	1.70	0.0902	0.1	0.06208	4.1612
EGSTMNUM*LEG_SORT	8	202	8	203	8.3680	1.2460	493	6.72	<.0001	0.1	6.3147	10.4213
EGSTMNUM*LEG_SORT	8	202	12	201	0.03862	1.2437	495	0.03	0.9752	0.1	-2.0109	2.0881
EGSTMNUM*LEG_SORT	8	202	12	202	0.05233	1.0797	1080	0.05	0.9613	0.1	-1.7251	1.8297
EGSTMNUM*LEG_SORT	8	202	12	203	6.3027	1.2460	493	5.06	<.0001	0.1	4.2494	8.3560
EGSTMNUM*LEG_SORT	8	202	24	201	-3.1164	1.2437	495	-2.51	0.0125	0.1	-5.1658	-1.0669
EGSTMNUM*LEG_SORT	8	202	24	202	-1.0514	1.0797	1080	-0.97	0.3304	0.1	-2.8288	0.7260
EGSTMNUM*LEG_SORT	8	202	24	203	4.5576	1.2460	493	3.66	0.0003	0.1	2.5043	6.6109
EGSTMNUM*LEG_SORT	8	203	12	201	-8.3294	1.2437	495	-6.70	<.0001	0.1	-10.3790	-6.2798
EGSTMNUM*LEG_SORT	8	203	12	202	-8.3157	1.2460	493	-6.67	<.0001	0.1	-10.3690	-6.2624
EGSTMNUM*LEG_SORT	8	203	12	203	-2.0653	1.0797	1080	-1.91	0.0560	0.1	-3.8427	-0.2879
EGSTMNUM*LEG_SORT	8	203	24	201	-11.4844	1.2437	495	-9.23	<.0001	0.1	-13.5339	-9.4348
EGSTMNUM*LEG_SORT	8	203	24	202	-9.4194	1.2460	493	-7.56	<.0001	0.1	-11.4727	-7.3661
EGSTMNUM*LEG_SORT	8	203	24	203	-3.8104	1.0797	1080	-3.53	0.0004	0.1	-5.5878	-2.0330
EGSTMNUM*LEG_SORT	12	201	12	202	0.01371	1.2437	495	0.01	0.9912	0.1	-2.0358	2.0632
EGSTMNUM*LEG_SORT	12	201	12	203	6.2641	1.2437	495	5.04	<.0001	0.1	4.2145	8.3137
EGSTMNUM*LEG_SORT	12	201	24	201	-3.1550	1.0797	1080	-2.92	0.0035	0.1	-4.9324	-1.3776
EGSTMNUM*LEG_SORT	12	201	24	202	-1.0900	1.2437	495	-0.88	0.3812	0.1	-3.1395	0.9594
EGSTMNUM*LEG_SORT	12	201	24	203	4.5190	1.2437	495	3.63	0.0003	0.1	2.4694	6.5686
EGSTMNUM*LEG_SORT	12	202	12	203	6.2504	1.2460	493	5.02	<.0001	0.1	4.1971	8.3037
EGSTMNUM*LEG_SORT	12	202	24	201	-3.1687	1.2437	495	-2.55	0.0111	0.1	-5.2182	-1.1192
EGSTMNUM*LEG_SORT	12	202	24	202	-1.1038	1.0797	1080	-1.02	0.3069	0.1	-2.8812	0.6737
EGSTMNUM*LEG_SORT	12	202	24	203	4.5053	1.2460	493	3.62	0.0003	0.1	2.4520	6.5586
EGSTMNUM*LEG_SORT	12	203	24	201	-9.4191	1.2437	495	-7.57	<.0001	0.1	-11.4686	-7.3695
EGSTMNUM*LEG_SORT	12	203	24	202	-7.3541	1.2460	493	-5.90	<.0001	0.1	-9.4074	-5.3008
EGSTMNUM*LEG_SORT	12	203	24	203	-1.7451	1.0797	1080	-1.62	0.1063	0.1	-3.5225	0.03230
EGSTMNUM*LEG_SORT	24	201	24	202	2.0649	1.2437	495	1.66	0.0975	0.1	0.01547	4.1144
EGSTMNUM*LEG_SORT	24	201	24	203	7.6740	1.2437	495	6.17	<.0001	0.1	5.6244	9.7235
EGSTMNUM*LEG_SORT	24	202	24	203	5.6090	1.2460	493	4.50	<.0001	0.1	3.5557	7.6623

Baseline is defined as the mean of the three average triplicate measurements taken at the following three time points (-1 hours, -0.5 hours, 0 hours) before dosing within each period.

Repeated measures model with sequence, period, treatment, time, treatment-by-time interaction as fixed effects, subjects within sequence as a random effect, and baseline QTcN as a covariate were used.

Completer ECG Analysis Population is defined as all subjects randomized and treated and have completed all three treatment periods, at least up to Day 15 (24 hour Day 14) ECG measurements.

Unplanned readings have been excluded from the presentation.

For sensitivity analysis, ECG measurements on Day 14 up to 24 hours will be used.

Leg\_sort: 201 - stands for Sertraline, 202 - stands for Moxifloxacin, 203 - stands for Placebo.


Source Data: Table 16.2.8.3.1 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:19)

Table 16.1.9.3.1  
SERTRALINE Protocol A0501104  
SAS Output for Statistical Analysis of Relationship between QT and RR (Pre-dose)

Page 1 of 4

SAS Code for Mixed Model

```
proc mixed data=ana2 method=REML;  
class subjid;  
model YAXIS = RR/ddfm=kr solution;  
random int RR/subject=subjid type=un;  
run;
```

 Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:20)

The Mixed Procedure

Model Information

Data Set	WORK.ANA2
Dependent Variable	YAXIS
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	4
Columns in X	2
Columns in Z Per Subject	2
Subjects	54
Max Obs Per Subject	9

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

██████████ Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:20)

The Mixed Procedure

Iteration History			
Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3882.35823833	
1	2	3216.94766508	0.01096975
2	1	3199.17922859	0.00862730
3	1	3185.63319022	0.00517034
4	1	3177.81121155	0.00214060
5	1	3174.72061625	0.00049619
6	1	3174.05330742	0.00003708
7	1	3174.05330724	0.00003708
8	1	3174.05330700	0.00003707
9	1	3174.05330458	0.00003707
10	1	3174.05328050	0.00003705
11	1	3174.05304784	0.00003687
12	1	3174.05134434	0.00003553
13	1	3174.04827840	0.00003312
14	1	3174.04796135	0.00003287
15	1	3174.04796037	0.00003287
16	1	3174.04795625	0.00003287
17	1	3174.04791509	0.00003284
18	1	3174.04750689	0.00003251
19	1	3174.04638624	0.00003163
20	1	3174.04529825	0.00003077
21	1	3174.04424191	0.00002993
22	1	3174.04321623	0.00002912
23	1	3174.04222028	0.00002833
24	1	3174.04125314	0.00002756
25	1	3174.04031394	0.00002682
26	1	3174.03940181	0.00002609
27	1	3174.03851594	0.00002539
28	1	3174.03765552	0.00002470
29	1	3174.03681979	0.00002404
30	1	3174.03600799	0.00002339
31	1	3174.03521942	0.00002276
32	1	3174.03445336	0.00002215
33	1	3174.03370914	0.00002155
34	1	3174.03298611	0.00002097
35	1	3174.03228363	0.00002041
36	1	3174.03160108	0.00001986
37	1	3174.03093789	0.00001933
38	1	3174.03029346	0.00001881
39	1	3174.02966725	0.00001830
40	1	3174.02905871	0.00001781
41	1	3174.02846732	0.00001734
42	1	3174.02789258	0.00001687
43	1	3174.02733399	0.00001642
44	1	3174.02679108	0.00001599

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:20)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
45	1	3174.02626340	0.00001556
46	1	3174.02575049	0.00001514
47	1	3174.02525193	0.00001474
48	1	3174.02476729	0.00001435
49	1	3174.02429617	0.00001397
50	1	3174.02383818	0.00001359

WARNING: Did not converge.

Covariance Parameter Values  
At Last Iteration

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	3619.99
UN(2,1)	SUBJID	-3.5901
UN(2,2)	SUBJID	0.003822
Residual		31.8486

Table 16.1.9.3.2  
SERTRALINE Protocol A0501104  
SAS Output for Statistical Analysis of Relationship between Log Transformed QT and RR (Pre-dose)

Page 1 of 4

SAS Code for Mixed Model

```
proc mixed data=ana2 method=REML;
class subjid;
model LNVAXIS = LNRR/ddfm=kr solution;
random int LNRR/subject=subjid type=un;
run;
```

██████████ Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.3.2  
SERTRALINE Protocol A0501104  
SAS Output for Statistical Analysis of Relationship between Log Transformed QT and RR (Pre-dose)

The Mixed Procedure

Model Information

Data Set	WORK.ANA2
Dependent Variable	LN YAXIS
Covariance Structure	Unstructured
Subject Effect	SUBJID
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	4
Columns in X	2
Columns in Z Per Subject	2
Subjects	54
Max Obs Per Subject	9

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

██████████ Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:21)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	-1604.75099842	
1	2	-2309.74659708	0.00393834
2	1	-2317.72764409	0.00165738
3	1	-2320.95560349	0.00039907
4	1	-2321.68233479	0.00003227
5	1	-2321.73612334	0.00000026
6	1	-2321.73654339	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	0.9566
UN(2,1)	SUBJID	-0.1390
UN(2,2)	SUBJID	0.02022
Residual		0.000182

Fit Statistics

-2 Res Log Likelihood	-2321.7
AIC (smaller is better)	-2313.7
AICC (smaller is better)	-2313.6
BIC (smaller is better)	-2305.8

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
3	716.99	<.0001

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr >  t
Intercept	3.6796	0.1629	45.4	22.59	<.0001
LNRR	0.3394	0.02364	45.6	14.36	<.0001

Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.3.2  
SERTRALINE Protocol A0501104  
SAS Output for Statistical Analysis of Relationship between Log Transformed QT and RR (Pre-dose)

The Mixed Procedure

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
LNRR	1	45.6	206.10	<.0001

 Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.4.1  
SERTRALINE Protocol A0501104  
Supporting Output for Regression Analysis of QTcB versus RR

Page 1 of 3

SAS Code for Mixed Model

```
proc mixed data=ana3;  
class subjid;  
model QTcB=RR/s cl ddfm=kr alpha=0.05;  
random subjid;  
ods output SolutionF=datrprot.mixed_QTcB;  
run;
```

██████████ Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.4.1  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcB versus RR

The Mixed Procedure

Model Information

Data Set	WORK.ANA3
Dependent Variable	QTcB
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	2
Columns in X	2
Columns in Z	54
Subjects	1
Max Obs Per Subject	456

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

██████████ Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.4.1  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcB versus RR

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3879.51311708	
1	2	3233.81390081	0.00000005
2	1	3233.81384045	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID	247.17
Residual	44.2588

Fit Statistics

-2 Res Log Likelihood	3233.8
AIC (smaller is better)	3237.8
AICC (smaller is better)	3237.8
BIC (smaller is better)	3241.8

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
Intercept	471.14	5.5369	425	85.09	<.0001	0.05	460.26	482.03
RR	-0.05740	0.005012	438	-11.45	<.0001	0.05	-0.06725	-0.04755

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
RR	1	438	131.17	<.0001

Date of Reporting Dataset Creation: 12SEP2016


Date of Table Generation: 18SEP2016 (01:21)

Table 16.1.9.4.2  
SERTRALINE Protocol A0501104  
Supporting Output for Regression Analysis of QTcF versus RR

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SAS Code for Mixed Model

```
proc mixed data=ana3;  
class subjid;  
model QTcF=RR/s cl ddfm=kr alpha=0.05;  
random subjid;  
ods output SolutionF=datrprot.mixed_QTcF;  
run;
```

 Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:22)

Table 16.1.9.4.2  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcF versus RR

The Mixed Procedure

Model Information

Data Set	WORK.ANA3
Dependent Variable	QTCF
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	2
Columns in X	2
Columns in Z	54
Subjects	1
Max Obs Per Subject	456

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

██████████ Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:22)

Table 16.1.9.4.2  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcF versus RR

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3875.62974387	
1	2	3234.11558603	0.00000011
2	1	3234.11545807	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID	244.38
Residual	44.3569

Fit Statistics

-2 Res Log Likelihood	3234.1
AIC (smaller is better)	3238.1
AICC (smaller is better)	3238.1
BIC (smaller is better)	3242.1

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
Intercept	402.98	5.5359	426	72.79	<.0001	0.05	392.10	413.86
RR	0.01016	0.005016	438	2.03	0.0434	0.05	0.000305	0.02002

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
RR	1	438	4.11	0.0434


Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:22)

Table 16.1.9.4.3  
SERTRALINE Protocol A0501104  
Supporting Output for Regression Analysis of QTcI versus RR

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SAS Code for Mixed Model

```
proc mixed data=ana3;  
class subjid;  
model QTcI=RR/s cl ddfm=kr alpha=0.05;  
random subjid;  
ods output SolutionF=datrprot.mixed_QTcI;  
run;
```

 Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:23)

Table 16.1.9.4.3  
SERTRALINE Protocol A0501104  
Supporting Output for Regression Analysis of QTcI versus RR

The Mixed Procedure

Model Information

Data Set	WORK.ANA3
Dependent Variable	QTCI
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	2
Columns in X	2
Columns in Z	54
Subjects	1
Max Obs Per Subject	456

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

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Table 16.1.9.4.3  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcI versus RR

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3855.58116503	
1	2	3061.02660395	0.00000061
2	1	3061.02592399	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID	250.36
Residual	28.7478

Fit Statistics

-2 Res Log Likelihood	3061.0
AIC (smaller is better)	3065.0
AICC (smaller is better)	3065.1
BIC (smaller is better)	3069.0

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
Intercept	413.91	4.6783	392	88.47	<.0001	0.05	404.71	423.10
RR	-0.00031	0.004076	427	-0.08	0.9392	0.05	-0.00832	0.007701

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
RR	1	427	0.01	0.9392

Date of Reporting Dataset Creation: 12SEP2016


Date of Table Generation: 18SEP2016 (01:23)

Table 16.1.9.4.4  
SERTRALINE Protocol A0501104  
Supporting Output for Regression Analysis of QTcN versus RR

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SAS Code for Mixed Model

```
proc mixed data=ana3;  
class subjid;  
model QTcN=RR/s cl ddfm=kr alpha=0.05;  
random subjid;  
ods output SolutionF=datrprot.mixed_QTcN;  
run;
```

 Date of Reporting Dataset Creation: 12SEP2016

Date of Table Generation: 18SEP2016 (01:23)

Table 16.1.9.4.4  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcN versus RR

The Mixed Procedure

Model Information

Data Set	WORK.ANA3
Dependent Variable	QTcN
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Kenward-Roger
Degrees of Freedom Method	Kenward-Roger

Class Level Information

Class	Levels	Values
SUBJID	54	10011001 10011002 10011003
		10011004 10011005 10011006
		10011007 10011008 10011009
		10011010 10011011 10011012
		10011013 10011014 10011015
		10011016 10011017 10011018
		10011019 10011020 10011021
		10011022 10011023 10011024
		10011025 10011026 10011027
		10011028 10011029 10011030
		10011031 10011032 10011033
		10011034 10011035 10011036
		10011037 10011038 10011039
		10011040 10011041 10011042
		10011043 10011044 10011045
		10011046 10011047 10011048
		10011049 10011050 10011051
		10011052 10011053 10011054

Dimensions

Covariance Parameters	2
Columns in X	2
Columns in Z	54
Subjects	1
Max Obs Per Subject	456

Number of Observations

Number of Observations Read	456
Number of Observations Used	456
Number of Observations Not Used	0

██████████ Date of Reporting Dataset Creation: 12SEP2016      Date of Table Generation: 18SEP2016 (01:23)

Table 16.1.9.4.4  
 SERTRALINE Protocol A0501104  
 Supporting Output for Regression Analysis of QTcN versus RR

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	3876.73338294	
1	2	3231.94441678	0.00000014
2	1	3231.94425188	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Estimate
SUBJID	245.23
Residual	44.0982

Fit Statistics

-2 Res Log Likelihood	3231.9
AIC (smaller is better)	3235.9
AICC (smaller is better)	3236.0
BIC (smaller is better)	3239.9

Solution for Fixed Effects

Effect	Estimate	Standard Error	DF	t Value	Pr >  t	Alpha	Lower	Upper
Intercept	405.30	5.5246	426	73.36	<.0001	0.05	394.45	416.16
RR	0.007734	0.005002	438	1.55	0.1228	0.05	-0.00210	0.01757

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
RR	1	438	2.39	0.1228

Date of Reporting Dataset Creation: 12SEP2016 Date of Table Generation: 18SEP2016 (01:23)